

Regulatory Procedures Manual

INTRODUCTION

This chapter includes the following sections:

Section	Topic	Page
1.	Purpose	1
2.	Scope.....	1
3.	Responsibility.....	1
4.	Background.....	1
5.	Attachment - Vision, Mission and Values.....	3

1. Purpose

The Regulatory Procedures Manual (RPM) is a reference manual that provides internal procedures and related information to be used by FDA employees who process certain regulatory and enforcement matters in support of the agency's public health mission. Adherence to this manual is paramount to assure quality, consistency, and efficiency in FDA operations.

2. Scope

Other FDA manuals and guidance supplement, but do not supersede, the information in this manual. We recognize this manual will not address all situations encountered in the performance of compliance-related activities. In such cases, your division management must be informed and concur with any significant departures from the RPM.

The RPM does not create or confer any rights for or on any person and does not operate to bind FDA or the public.

3. Responsibility

While the RPM is intended mainly to describe procedures for FDA investigation and compliance officers, and programs and divisions in ORA, the document is useful to all of FDA.

4. Background

This version of the RPM contains important changes which clarify or present new information and procedures. For example, this year we have

included information relating to the recent Program Alignment changes. We are continuing to update the RPM in response to our May 15, 2017 rollout of program alignment across ORA. These program alignment updates will continue as we incorporate new program-specific sections within the RPM. As with each new edition of the RPM, please take time to review sections of the manual for changes which may apply to your work.

We are committed to the continual improvement of the quality and usefulness of the RPM. Suggestions for the next edition of the RPM or recommended changes, deletions, additions to the RPM may be sent via e-mail to the Outlook address for ORA RPM Updates. If you are recommending a change or revision, please use the RPM Change Request Form available at [RPM Appendix A](#). Suggestions are accepted from the within the Agency, our state and local partners, industry and consumers. Thank you for your continued hard work and dedication in protecting and promoting the health and well-being of the American people.

The RPM has been posted on ORA's Internet Website at <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compliance-manuals/regulatory-procedures-manual>. Future updates to the RPM will be performed periodically during the year to the on-line version. Remember, whether reviewing a printed copy or the *on-line* version of the RPM, the most recent version online is the document of record.

5. Attachment - Vision, Mission and Values

Vision

All food is safe; all medical products are safe and effective; and the public health is advanced and protected.

Mission

Protecting consumers and enhancing public health by maximizing compliance of FDA regulated products and minimizing risk associated with those products. Quality Commitment ORA is committed to quality and continual improvement. Our actions are dedicated to effectively meeting our customers' needs.

Values

Accountability - We take personal responsibility for meeting individual, team, and organizational commitments

Commitment to Public Health - We demonstrate our commitment to safeguarding the public health in our actions.

Communication - We provide information that is accurate and clear, and in our interactions with others, we actively listen to understand other points of view.

Integrity and Respect - We adhere to the highest ethical standards by consistently being honest and trustworthy in our actions.

Quality - We set high standards of excellence for our work and take the necessary actions to continuously improve.

Regulatory Procedures Manual

Chapter 1: REGULATORY ORGANIZATION

This chapter includes the following sections:

Section	Topic	Page
1-1.	INTRODUCTION	1
1-2.	OFFICE OF REGULATORY AFFAIRS (ORA).....	2
1-2-1	OACRA Organization	2
1-2-2	OACRA Functions	2
1-3.	CENTER FOR BIOLOGICS EVALUATION AND RESEARCH (CBER).....	2
1-4.	CENTER FOR DRUG EVALUATION AND RESEARCH (CDER).....	3
1-5.	CENTER FOR DEVICES AND RADIOLOGICAL HEALTH (CDRH).....	3
1-6.	CENTER FOR FOOD SAFETY AND APPLIED NUTRITION (CFSAN).....	4
1-7.	CENTER FOR VETERINARY MEDICINE (CVM).....	5
1-8.	CENTER FOR TOBACCO PRODUCTS (CTP)	5
1-9.	ENFORCEMENT POLICY TELEPHONE DIRECTORY	6
1-9-1	Office of Regulatory Affairs – Headquarters and field	6
1-9-2	FDA Centers.....	6

1-1. INTRODUCTION

This Regulatory Procedures Manual (RPM) chapter is divided into sections based on major organizational units and includes a section for all centers and the Office of Regulatory Affairs (ORA).

The purpose of this Regulatory Procedures Manual (RPM) chapter is to provides an overview of the organizational structure of the offices involved in compliance related functions within FDA. It is not the intent to provide a complete description of FDA's organizational structure. FDA's functional statement for each office and division may be found in various chapters of FDA's Staff Manual Guide (SMG). This guide is available on FDA's Intranet and Internet websites.

1-2. OFFICE OF REGULATORY AFFAIRS (ORA)

As a result of the ORA reorganization efforts, new offices and divisions in ORA headquarters were established with realigned, and combined functions to help support the rapid modernization and globalization of FDA's regulated products and new legislative authorities provided by Congress. The Office of Regulatory Affairs (ORA) is under the direction of the Associate Commissioner of Regulatory Affairs (ACRA). The ACRA reports directly to the Commissioner of Food and Drugs.

1-2-1 OACRA Organization

The offices that report directly to the Office of the ACRA (OACRA) include:

- A. Office of Communications and Project Management (OCPM),
- B. Office of Enforcement and Import Operations (OEIO),
- C. Office of Human and Animal Food Operations (OHAFO),
- D. Office of Management (OM),
- E. Office of Medical Products and Tobacco Operations (OMPTO),
- F. Office of Partnerships and Operational Policy (OPOP),
- G. Office of Regulatory Science (ORS),
- H. Office of Training, Education and Development (OTED), and
- I. Office of Criminal Investigations

1-2-2 OACRA Functions

The Immediate Office of the ACRA and the offices listed above are described on the page on FDA.gov at [About FDA](#) > [FDA Organization](#) > [Organization Charts](#) and on [About the Office of Regulatory Affairs](#) titled [Office of Regulatory Affairs Organization Chart](#).

The functional statements for the Office of Regulatory Affairs and the offices within the OACRA are found in [Staff Manual Guides](#) starting at [SMG 1120.1, Office of Regulatory Affairs](#).

1-3. CENTER FOR BIOLOGICS EVALUATION AND RESEARCH (CBER)

The Center for Biologics Evaluation and Research (CBER) described on the page on FDA.gov at [About FDA](#) > [FDA Organization](#) > [Organization Charts](#) > [About the Center for Biologics Evaluation and Research](#).

The functional statements for CBER and the offices within the Center are found in FDA's [Staff Manual Guides](#) starting at [SMG 1210.1, Center for Biologics Evaluation and Research](#). The CBER offices routinely involved in regulatory and compliance actions are:

- A. Office of Compliance and Biologics Quality, with functional statements at [SMG 1212.1, Office of Compliance and Biologics Quality](#).

- B. Division of Case Management, with functional statements at [SMG 1212.2, Division of Case Management](#).
- C. Division of Inspections and Surveillance), with functional statements at [SMG 1212.4, Division of Inspections and Surveillance](#).
- D. Division of Manufacturing and Product Quality, with functional statements at [SMG 1212.5, Division of Manufacturing and Product Quality](#).
- E. Division of Biological Standards and Quality Control, with functional statements at [SMG 1212.6, Division of Biological Standards and Quality Control](#).

1-4. CENTER FOR DRUG EVALUATION AND RESEARCH (CDER)

The Center for Drug Evaluation and Research (CDER) described on the page on FDA.gov at [About FDA](#) > [FDA Organization](#) > [Organization Charts](#) > [About the Center for Drug Evaluation and Research](#).

The functional statements for CDER and the offices within the Center are found in FDA's [Staff Manual Guides](#) starting at [SMG 1260.1, Center for Drug Evaluation and Research](#). The CDER offices routinely involved in regulatory and compliance actions are:

- A. Office of Compliance, with functional statements at [SMG 1262.1, Office of Compliance](#)
- B. Office of Unapproved Drugs and Labeling Compliance, with functional statements at [SMG 1262.3, Office of Unapproved Drugs and Labeling Compliance](#)
- C. Office of Manufacturing Quality, with functional statements at [SMG 1262.4, Office of Manufacturing Quality](#)
- D. Office of Scientific Investigations, with functional statements at [SMG 1262.5, Office of Scientific Investigations](#)
- E. Office of Drug Security, Integrity and Recalls, with functional statements at [SMG 1262.6, Office of Drug Security, Integrity, and Response](#)
- F. Office of Pharmaceutical Quality, with functional statements at [SMG 1280.1a, Office of Pharmaceutical Quality](#)

1-5. CENTER FOR DEVICES AND RADIOLOGICAL HEALTH (CDRH)

The Center for Devices and Radiological Health (CDRH) described on the page on FDA.gov at [About FDA](#) > [FDA Organization](#) > [Organization Charts](#) > Center for Devices and Radiological Health: [Medical Devices](#) and [Radiation-Emitting Products](#)

The functional statements for CDRH and the offices within the Center are found in FDA's [Staff Manual Guides](#) starting at [SMG 1250.1, Center for Devices and Radiological Health](#). The CDRH offices routinely involved in regulatory and compliance actions are:

- A. Office of Product Evaluation and Quality, with functional statements at [SMG 1258.1, Office of Product Evaluation and Quality](#)
- B. Office of Communication and Education, with functional statements at [SMG 1255.1, Office of Communication and Education](#)

- C. Office of In Vitro Diagnostic Device Evaluation and Safety with functional statements at [SMG 1258.90, Office of In Vitro Diagnostics and Radiological Health](#).

1-6. CENTER FOR FOOD SAFETY AND APPLIED NUTRITION (CFSAN)

The Center for Food Safety And Applied Nutrition (CFSAN) is described on the page on FDA.gov at [About FDA](#) > [FDA Organization](#) > [Organization Charts](#) > [Center for Food Safety and Applied Nutrition](#).

The functional statements for CFSAN and the offices within the Center are found in FDA's [Staff Manual Guides](#) starting at [SMG 1230A.1, Center for Food Safety and Applied Nutrition](#). The CFSAN offices routinely involved in regulatory and compliance actions are:

- A. Office of Food Safety, with functional statements at [SMG 1231.13, Office of Food Safety](#)
- B. Division of Seafood Science & Technology, with functional statements at [SMG 1231.131, Division of Seafood Science and Technology](#)
- C. Division of Food Processing Science and Technology, with functional statements at [SMG 1231.132, Division of Food Processing Science and Technology](#)
- D. Division of Seafood Safety, with functional statements at [SMG 1231.134, Division of Seafood Safety](#)
- E. Produce Safety Staff, with functional statements at [SMG 1231.135, Division of Produce Safety](#)
- F. Division of Plant Products and Beverages, with functional statements at [SMG 1231.137, Division of Plant Products and Beverages](#)
- G. Office of Cosmetics and Colors, with functional statements at [SMG 1231.14, Office of Cosmetics and Colors](#)
- H. Division of Color Certification and Technology, with functional statements at [SMG 1231.141, Division of Color Certification and Technology](#)
- I. Division of Cosmetics, with functional statements at [SMG 1231.142, Division of Cosmetics](#)
- J. Office of Regulatory Science, with functional statements at [SMG 1231.15, Office of Regulatory Science](#)
- K. Division of Analytical Chemistry, with functional statements at [SMG 1231.151, Division of Analytical Chemistry](#)
- L. Division of Microbiology, with functional statements at [SMG 1231.152 Division of Microbiology](#)
- M. Division of Bioanalytical Chemistry, with functional statements at [SMG 1231.153, Division of Bioanalytical Chemistry](#)
- N. Office of Food Additive Safety, with functional statements at [SMG 1231.16, Office of Food Additive Safety](#)

- O. Division of Food Contact Notifications, with functional statements at [SMG 1231.161, Division of Food Contract Notifications](#)
- P. Division of Biotechnology and GRAS Notice Review, with functional statements at [SMG 1231.162, Division of Biotechnology and GRAS Notice Review](#)
- Q. Division of Petition Review, with functional statements at [SMG 1231.163, Division of Petition Review](#)
- R. Office of Compliance, with functional statements at [SMG 1231.17, Office of Compliance](#)
- S. Division of Enforcement, with functional statements at [SMG 1231.171, Division of Enforcement](#)
- T. Division of Field Programs and Guidance, with functional statements at [SMG 1231.172, Division of Field Programs and Guidance](#).
- U. Office of Nutrition and Food Labeling, with functional statements at [SMG 1231.20, Office of Nutrition and Food Labeling](#)
- V. Office of Dietary Supplement Programs, with functional statements at [SMG 1231.21, Office of Dietary Supplement Programs](#)

1-7. CENTER FOR VETERINARY MEDICINE (CVM)

The Center for Veterinary Medicine (CVM) is described on the page on FDA.gov at [About FDA > FDA Organization > Organization Charts > Center for Veterinary Medicine](#).

The functional statements for CVM and the offices within the Center are found in FDA's [Staff Manual Guides](#) starting at [SMG 1240.1, Center for Veterinary Medicine](#). The CVM offices routinely involved in regulatory and compliance actions are:

- A. Office of Surveillance and Compliance, with functional statements at [SMG 1244.1, Office of Surveillance and Compliance](#)
- B. Division of Surveillance, with functional statements at [SMG 1244.10, Division of Surveillance](#)
- C. Division of Animal Feeds, with functional statements at [SMG 1244.11, Division of Animal Feeds](#)
- D. Division of Compliance, with functional statements at [SMG 1244.12, Division of Compliance](#)
- E. Division of Veterinary Product Safety, with functional statements at, [SMG 1244.13, Division of Veterinary Product Safety](#)

1-8. CENTER FOR TOBACCO PRODUCTS (CTP)

The Center for Tobacco Products (CTP) is described on the page on FDA.gov at [About FDA > FDA Organization > Organization Charts > Center for Tobacco Products](#).

The functional statements for CTP and the offices within the Center are found in FDA's [Staff Manual Guides](#) starting at [SMG 1350.1 Center for Tobacco Products](#). The CTP offices routinely involved in regulatory and compliance actions are:

- A. Office of Compliance and Enforcement, with functional statements at [SMG 1357.1 Office of Compliance and Enforcement](#)
- B. Enforcement and Manufacturing, with functional statements at [SMG 1357.2, Division of Enforcement and Manufacturing](#)
- C. Promotion, Advertising and Labeling, with functional statements at [SMG 1357.3, Division of Promotion, Advertising and Labeling](#)
- D. State Programs, with functional statements at [SMG 1357.4, Division of State Programs](#)

1-9. ENFORCEMENT POLICY TELEPHONE DIRECTORY

The most current version of this directory is available on FDA's Intranet website.

1-9-1 Office of Regulatory Affairs – Headquarters and field

See "Contact ORA" on [Home](#) > [About FDA](#) > [FDA Organization](#) > [About the Office of Regulatory Affairs](#) > [Contact ORA](#)

1-9-2 FDA Centers

- A. Center for Biologics Evaluation and Research (CBER)
 - 1. [About the Center for Biologics Evaluation and Research](#)
 - 2. [CBER Offices & Divisions](#)
 - 3. [CBER Key Staff Directory](#)
- B. Center for Drug Evaluation and Research (CDER)
 - 1. [About the Center for Drug Evaluation and Research](#)
 - 2. [CDER Key Officials List](#) (PDF)
 - 3. [CDER Offices and Divisions](#)
- C. Center for Devices and Radiological Health (CDRH)
 - 1. [About the Center for Devices and Radiological Health](#)
 - 2. *CDRH Management Directory by Organization* is available on the FDA Intranet.
- D. Center For Food Safety And Applied Nutrition (CFSAN)
 - 1. [Contact CFSAN](#)
 - 2. *CFSAN Management Directory* is available on the FDA Intranet.
- E. Center for Veterinary Medicine (CVM)
 - 1. [Contact CVM](#)
 - 2. *CVM Staff Phone List* is available on the FDA Intranet.

F. Center for Tobacco Products (CTP)

1. [Contact CTP](#)
2. *CTP Directory by Office* is available on the FDA Intranet.

Regulatory Procedures Manual

Chapter 2 – FDA Authority August 2018

This chapter includes the following sections:

Section	Topic	Page



The information in this Chapter is current as of June 1, 2018. For the most up-to-date version of the US Code, go to the [US Government Publishing Office](http://www.gpo.gov) (GPO).

2-1	THE U.S. FEDERAL JUDICIAL SYSTEM.....	3
2.1.1	District.....	3
2.1.2	U.S. Circuit Court of Appeals	3
2.1.3.	The U.S. Supreme Court	4
2-2	SELECTED AMENDMENTS TO THE FEDERAL FOOD, DRUG, AND COSMETIC ACT.....	4
2.2.1.	Animal Drug User Fee (ADUFA).....	4
2.2.2.	Animal Medicinal Drug Use Clarification Act (AMDUCA)	4
2.2.3.	Anti-Drug Abuse Act	4
2.2.4.	Best Pharmaceuticals for Children Act (BPFCA)	4
2.2.5.	Dietary Supplement and Nonprescription Drug Consumer Protection Act (DSNPDCPA).....	5
2.2.6.	Dietary Supplement Health and Education Act (DSHEA)	5
2.2.1.	Drug Price Competition and Patent Term Restoration Act (DPCPTR)	5
2.2.2.	Drug Quality and Security Act (DQSA)	5
2.2.3.	Electronic Product Radiation Control Act (EPRCA)	6
2.2.4.	Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act)	6
2.2.5.	Food Allergen Labeling and Consumer Protection Act (FALCPA)	6
2.2.6.	Food and Drug Administration Amendments Act of 2007 (FDAAA).....	6
2.2.7.	Food and Drug Administration Export Reform and Enhancement Act (FDAEREA).....	7
2.2.8.	Food and Drug Administration Modernization Act of 1997 (FDAMA).....	7

2.2.9.	Food and Drug Administration Safety and Innovation Act (FDASIA)	7
2.2.10.	Food Quality Protection Act (FQPA)	7
2.2.11.	Food Safety Modernization Act (FSMA).....	7
2.2.12.	Generic Drug Enforcement Act (GDEA).....	7
2.2.13.	Health Promotion and Disease Prevention Amendments (HPDPA)	7
2.2.14.	Infant Formula Act (IFA).....	7
2.2.15.	Medical Device Amendments	8
2.2.16.	Medical Device User Fee and Modernization Act (MDUFMA I, II and III) ..	8
2.2.17.	Minor Use and Minor Species Animal Health Act (MUMS)	8
2.2.18.	Nutrition Labeling and Education Act (NLEA)	8
2.2.19.	Orphan Drug Act (ODA).....	9
2.2.20.	Pandemic and All-Hazards Preparedness Reauthorization Act (PAHPRA)	9
2.2.21.	Pediatric Research Equity Act (PREA)	9
2.2.22.	Prescription Drug Marketing Act of 1987 (PDMA).....	10
2.2.23.	Prescription Drug User Fee Act (PDUFA).....	10
2.2.24.	Project Bioshield Act.....	10
2-3	OTHER LAWS	10
2.3.1.	Public Health Service Act - Biological Products (Part F, Subpart 1)	10
2.3.2.	Public Health Service Act - Control of Communicable Diseases (Part G)	11
2.3.3.	Mammography Quality Standards Act of 1992	12
2.3.4.	Federal Anti-Tampering Act – 1983	12
2.3.5.	Freedom of Information Act – 1966	13
2.3.6.	Electronic Freedom of Information Amendments of 1996	14
2.3.7.	Sanitary Food Transportation Act of 1990	14
2.3.8.	Pesticides Monitoring Improvements Act of 1988	14
2.3.9.	AIDS Amendments of 1988	15
2.3.10.	Lead-Based Paint Poisoning Prevention Act – 1971	16
2.3.11.	Egg Products Inspection Act - 1970.....	16
2.3.12.	Fair Packaging and Labeling Act - 1966	17
2.3.13.	Federal Import Milk Act	17
2.3.14.	Health Insurance Portability and Accountability Act of 1996	18
2.3.15.	Equal Access to Justice Act - 1980	19
2.3.16.	Sentencing Reform Act of 1984	19
2.3.17.	Crimes And Criminal Procedure	20

2-1 THE U.S. FEDERAL JUDICIAL SYSTEM

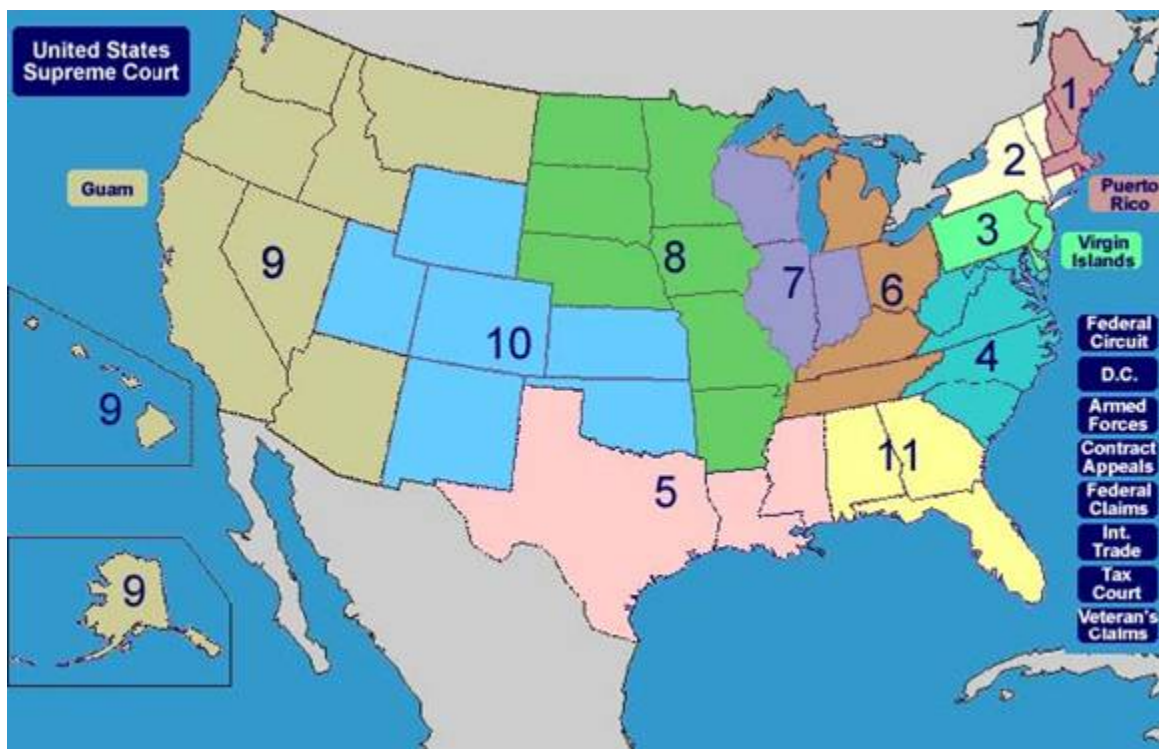
2.1.1 District Courts

There are 89 districts in the 50 states, which are listed with their divisions in Title 28 of the U.S. Code, Sections 81-144. District courts also exist in Puerto Rico, the Virgin Islands, the District of Columbia, Guam, and the Northern Mariana Islands. In total there are 94 U.S. district courts. Some states, such as Alaska, are composed of a single judicial district. Others, such as California, are composed of multiple judicial districts. The number of judgeships allotted to each district is set forth in Title 28 of the U.S. Code, Section 133. For a list of U.S. district courts and their rules, on the Internet go to: [List of US District Courts http://www.uscourts.gov/rules/distr-localrules.html](http://www.uscourts.gov/rules/distr-localrules.html).

2.1.2 U.S. Circuit Court of Appeals

There are 13 judicial circuits, each with a court of appeals. The smallest court is the First Circuit with six judgeships, and the largest court is in the Ninth Circuit, with 28 judgeships. A list of the states that compose each circuit is set forth in Title 28 of the U.S. Code, Section 41. The number of judgeships in each circuit is set forth in Title 28 of the U.S. Code, Section 44. Court rules for each circuit court are available on the Internet at [Court Rules http://www.uscourts.gov/RulesAndPolicies/rules/current-rules.aspx](http://www.uscourts.gov/RulesAndPolicies/rules/current-rules.aspx).

U.S. Circuit Court of Appeals



The U.S. Court of Appeals Federal Circuit and the District of Columbia bring the total number of circuit courts to 13. Additional information is available at the following Internet site, [Guide to Law Online](#) > [US Federal](#) > [Judiciary](#) by the Library of Congress.

2.1.3. The U.S. Supreme Court

The United States Supreme Court consists of the Chief Justice of the United States and eight associate justices. At its discretion, and within certain guidelines established by Congress, the Supreme Court each year hears a limited number of the cases it is asked to decide. Those cases may begin in the federal or state courts, and they usually involve important questions about the Constitution or federal law. For more information about the Supreme Court, visit the website for the [US Supreme Court](#).

2-2SELECTED AMENDMENTS TO THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

The following is a list of selected Amendments to the Federal Food, Drug, and Cosmetic Act (FD&C Act). The amendments are listed in alphabetical order with the corresponding enactment date noted.

2.2.1. Animal Drug User Fee (ADUFA)

The FDA User Fee page is at <https://www.fda.gov/ForIndustry/UserFees>.

Information on ADUFA, Aug 14, 2008, is available on CVM's [ADUFA](#) page at <http://www.fda.gov/ForIndustry/UserFees/AnimalDrugUserFeeActADUFA>.

2.2.2. Animal Medicinal Drug Use Clarification Act (AMDUCA)

Information on AMDUCA, is available on CVM's [Acts, Rules and Regulations](#) page at [http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/ ActsRulesRegulations/](http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/ActsRulesRegulations/).

2.2.3. Anti-Drug Abuse Act

Information on the [Controlled Substances Act](#), Nov 11, 1988, is available at <http://www.fda.gov/regulatoryinformation/legislation/ucm148726.htm>. It includes the [Anti-Drug Abuse Act](#), available at <http://www.gpo.gov/fdsys/pkg/STATUTE-102/pdf/STATUTE-102-Pg4181.pdf> and which is administered by FDA.

2.2.4. Best Pharmaceuticals for Children Act (BPFCA)

The BPFCA, Jan. 4, 2002, reauthorizes the pediatric studies provision of the Food and Drug Administration Modernization and Accountability Act (FDAMAA) of 1997. Information is available on the [Pediatric Product](#)

[Development](http://www.fda.gov/drugs/developmentapprovalprocess/developmentresources/ucm049867.htm) page at <http://www.fda.gov/drugs/developmentapprovalprocess/developmentresources/ucm049867.htm>.

2.2.5. Dietary Supplement and Nonprescription Drug Consumer Protection Act (DSNPDCPA)

Information on DSNPDCPA, Dec. 22, 2006, is available on the [OTC Products and Dietary Supplements](#) page.

2.2.6. Dietary Supplement Health and Education Act (DSHEA)

Information on DSHEA, Oct. 25, 1994, is available on the [Dietary Supplements](#) page at <http://www.fda.gov/food/dietarysupplements>.

NOTE: DSHEA does not apply to products intended for animal use. The FDA's [Center for Veterinary Medicine](#) (CVM) (<http://www.fda.gov/AnimalVeterinary>), [Division of Compliance](#) (<https://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/ComplianceEnforcement>), telephone 240-276-9200, should be consulted for appropriate guidance on these products for animal use.

2.2.1. Drug Price Competition and Patent Term Restoration Act (DPCPTRA)

DPCPTRA is available on the following Government's Printing Office web page (<http://www.gpo.gov/fdsys/pkg/STATUTE-98/pdf/STATUTE-98-Pg1585.pdf>), Sept. 24, 1984, consists of two titles:

- Title I authorizes the approval of generic drugs under an Abbreviated New Drug Application (ANDA) procedure.
- Title II authorizes the extension of patent terms for approved new drug products including antibiotics and biological drug products, some medical devices, food additives, and color additives.

2.2.2. Drug Quality and Security Act (DQSA)

DQSA, Nov 27, 2013, <https://www.congress.gov/bill/113th-congress/house-bill/3204/text> contains two titles:

- [Title I of DQSA, Compounding Quality Act](#) at <http://www.fda.gov/drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding> addresses compounding of human drugs. Information is available on the FDA [Compounding](#) page at <http://www.fda.gov/drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding>.
- [Title II of DQSA, Drug Supply Chain Security Act](#) (DSCSA) at <http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity> outlines steps for an electronic, interoperable system to identify and trace certain prescription drugs as they are distributed in the United States.

Additional information is available on the [Drug Supply Chain Integrity](http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity) page at <http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity>.

2.2.3. Electronic Product Radiation Control Act (EPRCA)

The EPRCA of 1990, 21 U.S.C. 360hh-360ss, is the new name for the [Radiation Control for Health and Safety Act](http://www.gpo.gov/fdsys/pkg/STATUTE-82/pdf/STATUTE-82-Pg1173.pdf) (<http://www.gpo.gov/fdsys/pkg/STATUTE-82/pdf/STATUTE-82-Pg1173.pdf>), Oct. 18, 1968 (formerly at 42 U.S.C. 263c-263n). The change was made as part of the [Safe Medical Devices Act of 1990](http://www.gpo.gov/fdsys/pkg/STATUTE-104/pdf/STATUTE-104-Pg4511.pdf) (SMDA) (<http://www.gpo.gov/fdsys/pkg/STATUTE-104/pdf/STATUTE-104-Pg4511.pdf>) which was itself amended by the [FDA Amendments Act](http://www.fda.gov/regulatoryinformation/legislation/federalfooddrugandcosmeticactfdca/significantamendmentstotheftdcact/foodanddrugadministrationamendmentsof2007/default.htm) at <http://www.fda.gov/regulatoryinformation/legislation/federalfooddrugandcosmeticactfdca/significantamendmentstotheftdcact/foodanddrugadministrationamendmentsof2007/default.htm>. Additional information is on the [Summary of the Electronic Product Radiation Control Provisions](http://www.fda.gov/radiation-emittingproducts/electronicproductradiationcontrolprogram/lawsandregulations/ucm118156.htm) page at <http://www.fda.gov/radiation-emittingproducts/electronicproductradiationcontrolprogram/lawsandregulations/ucm118156.htm>.

2.2.4. Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act)

Information on the [Tobacco Control Act](http://www.accessdata.fda.gov/scripts/tobaccocontrol/index.cfm) (<http://www.accessdata.fda.gov/scripts/tobaccocontrol/index.cfm>), June 22, 2009, is available on the [Tobacco Control Act](http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/ucm298595.htm) page at <http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/ucm298595.htm>.

2.2.5. Food Allergen Labeling and Consumer Protection Act (FALCPA)

Additional Information on [FALCPA](http://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/allergens/ucm106187.htm) (<http://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/allergens/ucm106187.htm>), Aug. 2, 2004, is available on the [Food Allergens Guidance documents and Regulatory Information](http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Allergens) page at <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Allergens>.

2.2.6. Food and Drug Administration Amendments Act of 2007 (FDAAA)

Information on [FDAAA](http://www.fda.gov/regulatoryinformation/legislation/federalfooddrugandcosmeticactfdca/significantamendmentstotheftdcact/foodanddrugadministrationamendmentsof2007), Sept. 27, 2007, is available at <http://www.fda.gov/regulatoryinformation/legislation/federalfooddrugandcosmeticactfdca/significantamendmentstotheftdcact/foodanddrugadministrationamendmentsof2007>.

Information on device-related legislation that FDAAA amended is available on the page for the [Safe Medical Devices Act of 1990](http://www.gpo.gov/fdsys/pkg/STATUTE-104/pdf/STATUTE-104-Pg4511.pdf) (SMDA), Nov. 28, 1990, at <http://www.gpo.gov/fdsys/pkg/STATUTE-104/pdf/STATUTE-104-Pg4511.pdf> and on the page for the [Medical Devices Amendments of 1992](http://www.gpo.gov/fdsys/pkg/STATUTE-106/pdf/STATUTE-106-Pg238.pdf) (the 1992 Amendments), June 16, 1992, at <http://www.gpo.gov/fdsys/pkg/STATUTE-106/pdf/STATUTE-106-Pg238.pdf>.

2.2.7. Food and Drug Administration Export Reform and Enhancement Act (FDAEREA)

Information on [FDAEREA](http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/SignificantAmendmentstotheFDCAct/ucm148005.htm), April 26, 1996, is available at <http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/SignificantAmendmentstotheFDCAct/ucm148005.htm>.

2.2.8. Food and Drug Administration Modernization Act of 1997 (FDAMA)

Information on [FDAMA](http://www.fda.gov/regulatoryinformation/legislation/federalfooddrugandcosmeticactfdcact/significantamendmentstotheFDCAct/fdama), Nov. 21, 1997 is available at <http://www.fda.gov/regulatoryinformation/legislation/federalfooddrugandcosmeticactfdcact/significantamendmentstotheFDCAct/fdama>.

2.2.9. Food and Drug Administration Safety and Innovation Act (FDASIA)

Information on [FDASIA](http://www.gpo.gov/fdsys/pkg/PLAW-112publ144/pdf/PLAW-112publ144.pdf) (<http://www.gpo.gov/fdsys/pkg/PLAW-112publ144/pdf/PLAW-112publ144.pdf>) July 9, 2012, is available on FDA's [FDASIA](http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/SignificantAmendmentstotheFDCAct/FDASIA) page at <http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/SignificantAmendmentstotheFDCAct/FDASIA>.

2.2.10. Food Quality Protection Act (FQPA)

Information on [FQPA](http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/SignificantAmendmentstotheFDCAct/ucm148008.htm), Aug. 3, 1996, is available at <http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/SignificantAmendmentstotheFDCAct/ucm148008.htm>.

2.2.11. Food Safety Modernization Act (FSMA)

Information on [FSMA](http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/SignificantAmendmentstotheFDCAct/ucm148008.htm), Jan. 4, 2011 is available at <http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/SignificantAmendmentstotheFDCAct/ucm148008.htm>.

2.2.12. Generic Drug Enforcement Act (GDEA)

Additional information on [GDEA](http://www.gpo.gov/fdsys/pkg/STATUTE-106/pdf/STATUTE-106-Pg149.pdf) (<http://www.gpo.gov/fdsys/pkg/STATUTE-106/pdf/STATUTE-106-Pg149.pdf>), May 13, 1992 is available on the FDA [debarment](http://www.fda.gov/ICECI/EnforcementActions/FDADebarmentList) page at <http://www.fda.gov/ICECI/EnforcementActions/FDADebarmentList>.

2.2.13. Health Promotion and Disease Prevention Amendments (HPDPA)

Information on [HPDPA](http://www.gpo.gov/fdsys/pkg/STATUTE-98/pdf/STATUTE-98-Pg2815.pdf), Oct. 30, 1984, is available at <http://www.gpo.gov/fdsys/pkg/STATUTE-98/pdf/STATUTE-98-Pg2815.pdf>.

2.2.14. Infant Formula Act (IFA)

The [IFA](http://www.gpo.gov/fdsys/pkg/STATUTE-94/pdf/STATUTE-94-Pg1190.pdf), (<http://www.gpo.gov/fdsys/pkg/STATUTE-94/pdf/STATUTE-94-Pg1190.pdf>), Sept. 26, 1980, and subsequent amendments in 1986 (Section 412) establish nutrient requirements for infant formulas. Information is available on the pages for [Guidelines Concerning Notification and Testing of Infant Formulas](http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegul) (<http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegul>

[RegulatoryInformation/InfantFormula/ucm169730.htm](http://www.fda.gov/RegulatoryInformation/InfantFormula/ucm169730.htm)) and [Briefing Materials for the Food Advisory Committee Meeting on Infant Formula](http://www.fda.gov/RegulatoryInformation/InfantFormula/BriefingMaterialsfortheFoodAdvisoryCommitteeMeetingonInfantFormula) (http://www.fda.gov/ohrms/dockets/ac/02/briefing/3852b1_01.htm).

2.2.15. Medical Device Amendments

Information on the Medical Device Amendments, May 24, 1976, is available on the pages for [Overview of Device Regulation](http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview) (<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview>) and [Overview of Medical Device Classification and Reclassification](http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHTransparency/ucm378714.htm) (<http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHTransparency/ucm378714.htm>).

2.2.16. Medical Device User Fee and Modernization Act (MDUFMA I, II and III)

The FDA User Fee page is at <https://www.fda.gov/ForIndustry/UserFees>.

Information on [MDUFMA III](http://www.gpo.gov/fdsys/pkg/PLAW-112publ144/html/PLAW-112publ144.htm) (<http://www.gpo.gov/fdsys/pkg/PLAW-112publ144/html/PLAW-112publ144.htm>), July 9, 2012, is included in FDASIA. Additional information is available on the pages for [MDUFMA](http://www.fda.gov/medicaldevices/deviceregulationandguidance/overview/medicaldeviceuserfeeandmodernizationactmdufma) (<http://www.fda.gov/medicaldevices/deviceregulationandguidance/overview/medicaldeviceuserfeeandmodernizationactmdufma>) and [MDUFMA III](http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MDUFMAIII) (<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MDUFMAIII>).

MDUFMA III amended [MDUFMA I](http://www.fda.gov/medicaldevices/deviceregulationandguidance/overview/medicaldeviceuserfeeandmodernizationactmdufma/ucm109133.htm) (<http://www.fda.gov/medicaldevices/deviceregulationandguidance/overview/medicaldeviceuserfeeandmodernizationactmdufma/ucm109133.htm>), Oct. 26, 2002.

[MDUFMA II](http://www.fda.gov/medicaldevices/deviceregulationandguidance/overview/medicaldeviceuserfeeandmodernizationactmdufma/ucm109316.htm) (<http://www.fda.gov/medicaldevices/deviceregulationandguidance/overview/medicaldeviceuserfeeandmodernizationactmdufma/ucm109316.htm>) was included in the [Food and Drug Administration Amendments Act of 2007](http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAAct/SignificantAmendmentstotheFDCAAct/FoodandDrugAdministrationAmendmentsActof2007/FullTextofFDAAALaw) (<http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAAct/SignificantAmendmentstotheFDCAAct/FoodandDrugAdministrationAmendmentsActof2007/FullTextofFDAAALaw>) (FDAAA), Sept. 27, 2007.

2.2.17. Minor Use and Minor Species Animal Health Act (MUMS)

Information on [MUMS](http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAAct/SignificantAmendmentstotheFDCAAct/MinorUseandMinorSpeciesAnimalHealthActof2004) (<http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAAct/SignificantAmendmentstotheFDCAAct/MinorUseandMinorSpeciesAnimalHealthActof2004>), Aug. 2, 2004, is available on the [MUMS resource](http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/MinorUseMinorSpecies) page at <http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/MinorUseMinorSpecies>.

2.2.18. Nutrition Labeling and Education Act (NLEA)

Information on the [NLEA](http://www.fda.gov/iceci/inspections/inspectionguides/ucm074948.htm) (<http://www.fda.gov/iceci/inspections/inspectionguides/ucm074948.htm>), Nov. 8, 1990, is available on the pages for [Labeling & Nutrition Guidance Documents & Regulatory](#)

Information at <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition> and for [Inspection Guide to NLEA Requirements](http://www.fda.gov/iceci/inspections/inspectionguides/ucm074948.htm) at <http://www.fda.gov/iceci/inspections/inspectionguides/ucm074948.htm>.

2.2.19. Orphan Drug Act (ODA)

Information on the [ODA](http://www.fda.gov/regulatoryinformation/legislation/federalfooddrugandcosmeticactfdca/significantamendmentstothefdcact/orphandrugact) (<http://www.fda.gov/regulatoryinformation/legislation/federalfooddrugandcosmeticactfdca/significantamendmentstothefdcact/orphandrugact>), April 18, 1988, is available on the pages for regulatory history of Orphan Drugs (<http://www.fda.gov/ForIndustry/DevelopingProductsforRareDiseasesConditions/HowtoapplyforOrphanProductDesignation/ucm356481.htm>) and requirements for industry (<http://www.fda.gov/forindustry/DevelopingProductsforrareDiseasesConditions>). The ODA of 1988 amended the [Orphan Drug Act](http://www.gpo.gov/fdsys/pkg/STATUTE-96/pdf/STATUTE-96-Pg2049.pdf) of 1983 (<http://www.gpo.gov/fdsys/pkg/STATUTE-96/pdf/STATUTE-96-Pg2049.pdf>) Jan. 4, 1983.

2.2.20. Pandemic and All-Hazards Preparedness Reauthorization Act (PAHPRA)

Information on [PAHPRA](http://www.gpo.gov/fdsys/pkg/PLAW-113publ5/pdf/PLAW-113publ5.pdf) (<http://www.gpo.gov/fdsys/pkg/PLAW-113publ5/pdf/PLAW-113publ5.pdf>), March 13, 2013 is available on the [MCM-related Legislation](http://www.fda.gov/EmergencyPreparedness/Counterterrorism/MedicalCountermeasures/MCMLegalRegulatoryandPolicyFramework/ucm2007271.htm#PAHPRA) page at <http://www.fda.gov/EmergencyPreparedness/Counterterrorism/MedicalCountermeasures/MCMLegalRegulatoryandPolicyFramework/ucm2007271.htm#PAHPRA>.

PAHPRA updated and reauthorized related provisions of the [Pandemic and All-Hazards Preparedness Act of 2006](http://www.gpo.gov/fdsys/pkg/PLAW-109publ417/pdf/PLAW-109publ417.pdf) (<http://www.gpo.gov/fdsys/pkg/PLAW-109publ417/pdf/PLAW-109publ417.pdf>) (PAHPA), Dec. 19, 2006; the [Public Readiness and Emergency Preparedness Act of 2005](http://www.gpo.gov/fdsys/pkg/PLAW-109publ148/pdf/PLAW-109publ148.pdf) (<http://www.gpo.gov/fdsys/pkg/PLAW-109publ148/pdf/PLAW-109publ148.pdf>) (PREP Act), Dec. 30, 2005; and the [Public Health Security and Bioterrorism Preparedness and Response Act](http://www.fda.gov/RegulatoryInformation/Legislation/ucm148797.htm) (<http://www.fda.gov/RegulatoryInformation/Legislation/ucm148797.htm>) (the Bioterrorism Act), June 12, 2002. General information about medical counter measures (MCM), emergency preparedness and response, and the various recent counter-terrorism legislation is available on the [MCM-related Legislation](http://www.fda.gov/EmergencyPreparedness/Counterterrorism/MedicalCountermeasures/MCMLegalRegulatoryandPolicyFramework/ucm2007271.htm) page at <http://www.fda.gov/EmergencyPreparedness/Counterterrorism/MedicalCountermeasures/MCMLegalRegulatoryandPolicyFramework/ucm2007271.htm>.

2.2.21. Pediatric Research Equity Act (PREA)

[PREA](http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/DevelopmentResources/UCM077853.pdf) (<http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/DevelopmentResources/UCM077853.pdf>), Dec. 2, 2003, has been amended by subsequent legislation. See the pages for the [pediatric provisions in FDASIA](http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCA/SignificantAmendments-to-the-FDCA/FDASIA/ucm311038.htm) (<http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCA/SignificantAmendments-to-the-FDCA/FDASIA/ucm311038.htm>) and for the [Food and Drug](#)

Administration Amendments Act (FDAAA) (<http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCA/SignificantAmendmentstotheFDCA/FoodandDrugAdministrationAmendmentsActof2007/FullTextofFDAAALaw>), Sept. 27, 2007.

2.2.22. Prescription Drug Marketing Act of 1987 (PDMA)

Information on PDMA, April 22, 1988 is at <http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCA/SignificantAmendmentstotheFDCA/PrescriptionDrugMarketingActof1987>).

2.2.23. Prescription Drug User Fee Act (PDUFA)

The FDA User Fee page is at <https://www.fda.gov/ForIndustry/UserFees>.

Information on PDUFA (<http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCA/SignificantAmendmentstotheFDCA/PrescriptionDrugAmendmentsof1992PrescriptionDrugUserFeeActof1992>) Oct. 29, 1992, is available on the PDUFA pages for industry (<http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee>) and for small business (<http://www.fda.gov/Drugs/DevelopmentApprovalProcess/SmallBusinessAssistance/ucm069943.htm>).

2.2.24. Project Bioshield Act

Information Project Bioshield Act (<http://www.gpo.gov/fdsys/pkg/PLAW-108publ276/pdf/PLAW-108publ276.pdf>), July 21, 2004, FDA's emergency preparedness and response, and the more recent counter-terrorism legislation is available on the MCM-related Legislation page at <http://www.fda.gov/EmergencyPreparedness/Counterterrorism/MedicalCountermeasures/MCMLegalRegulatoryandPolicyFramework/ucm2007271.htm>.

2-3 OTHER LAWS

2.3.1. Public Health Service Act - Biological Products (Part F, Subpart 1)

Biological products are approved for marketing under provisions of the Public Health Service Act (PHS Act). However, because most biological products also meet the definition of "drugs" under the Federal Food, Drug, and Cosmetic Act (FD&C Act), they are also subject to regulation under FD&C Act provisions.

A biological product is a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product, or arsphenamine or its derivatives (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings. For example, biologics include vaccines, various toxoids, skin test antigens, allergenic extracts, blood and blood products, and certain in vitro test kits intended for testing of biological products. The PHS Act requires individuals or companies who

manufacture biologics for introduction into interstate commerce to hold a license for the products. These licenses are issued by FDA's Center for Biologics Evaluation and Research (CBER). Biological products intended for veterinary use are regulated under a separate law, the Virus, Serum, and Toxin Act, which is administered by the U.S. Department of Agriculture.

In May 1996, FDA amended the biologics regulations to eliminate the Establishment License Application (ELA) for certain biotechnology and synthetic biological products subject to licensing under the PHS Act. Manufacturers of those products are now required to submit only a biologics license application (BLA), thereby enabling companies to devote more resources to ensuring that manufacturing processes are properly validated and fewer resources to submitting documentation to the agency. A BLA may be used for submissions for specified biotechnology products such as products manufactured by recombinant DNA technology and monoclonal antibody products. This regulatory change will reduce unnecessary burdens for industry without diminishing public health protection.

The PHS Act also provides authority to immediately suspend licenses in situations where there exists a danger to public health. This statute also allows us to prepare or procure products in the event of shortages and critical public health needs and authorizes the creation and enforcement of regulations to prevent the introduction, or spread of communicable disease in the US and/or between states. This law also provides important flexibility in regulation of biotechnology products, which facilitates the introduction and development of new medicines.

The PHS Act specifies that manufacturers must plainly label the biological products with the proper name of the article, the name, address, and license number of the manufacturer, and the appropriate expiration date of the product. No person shall falsely label any package containing a biological product. The PHS Act authorizes the inspection of biological product manufacturers. Section 351 provides for civil money penalties, fines and imprisonment for violations, and specifies export requirements for biological products.

2.3.2. Public Health Service Act - Control of Communicable Diseases (Part G)

Section 361 of the Public Health Service Act (PHS Act) authorizes the creation and enforcement of regulations to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the U.S. or possessions or between states and possessions. These regulations may provide for inspection, fumigation, disinfection, sanitation, pest extermination, and destruction of animals or articles found infected or contaminated and as sources of dangerous infection to human beings.

See PHS Act 42 U.S.C. 264-272, 42 U.S.C. 264-272, July 1, 1944, as amended 1957, 1958, 1960 and 1976.

2.3.3. Mammography Quality Standards Act of 1992

The Mammography Quality Standards Act (MQSA) was signed into law on October 27, 1992, to establish national quality standards for mammography. The MQSA required that to provide mammography services legally after October 1, 1994, all facilities, except facilities of the Department of Veterans Affairs, must be accredited by an approved accreditation body and certified by the Secretary of Health and Human Services (the Secretary) or by an approved State certification body. The authority to approve accreditation bodies, State certification bodies, and to certify facilities was delegated by the Secretary to the FDA.

On October 28, 1997, the FDA published regulations to implement the MQSA in the Federal Register. The regulations (21 CFR Part 900) became effective April 28, 1999. The FDA compiled all final guidance related to MQSA into a computerized searchable Policy Guidance Help System in November 1998. The Policy Guidance Help System is available on the Internet at: <http://www.fda.gov/Radiation-Emitting/Products/MammographyQualityStandardsActandProgram/Guidance/PolicyGuidanceHelpSystem>.

Also at: <http://www.fda.gov/RegulatoryInformation/Legislation/ucm148794.htm>.

2.3.4. Federal Anti-Tampering Act – 1983

On October 13, 1983, the President signed the Federal Anti-Tampering Act (P.L. 98-127). This Act amends Title 18 of the United States Code (U.S.C.) to establish graduated penalties for tampering with a consumer product with intent to cause injury or death. The penalties range from a maximum of \$25,000 and 10 years imprisonment in the case of an attempt to tamper, to a maximum of \$100,000 and life imprisonment, in a case where death results from the tampering.

In addition, FATA establishes penalties for:

- A. Tampering with or mislabeling consumer products with intent to injure a business;
- B. Knowingly communicating false information about tainting of a consumer product, if such tainting occurred, that would create a risk of death or bodily injury;
- C. Threatening to tamper with a consumer product in a manner to create a risk of death or bodily injury; and,
- D. Conspiracy to tamper with a consumer product.

A “consumer product” is any article subject to the Act and FDA is the designated authority to investigate violations.

Additional information is available on the FDA Internet at:
<http://www.fda.gov/RegulatoryInformation/Legislation/ucm148785.htm>.

2.3.5. Freedom of Information Act – 1966

The Freedom of Information Act (FOIA) (P.L. 104-231) was passed by Congress in 1966 and amended in 1974 (5 U.S.C. 552). The FOIA created procedures by which any member of the public may obtain the records of the agencies of the federal government. Section 552 (a) of FOIA directs government agencies to disclose certain types of records and describes the manner of disclosure required.

The FOIA applies only to federal agencies and does not create a right of access to records held by Congress, the courts, or by state or local government agencies. Each state has its own public access laws that should be consulted for access to state and local records.

Like all federal agencies, the Food and Drug Administration is required under the Freedom of Information Act (FOIA) to disclose records requested in writing by any person. However, agencies may withhold information pursuant to nine exemptions and three exclusions contained in the statute.

The FOIA contains six subsections, the first two of which establish certain categories of information that must automatically be disclosed by federal agencies. Subsection (a)(1) of the FOIA requires disclosure through publication in the *Federal Register* of information such as descriptions of agency organization, functions, procedures, substantive rules, and statements of general policy. This requirement provides automatic public access to very basic information regarding the transaction of agency business.

Subsection (a)(2) of the FOIA requires that certain types of records--final opinions rendered in the adjudication of cases, specific policy statements, certain administrative staff manuals and some records previously processed for disclosure under the Act--be routinely made "available for public inspection and copying." At the Food and Drug Administration (FDA), this is generally accomplished through FDA's two "reading rooms," and as a result of the Electronic FOIA Amendments (hereafter referred to as (EFOIA)), many of the records in the reading rooms also are located in FDA's "electronic reading room."

On the FDA Internet at: <http://www.fda.gov/foi/foia2.htm>, <http://www.usdoj.gov/oip/amended-foia-redlined.pdf> and <http://www.fda.gov/RegulatoryInformation/FOI/ReferenceMaterials>. For additional information and guidance on the FOIA, see FDA's Information Disclosure Manual on the FDA Intranet.

2.3.6. Electronic Freedom of Information Amendments of 1996

The Electronic Freedom of Information Act (E-FOIA) Amendments signed into law in 1996 amended the Freedom of Information Act (FOIA), adding a requirement that agencies had to establish an electronic reading room. The reading room must include agency policy manuals, opinions made in the adjudication of cases, and an index of records released by FOIA that are likely to become the subject of subsequent FOIA requests.

In addition, E-FOIA:

- A. Extends from 10 to 20 business days (excluding holidays) the time agencies have to respond to requests for information;
- B. Requires agencies to make reasonable efforts to make records available in the form desired by requesters;
- C. Requires agencies to submit an FDA FOIA Report by the fiscal year;
- D. Requires agencies to make the reports available to the public by computer telecommunications or other electronic means;
- E. Requires agencies to list their major information systems record locator system and a reference guide or guide for obtaining information; and,
- F. Requires that the provisions of the E-FOIA be implemented by specific dates.

2.3.7. Sanitary Food Transportation Act of 1990

The Sanitary Food Transportation Act (P.L. 101-500) requires the Department of Transportation (DOT), in consultation with the Department of Health and Human Services, Environmental Protection Agency, and the United States Department of Agriculture, to issue regulations to provide for the safe transportation of food, food additives, cosmetics, drugs, and medical devices. The requirement includes safe transportation that occurs in vehicles used to transport nonfood products or waste, and the use of dedicated vehicles to transport hazardous materials such as asbestos or municipal waste. SFTA authorizes funding for food transportation inspections from funds designated to carry out the motor carrier safety assistance program if the Recipient State agrees to assist in enforcement. DOT is required to issue regulations.

Codified at: 49 U.S.C. 5701 et. Seq. Additional information is available on the FDA Internet at: <http://www.fda.gov/RegulatoryInformation/Legislation/ucm148790.htm>.

2.3.8. Pesticides Monitoring Improvements Act of 1988

On August 23, 1988, the President signed into law the Omnibus Trade and Competitiveness Act (P.L. 100-418). Included in this law is the Pesticide Monitoring Improvements Act of 1988 which is intended to improve the analytical approaches used by the FDA to determine residues of pesticides in foods. Specifically, Subtitle G requires FDA to computerize

its pesticide monitoring activities, to compile a summary of the information gathered through computerized monitoring activities, and to make its summary and report available to Federal and State agencies and other interested persons.

The PMIA also requires the Secretary of Health and Human Services (HHS) to attempt to enter into cooperative agreements with governments of foreign countries that are major sources of food imports into the U.S., for the purpose of better enabling FDA to assure compliance with pesticide tolerances, or otherwise to obtain, information on pesticides used on imported foods where such agreements cannot be obtained. Finally, the PMIA requires the Secretary of HHS to develop, in consultation with the Environmental Protection Agency (EPA), a long-range plan for the development of new and improved methods for detecting pesticide residues, and to make a report and recommendations to appropriate congressional committees.

The PMIA is codified at 21 U.S.C. Sections 1401-1403 Part 4702, 4703, and 4704, included as part of the Omnibus Trade and Competitiveness Act.

2.3.9. AIDS Amendments of 1988

The AIDS amendments (P.L. 100-607) set up broad programs for research, counseling, testing, education and information programs, and health care for acquired immune deficiency syndrome (AIDS) patients. Of interest to FDA are provisions that specify requirements of the Secretary.

- A. Require the Secretary to encourage manufacturers of drugs with potential effectiveness as AIDS treatments to apply for investigational exemptions under the Act. The Secretary has authorization to provide technical assistance through grants or contracts to manufacturers, researchers, and physicians to expedite submission of applications and the availability of new drugs under treatment INDS.
- B. Require the Secretary to establish a data bank that includes a registry of clinical trials and information on AIDS drugs available under INDS, including treatment INDS, superseding the confidentiality provisions of the Act with respect to these drugs.
- C. Authorize the Secretary to add 780 new positions to the Public Health Service (PHS) before October 1, 1990, and require the Secretary to report to Congress after three months on the allocation among the agencies.
- D. Require the Office of Personnel Management or the General Services Administration (GSA) to respond to priority requests for personnel and administrative support from FDA and PHS agencies within 21 days after the request.
- E. Establish a National Commission on AIDS that would, among other things, evaluate the adequacy of clinical trials and make

recommendations on streamlining regulations relating to FDA approval of new drugs and medical devices, including procedures for the release of experimental drugs.

- F. Require the Secretary to submit an annual report to Congress on all expenditures by the Department with respect to AIDS.
- G. Require the National Institute of Allergy and Infectious Diseases (NIAID), after consulting with FDA, to establish the AIDS Clinical Research Review Committee. The Committee is physicians in clinical practice. They advise NIAID on appropriate research activities to undertake, including research on drugs, with respect to clinical treatment of AIDS.
- H. Authorize NIH, after consulting with FDA, to provide grants and contracts to community- based organizations to conduct clinical trials approved by FDA, and require that FDA, among others, approve applications for financial assistance.
- I. Require the Secretary to establish a program to evaluate the effectiveness and risks associated with unapproved drugs in use by AIDS patients.
- J. Require the Secretary, after consultation with FDA, among others, to establish a program of research and education regarding blood donations and transfusions.
- K. Require that the grant programs for clinical care of AIDS patients must provide patients with information and counseling on the availability of treatments both approved and not yet approved by FDA.
- L. Require the Secretary to expedite the award of grants, contracts, and cooperative agreements for research projects relating to AIDS and require the submission of a quarterly report to Congress.
- M. Require the Secretary to request the National Academy of Science and others to report on the potential use of consortia for research and development of vaccines and drugs.

2.3.10. Lead-Based Paint Poisoning Prevention Act – 1971

The Lead-Based Paint Poisoning Prevention Act required the Secretary of Health and Human Services to take such steps and impose such conditions as may be necessary or appropriate to prohibit the application of lead-based paint to any cooking utensil, drinking utensil, or eating utensil manufactured and distributed after January 13, 1971.

Codified at 42 U.S.C. 4831. Additional information is available at: <http://www.fda.gov/RegulatoryInformation/Legislation/ucm148755.htm> .

2.3.11. Egg Products Inspection Act - 1970

The Egg Products Inspection Act enacted in 1970 is administered by the U.S. Department of Agriculture and imposes specific inspection

requirements for the two categories of eggs—egg products and shell eggs to assure wholesome shell eggs and egg products in the marketplace.

The Act gives enforcement authority to the USDA and to the Food and Drug Administration. Federal agriculture officials or state officials acting on behalf of USDA visit egg packers and hatcheries at least every three months to see that they are in compliance with the law. Firms which transport, ship or receive shell eggs and egg products may also be checked periodically. Under the Egg Products Inspection Act, plants that break, dry and process shell eggs into liquid, frozen or dried egg products must operate under the continuous inspection program of the USDA. An official inspector must be present at all times when eggs are being processed. The law applies to all egg-breaking plants, regardless of size, and to those selling products locally, across state lines and in foreign commerce. Disposition of undesirable shell eggs is controlled to prevent their entering consumer food channels.

Egg Products Inspection Act, 21 U.S.C. Sections 1031 et seq., see <http://www.fda.gov/RegulatoryInformation/Legislation/ucm148752.htm> .

2.3.12. Fair Packaging and Labeling Act - 1966

The Fair Packaging and Labeling Act enacted in 1966 and substantially amended in 1992, prohibits any person who packages or labels consumer commodities, as defined, from distributing commodities that are not packaged and labeled as required by this law and its implementing regulations. See 15 U.S.C. 1452. The law is designed to ensure that consumers receive accurate and usable information about consumer commodities from the labeling on their packages. Consumer commodities include any food, drug, device or cosmetic, as defined by the Federal Food, Drug, and Cosmetics Act, and any other article, product or commodity customarily produced or distributed through retail sales agencies for use or consumption by individuals. 15 U.S.C. 1459(a). Meat, poultry, tobacco products, and specified beverages, drugs, and agricultural products regulated under other statutes and programs are excluded from the definition of consumer commodity. 15 U.S.C. 1459(a)(1)-(5).

Codified at 15 U.S.C. 1451 et seq. On the FDA Internet at: <http://www.fda.gov/RegulatoryInformation/Legislation/ucm148722.htm>.

2.3.13. Federal Import Milk Act

In addition to being subject to the requirements of the FFD&C Act, milk and cream (including sweetened condensed milk) offered for import into the U.S. are subject to the Federal Import Milk Act (P.L. 69-625) enforced by the FDA. Such products may be imported only under permit after certain sanitary and other prerequisites have been fulfilled.

2.3.14. Health Insurance Portability and Accountability Act of 1996

The Health Insurance Portability and Accountability Act of 1996 (HIPAA), Title II (Administration Simplification) requires the Secretary to issue several regulations, one of which would protect the privacy of individually identifiable health information. The Final "Privacy" Rule published on December 20, 2000 and was amended on May 31, 2002 and August 14, 2002. The Privacy Rule provides that a "covered entity" may not use or disclose protected health information ("PHI") except as permitted or required by the Rule. It permits the continued use of PHI for treatment, payment, or operations purposes. There are only two required disclosures: (1) to the individual pursuant to the access requirements; and, (2) to the Secretary to determine compliance with the Rule. Covered entities are defined as health plans, health care clearinghouses, and health care providers who engaged in certain electronic transactions. FDA is not a covered entity. PHI includes individually identifiable health information that is electronically transmitted or maintained by a covered entity in any form or medium.

The Privacy Rule permits covered entities to disclose PHI without the individual's consent or authorization, to a person or entity subject to FDA jurisdiction, for public health purposes related to quality, safety or effectiveness of the FDA regulated product or activity. Such purposes include the reporting of adverse events or product defects or problems; the tracking of FDA regulated products; the ability to effectuate products recalls, repairs, replacement or lookback (traceback); and conducting post marketing surveillance. The Privacy Rule is not intended to discourage or prevent adverse event reporting or otherwise disrupt the flow of essential information needed by the FDA to carry out its public health activities.

The Privacy Rule also permits covered entities to disclose PHI to the FDA without consent or authorization pursuant to several other exemptions in the rule. These include where the use or disclosure is required by law; for the purpose of preventing or controlling disease, injury, or disability (including, but not limited to the conduct of public health surveillance, public health investigations, and public health interventions); for oversight activities authorized by law (including audits, civil, administrative or criminal investigations, inspections, disciplinary actions, civil, administrative, or criminal proceedings or other actions, or other activities necessary for appropriate oversight of the health care system); and for law enforcement purposes, when certain conditions are met. The information disclosed in these instances may only be the minimum amount necessary for the purpose. Before disclosing protected health information to their "business associate," covered entities must have a contract assuring that the business associate will safeguard the information pursuant to the Privacy Rule. At times, some covered entities, such as hospitals, mistakenly believe that FDA is their business associate and ask FDA to sign a confidentiality statement before the hospital gives FDA individually

identifiable health information. FDA is not a business associate and is not required to sign such a statement. Additional information about HIPAA and the Privacy Rule is on the Internet at:

<http://www.hhs.gov/ocr/hipaa> .

2.3.15. Equal Access to Justice Act - 1980

The winning party has traditionally been awarded court costs. However, these costs do not include fees and expenses for attorneys and expert witnesses. The purpose of the EAJA of 1980 (P.L. 96-481) and the subsequent 1985 amendments (P.L. 99-80) was to prevent overbearing conduct on the part of the government against individuals and small firms who might not have the financial resources to oppose improper government acts.

Under the EAJA (28 U.S.C. 2412), a "party" is defined as an individual whose net worth does not exceed \$2,000,000 or the owner of an unincorporated business or any partnership, corporation, association, or unit of local government whose net worth does not exceed

\$7,000,000 and which does not have more than 500 employees. Cooperative agricultural associations and tax exempt organizations may be parties without regard to these parameters.

A party prevailing against the government is entitled to be reimbursed for reasonable attorney fees, expenses for expert witnesses and the cost of any study, analysis, engineering report, test, or project which is found by the court to be necessary for the preparation of the party's case. The EAJA applies to civil litigation but does not include torts (injury claims for a civil wrong). The EAJA does not apply to criminal cases.

Pursuant to the EAJA, costs will be awarded to a private party "unless the court finds that the position of the United States was substantially justified or that special circumstances make an award unjust."

2.3.16. Sentencing Reform Act of 1984

The Sentencing Reform Act of 1984 (Title II of the Comprehensive Crime Control Act of 1984) provides for the development of guidelines that will further the basic purposes of criminal punishment: deterrence, incapacitation, just punishment, and rehabilitation. The Act delegates broad authority to the Commission to review and rationalize the federal sentencing process.

The Act contains detailed instructions as to how this determination should be made, the most important of which directs the Commission to create categories of offense behavior and offender characteristics. An offense behavior category might consist, for example, of "bank robbery/committed with a gun/\$2500 taken." An offender characteristic category might be "offender with one prior conviction not resulting in imprisonment." The Commission is required to prescribe guideline ranges that specify an appropriate sentence for each class of convicted persons determined by

coordinating the offense behavior categories with the offender characteristic categories. Where the guidelines call for imprisonment, the range must be narrow: the maximum of the range cannot exceed the minimum by more than the greater of 25 percent or six months.

Pursuant to the Act, the sentencing court must select a sentence from within the guideline range. If, however, a particular case presents atypical features, the Act allows the court to depart from the guidelines and sentence outside the prescribed range. In that case, the court must specify reasons for departure. 18 U.S.C. 3553(b). If the court sentences within the guideline range, an appellate court may review the sentence to determine whether the guidelines were correctly applied. If the court departs from the guideline range, an appellate court may review the reasonableness of the departure. 18 U.S.C. 3742. The Act also abolishes parole, and substantially reduces and restructures good behavior adjustments.

The guidelines took effect on November 1, 1987, and apply to all offenses committed on or after that date. The Commission has the authority to submit guideline amendments each year to Congress between the beginning of a regular Congressional session and May 1. Such amendments automatically take effect 180 days after submission unless a law is enacted to the contrary. 28 U.S.C. 994(p).

2.3.17. Crimes And Criminal Procedure

A. Sec. 111. - Assaulting, resisting, or impeding certain officers or employees

(a) In General - Whoever –

(1) Forcibly assaults, resists, opposes, impedes, intimidates, or interferes with any person designated in section 1114 of this title while engaged in or on account of the performance of official duties; or

(2) Forcibly assaults or intimidates any person who formerly served as a person designated in section 1114 on account of the performance of official duties during such person's term of service, shall, where the acts in violation of this section constitute only simple assault, be fined under this title or imprisoned not more than one year, or both, and in all other cases, be fined under this title or imprisoned not more than 8 years, or both.

(b) Enhanced Penalty –

Whoever, in the commission of any acts described in subsection (a), uses a deadly or dangerous weapon (including a weapon intended to cause death or danger but that fails to do so by reason of a defective component) or inflicts bodily injury, shall be fined under this title or imprisoned not more than 20 years, or both.

B. Sec. 1114. - Protection of officers and employees of the United States

Whoever kills or attempts to kill any officer or employee of the United States or of any agency in any branch of the United States Government (including any member of the uniformed services) while such officer or employee is engaged in or on account of the performance of official duties, or any person assisting such an officer or employee in the performance of such duties or on account of that assistance, shall be punished...

C. Sec. 371. - Conspiracy to commit offense or to defraud United States

If two or more persons conspire either to commit any offense against the United States, or to defraud the United States, or any agency thereof in any manner or for any purpose, and one or more of such persons do any act to effect the object of the conspiracy, each shall be fined under this title or imprisoned not more than five years, or both.

If, however, the offense, the commission of which is the object of the conspiracy, is a misdemeanor only, the punishment for such conspiracy shall not exceed the maximum punishment provided for such misdemeanor.

D. Sec. 1001. - Statements or entries generally

(a) Except as otherwise provided in this section, whoever, in any matter within the jurisdiction of the executive, legislative, or judicial branch of the Government of the United States, knowingly and willfully -

(1) falsifies, conceals, or covers up by any trick, scheme, or device a material fact;

(2) makes any materially false, fictitious, or fraudulent statement or representation;

or

(3) makes or uses any false writing or document knowing the same to contain any materially false, fictitious, or fraudulent statement or entry;

shall be fined under this title or imprisoned not more than 5 years, or both.

(b) Subsection (a) does not apply to a party to a judicial proceeding, or that party's counsel, for statements, representations, writings or documents submitted by such party or counsel to a judge or magistrate in that proceeding.

(c) With respect to any matter within the jurisdiction of the legislative branch, subsection (a) shall apply only to -

(1) Administrative matters, including a claim for payment, a matter related to the procurement of property or services, personnel or employment practices, or support services, or a document required by law, rule, or regulation to be submitted to the Congress or any office or officer within the legislative branch; or

(2) Any investigation or review, conducted pursuant to the authority of any committee, subcommittee, commission or office of the Congress, consistent with applicable rules of the House or Senate.

E. Sec. 1341. - Frauds and swindles

Whoever, having devised or intending to devise any scheme or artifice to defraud, or for obtaining money or property by means of false or fraudulent pretenses, representations, or promises, or to sell, dispose of, loan, exchange, alter, give away, distribute, supply, or furnish or procure for unlawful use any counterfeit or spurious coin, obligation, security, or other article, or anything represented to be or intimated or held out to be such counterfeit or spurious article, for the purpose of executing such scheme or artifice or attempting so to do, places in any post office or authorized depository for mail matter, any matter or thing whatever to be sent or delivered by the Postal Service, or deposits or causes to be deposited any matter or thing whatever to be sent or delivered by any private or commercial interstate carrier, or takes or receives therefrom, any such matter or thing, or knowingly causes to be delivered by mail or such carrier according to the direction thereon, or at the place at which it is directed to be delivered by the person to whom it is addressed, any such matter or thing, shall be fined under this title or imprisoned not more than 20 years, or both. If the violation affects a financial institution, such person shall be fined not more than \$1,000,000 or imprisoned not more than 30 years, or both.

F. Sec. 1343. - Fraud by wire, radio, or television

Whoever, having devised or intending to devise any scheme or artifice to defraud, or for obtaining money or property by means of false or fraudulent pretenses, representations, or promises, transmits or causes to be transmitted by means of wire, radio, or television communication in interstate or foreign commerce, any writings, signs, signals, pictures, or sounds for the purpose of executing such scheme or artifice, shall be fined under this title or imprisoned not more than 20 years, or both. If the violation affects a financial institution, such person shall be fined not more than \$1,000,000 or imprisoned not more than 30 years, or both.

G. Sec. 1505. - Obstruction of proceedings before departments, agencies, and committees

Whoever, with intent to avoid, evade, prevent, or obstruct compliance, in whole or in part, with any civil investigative demand duly and properly

made under the Antitrust Civil Process Act, willfully withholds, misrepresents, removes from any place, conceals, covers up, destroys, mutilates, alters, or by other means falsifies any documentary material, answers to written interrogatories, or oral testimony, which is the subject of such demand; or attempts to do so or solicits another to do so; or

Whoever corruptly, or by threats or force, or by any threatening letter or communication influences, obstructs, or impedes or endeavors to influence, obstruct, or impede the due and proper administration of the law under which any pending proceeding is being had before any department or agency of the United States, or the due and proper exercise of the power of inquiry under which any inquiry or investigation is being had by either House, or any committee of either House or any joint committee of the Congress -

Shall be fined under this title or imprisoned not more than five years, or both.

H. Sec. 1905. - Disclosure of confidential information generally

Whoever, being an officer or employee of the United States or of any department or agency thereof, any person acting on behalf of the Office of Federal Housing Enterprise Oversight, or agent of the Department of Justice as defined in the Antitrust Civil Process Act (15 U.S.C. 1311-1314), or being an employee of a private sector organization who is or was assigned to an agency under chapter 37 of title 5, publishes, divulges, discloses, or makes known in any manner or to any extent not authorized by law any information coming to him in the course of his employment or official duties or by reason of any examination or investigation made by, or return, report or record made to or filed with, such department or agency or officer or employee thereof, which information concerns or relates to the trade secrets, processes, operations, style of work, or apparatus, or to the identity, confidential statistical data, amount or source of any income, profits, losses, or expenditures of any person, firm, partnership, corporation, or association; or permits any income return or copy thereof or any book containing any abstract or particulars thereof to be seen or examined by any person except as provided by law; shall be fined under this title, or imprisoned not more than one year, or both; and shall be removed from office or employment.

Regulatory Procedures Manual

Chapter 3: COMMISSIONING AND INFORMATION SHARING

COMMISSIONING FEDERAL, STATE, AND LOCAL OFFICIALS AND SHARING NON-PUBLIC INFORMATION

This chapter contains sections on commissioning, information sharing agreements, and information disclosure.

Section	Topic	Page
3-1	INTRODUCTION	2
3-2	COMMISSIONING DEFINITION	2
3-3	COMMISSIONING AUTHORITIES.....	3
3-4	OTHER INFORMATION SHARING AUTHORITIES.....	4
3-5	COMMISSIONING AND OTHER INFORMATION SHARING AGREEMENT TYPES.....	5
3-5-1	Commissioning Types.....	5
3-5-2	Other Information Sharing Agreement Types.....	6
	20.88 ISA	6
	20.85 ISA	6
3-6	COMMISSIONING CONFLICT OF INTEREST.....	6
3-6-1	Written Assurances.....	6
3-7	INFORMATION SHARING AND PROTECTION OF NON-PUBLIC INFORMATION	8
3-7-1	Written Assurance.....	8
3-7-2	Protection of Non-Public Information.....	9
3-7-3	Sharing Non-public Information Under Commission	10
3-7-4	Sharing Non-public Information Under 21 CFR § 20.88 (State or Local)	11
3-7-5	Sharing Non-public Information Under 21 CFR § 20.85 (Federal)	12
3-7-6	Information Sharing Training.....	12
3-7-7	Privacy Act.....	13

3-8 COMMISSIONING ADMINISTRATIVE CONSIDERATIONS.....13

3-8-1 Duration 13

3-8-2 Commissioning Request 13

3-8-3 Authorities Granted 14

3-8-4 Suitability for a Commission 15

3-8-5 Accountability 16

3-8-6 Renewal of Commission 17

3-8-7 Non-renewal of Commission 18

3-8-8 Administrative Hold of Commission.....18

3-8-9 Suspension of Commission.....20

3-8-10 Revocation of Commission 21

3-8-11 Returning of Pocket Credentials 22

3-8-12 Relationship with Commissioned Officials.....22

3-9 FDA EMPLOYEE ACCEPTING A STATE’S COMMISSION 23

3-10 EXHIBITS 24

Exhibit 3-1: SAMPLE STATE POCKET CREDENTIAL CARD.....24

Exhibit 3-2: SAMPLE FORM FDA 3716: CERTIFICATE OF COMMISION.....25

3-1 INTRODUCTION

This chapter describes the Food and Drug Administration’s (FDA) procedures and responsibilities for commissioning and entering into other information sharing agreements (ISA) with other government employees and officials and an overview of information sharing with these employees and officials.

3-2 COMMISSIONING DEFINITION

An FDA commission is a delegated authority from the Commissioner of Food and Drugs to an individual to act on his/her behalf. A health, food, or drug officer or employee of any State, Territory, or political subdivision thereof (herein referred to as “state and local officials”) may be commissioned to conduct examinations and investigations on FDA’s behalf for the purposes of the Act. For example, a commissioned official may work on behalf of the FDA under contract, partnership, or for the purposes of other cooperative agreements. It may be necessary for state or local officials to carry pocket credentials in cases where they are conducting assignments under FDA authority, such as conducting examinations, inspections, investigations or collecting samples, and copying and

verifying records. In other cases, it may be necessary for them to only be commissioned with certificate to receive and review information.

FDA developed its commissioning program to make inter-agency cooperation more effective thereby increasing the amount of public health protection afforded to the American consumer. FDA achieves its goal by:

1. Permitting commissioned federal, state, and local officials to operate under Section 702(a)(1)(A) of the federal Food, Drug, and Cosmetic Act (hereafter referred to as the Act).
2. Enabling those commissioned officials to effectively carry out their responsibilities by reviewing FDA information, such as draft policy, that is protected from disclosure to the public by the Freedom of Information Act (FOIA).

A state and local official may be either be commissioned with a certificate of commission or pocket credentials. A certificate of commission grants federal authority to receive and review non-public information “for use only in their work with the FDA”.¹ Pocket credentials grant federal authority to conduct contract inspections on behalf of FDA when the state doesn’t have similar authorities and also grants federal authority to receive and review non-public information for use in their work with the FDA.

An EXECUTIVE (EXEC) Certificate of Commission is a specialized subset of the certificate of commission. This grant of authority for top state agency officials allows for the receipt and review of all FDA program/commodity areas under the official’s purview. This certificate is exclusively restricted to top state agency officials that meet the following criteria: a) US Citizen or National that is the Head of Agency, or Principle Deputy/Delegate and b) Directly responsible for more than four program/commodity areas. While this grant authority allows access to more commodity specific information than other types of commissioning, the holder of an Executive Certificate is still required to follow all of the requirements related to the protection of non-public information listed within the Commissioning Guide and the Acceptance of Commission Agreement.

This chapter focuses on commissioning of state and local officials, and references FDA’s authority to commission officials from other Federal government departments and agencies under important provisions regarding the safety and security of regulated products, including the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (hereafter referred to as the BT Act); and the Drug Quality and Security Act of 2013 (DQSA). It also discusses other types of information sharing agreements used to share non-public information with federal, state, and local officials.

3-3 COMMISSIONING AUTHORITIES

Section 702(a)(1)(A) of the Act authorizes FDA “to conduct examinations and

¹ <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=20.84>

investigations for the purposes of this Act...through any health, food, or drug officer or employee of any State, Territory, or political subdivision thereof, duly commissioned by the Secretary as an officer of the Department.”

Section 702(a)(2) of the Act, as amended by the BT Act, authorizes FDA, pursuant to a memorandum of understanding, to “conduct examinations and investigations for the purposes of the Act through the officers and employees” of other federal departments and agencies. Under this provision, FDA may commission other federal officials pursuant to a memorandum of understanding between the Secretary and the head of the other federal department or agency. Such a memorandum of understanding is only effective in the case of examinations or inspections at facilities or other locations that are “jointly regulated” by FDA and the other federal agency or department.

Section 503A and 503B of the Act, as amended by the DQSA, requires the Secretary to establish a mechanism to receive submissions from state boards of pharmacy concerning certain actions taken against compounding pharmacies or expressing concerns that a compounding pharmacy may be acting contrary to section 503A. This section is to be implemented in consultation with the National Association of Boards of Pharmacy (NABP). In addition, state boards of pharmacy must be notified when the Secretary receives certain state submissions or makes a determination that a compounding pharmacy is acting contrary to section 503A.

FDA’s Office of Regulatory Affairs (ORA), Office of Partnerships (OP) has primary responsibility for overseeing the implementation of FDA’s Commissioning Program and its maintenance on a national scale. The Program Division Directors (PDDs) have primary responsibility for administering and executing the program for commissioning state and local officials. Commissioning for tobacco retail contract inspections is executed jointly between Center for Tobacco Products (CTP) and OP. For federal officials, the inter-agency Memorandum of Understanding (MOU) that is required by the BT Act should include provisions regarding the implementation of the commissioning procedures. For that reason, those provisions are briefly mentioned.

Individuals seeking commissions should be referred to their relevant FDA District Office or State Liaison. The exception is those seeking commissions for tobacco retail compliance should contact FDA’s Center for Tobacco Products at CTPTrainer@fda.hhs.gov.

3-4 OTHER INFORMATION SHARING AUTHORITIES

Section 21 CFR § 20.88 authorizes FDA to share certain non-public information with counterpart state, local and U.S. territory government agencies provided that agency

has entered into a written agreement to protect FDA's information from further disclosure. Information shared with these agencies under this section allows FDA's discretionary sharing of authorized non-public information, under certain circumstances (see section 3-7 below).

Section 21 CFR § 20.85 authorizes FDA to share certain non-public information with non-HHS federal government agencies provided the agency has entered into a written agreement to protect FDA's information from further disclosure.

ORA's Division of Information Disclosure Policy (DIDP) is responsible for developing and maintaining 20.88 and 20.85 agreements. Any state or federal agency should first contact DIDP to properly determine if the state and federal agency can enter into such an agreement with FDA. Division representatives must also contact DIDP first before further sharing any non-public information with any outside agency to ensure proper agreements are in place before sharing. DIDP is responsible for oversight in developing ORA's information sharing policies as well as helping administer the sharing of ORA's information with outside parties, including Freedom of Information (FOI) requests. To contact DIDP, e-mail ORAInfoShare@fda.hhs.gov.

3-5 COMMISSIONING AND OTHER INFORMATION SHARING AGREEMENT TYPES

3-5-1 Commissioning Types

Federal authority can be granted via pocket credentials to state and local officials who will actively engage in investigational and inspectional activities on behalf of the FDA. FDA may issue pocket credentials to other federal officials pursuant to a memorandum of understanding between the Secretary and the head of the other federal department or agency ([see Exhibit 3-1 for a sample credential](#)). Such a memorandum of understanding is only effective in the case of examinations or inspections at facilities or other locations that are "jointly regulated" by FDA and the other federal agency or department. Adequate justification that pocket credentials are needed for inspection or investigation activities under federal authority must be provided for all state and local officials requesting pocket credentials. Pocket credentials are for official business only for inspections and investigations. They shall not be used as a means of personal identification or for other personal purposes.

Federal authority can be granted via a certificate of commission to state and local officials allowing them to receive and review non-public information. ([See Exhibit 3-2 for a sample certificate of commission](#)).

Adequate justification that a certificate of commission is required must be provided for all state and local officials requesting a certificate of commission. Refer to section 3-7 below for information about sharing information under commission and section 3-8 below for additional information regarding issues to consider prior to commissioning including needs and process for justification.

3-5-2 Other Information Sharing Agreement Types

20.88 ISA

States and local governments can enter into 20.88 information sharing agreements with FDA to allow for sharing of FDA information, with limitations (see also section 3-7). There are two types of information sharing agreements states and local governments can enter into: single-signature long-term and case-specific agreements. Entering into either type of agreement doesn't prevent entering into the other. Long-term agreements are commodity specific (food (including animal food) and cosmetics; pharmacy compounding and drug security; imports; and drugs and biologics) and last a duration of up to 5 years (all 20.88 agreements expire at the same time, regardless of when entered into with FDA). Information can be further shared within the agency with anyone under the signatory's chain of command.

State and local governments may also enter into case-specific agreements, especially if entering into long-term agreements aren't possible. Case-specific agreements are written for specific events or situations, allowing ORA to share only within what is detailed in the agreement. Information can only be shared with those that have signed the confidentiality form.

20.85 ISA

Similarly, non-HHS federal agencies can enter into 20.85 case-specific agreements that allow sharing with the agency/office/division that have signed the agreement.

3-6 COMMISSIONING CONFLICT OF INTEREST

3-6-1 Written Assurances

1. *State or local officials*

State or local officials seeking commissioning and Commissioned Officials considered for renewal are required to attest in writing, e.g., through the

Acceptance of the Commission form, that they do not have certain personal financial interests or financial or business relationships with firms operating in the specific fields where authority would be granted to the official under the commission.

A state or local government employee recommended for a commission should discuss questions about the conflict of interest with his/her sponsoring FDA district official, or CTP Contract Officer Representative (COR). If the candidate/official becomes aware of a potential financial interest that would affect participation under the FDA Commissioning Program, the sponsoring FDA district official or CTP COR will summarize the issues and submit them along with other documentation to the FDA Division, OP, and/or CTP for resolution. OP will discuss the matter with the PDD/DD, or CTP, and appropriate FDA Ethics Officials; a decision will be reached as to whether the individual can be commissioned. OP may contact the FDA's Ethics and Integrity Staff (HFA-320). This discussion should ideally be conducted in person by the PDD/DD in the case of a state agency head. If circumstances make this impractical, a PDD/DD, director of state programs, or deputy director may make a visit for this purpose for intergovernmental affairs. Agency heads who are already familiar with the program and for whom this information need not be duplicated may be contacted by telephone to get the assurance that the commission, when offered, will be accepted. In the case of a program director or a subordinate official, a PDD/DD, deputy director for intergovernmental affairs, or the director of state programs should conduct this discussion. However, in situations where the commissioning program is ongoing and well understood by the program director, the discussion may be held with a supervisory investigator with whom the program director already works. Since it is not always practical to meet with each subordinate, the program director may vouch for his or her subordinate.

FDA will not commission any official/candidate if determined to have a conflict of interest. All issues affecting candidate's financial interests must be resolved prior to granting a commission.

The FDA commissioned official must remain free from financial interests that may affect the specified authorities in the FDA commission. If the official acquires a financial interest after receiving a commission, he/she must notify FDA and not participate in any assignment related to the financial interest.

If problems arise about the commissioned status of any official, FDA's resolution may range from disqualification from participating in any commission related activities pertaining to the firm, to the revocation of the commission and return of the FDA pocket credentials. If FDA determines that the problem is resolved, it may consider commissioning the official again.

2. Federal officials

For federal officials, the governing MOU may contain provisions about the conflict of interest standard, e.g., the standard that is imposed by that other federal agency.

3-7 INFORMATION SHARING AND PROTECTION OF NON-PUBLIC INFORMATION

3-7-1 Written Assurance

Outside agencies, whether entering into either a commission or an information sharing agreement with FDA, must be able to maintain the confidentiality of any and all information FDA shares, unless ORA has reviewed and approved the information for further disclosure. For example, state or local officials seeking a commission or commission renewal are required to attest in writing, e.g., through the Acceptance of Commission form for commissioning or the Tobacco Acceptance of Commission form for tobacco commissioning, that they understand that any non-public information FDA provides for review is entitled to significant protection under federal law. The state or local official further understands that if they make any unauthorized disclosures of non-public information, they may be committing a possible violation under federal Law (21 U.S.C. § 331(j), 5 U.S.C. § 552a(i)(1), and 18 U.S.C. § 1905) which could result in civil or criminal penalties including fines and/or imprisonment. In long-term 20.88 and 20.85 agreements, agency or department signatories attest to a confidentiality commitment for their organization contained within the agreement establishing that the state or federal government agency has the authority to protect the non-public information from disclosure and the government agency will not further disclose any such information provided to it. Furthermore, a single-signature non-disclosure agreement, is signed by state agencies awarded contracts. These commitments apply to anyone under the signatory's chain of command. In case-specific 20.88 and 20.85 agreements, individuals receiving non-public information must sign the agreement's confidentiality form.

3-7-2 Protection of Non-Public Information

FDA may share “non-public information” outside of FDA for various reasons (for example, during an outbreak investigation). Non-public information generally includes confidential commercial information, trade secrets information), deliberative process, open investigatory records, and personal privacy information). This may include, but not limited to: written reports, manufacturing and production techniques, equipment used, official FDA documents, etc. The only individuals eligible to see or hear FDA-provided non-public information are:

- a) Commissioned officer(s) who collected or received the information that have a valid FDA use for the information,
- b) An employee at the same state/territorial agency who **also holds** an FDA commission within the same commodity area,
- c) Officers or employees of the Food and Drug Administration or the Department of Health and Human Services,
- d) Any state official covered by an appropriate 20.88 information sharing agreement (with the exception of trade secret information),
- e) Any non-HHS federal official covered by an appropriate 20.85 information sharing agreement (with the exception of trade secret information).
- f) A state official covered by a state contract’s single signature non-disclosure agreement.

Information obtained during a contract inspection, through FDA systems, or any other information obtained pursuant to a commission by a commissioned official is an official FDA record. Information obtained pursuant to a commission is for that official’s use exclusive in their work with the FDA unless further disclosure is authorized by FDA. Information shared by FDA under commission cannot be copied into state memoranda, emails, or other documents, or discussed with individuals not covered above, without first consulting FDA. If in doubt, consult with FDA. Any requests to further share FDA’s information received beyond that which is authorized in the above paragraph should be referred to ORA’s Division of Information Disclosure Policy (DIDP) at ORAInfoShare@fda.hhs.gov.

Pursuant to 21 U.S.C. § 372(a), commissioned state and local government officials are “officers” of the U.S. Department of Health and Human Services, making them subject to the same disclosure restrictions and penalties as any other employee of FDA. Any public requests for information shared by FDA under a commission, including FDA contract inspections performed by an agency using FDA authority, are to be directed to file a Freedom of Information Act request directly with the FDA FOIA office to obtain copies of those records. Information obtained during an inspection by a commissioned official is an official FDA record

and may not be disclosed by an agency in response to such a request. If presented with a formal request or subpoena for information obtained in the course of using the FDA commission, the commissioned official or state agency should immediately contact ORA's DIDP at ORAInfoShare@fda.hhs.gov.

Information shared under 20.88 or 20.85 information sharing agreements must be first reviewed and redacted for trade secret information. Per 21 CFR § 20.61 and 21 U.S.C. § 331(j), trade secret information cannot be shared under any of these agreements. Information shared under either of these types of agreements can be used by states to inform decisions made by the agency (i.e., state-level compliance actions, the need for non-contract inspections, etc.).

Further, while FDA's sharing of personal privacy information is discretionary, FDA's practice is not to share any personal privacy information with any non-FDA federal (including other HHS agencies), state, or local agencies, including any whistleblower information. This includes any information that could potentially aid anyone to determine a whistleblower or complaint's identity. FDA may decide to share certain personal privacy information only if a substantive rationale is provided in order to complete follow up work as needed. In addition, some information containing personal privacy information is subject to the Privacy Act and may not be shared under these agreements unless authorized under the Privacy Act (e.g., written consent or a routine use). Prior to releasing any personal privacy information, DIDP should be contacted before any information disclosure occurs. Redactions in any of these situations, or questions regarding the need to redact, are to be directed to DIDP at ORAInfoShare@fda.hhs.gov.

3-7-3 Sharing Non-public Information Under Commission

FDA may provide a state or local official commissioned in a commodity area to "receive and review FDA information", with information for use only for their work with the FDA (including for situational awareness). The information shared may only pertain to their authorized commodity area if it is protected from disclosure to the public by the Freedom of Information Act (see 21 CFR § 20.84). Per this regulation, this information may not be used to inform state action and is for use only in their work with the Food and Drug Administration.

Trade secret information can be shared under a commission (either credential or certificate) for a valid FDA use. Personal privacy information is not be shared outside of FDA unless the non-FDA user can demonstrate a sustainable need for that information (see above section on sharing of non-public information).

To verify an individual's commission and their approved commodity area prior to transmitting information, please contact StateCommissioning@fda.hhs.gov for

access to the Commissioning Officials database and for any other questions you might have regarding commissioning.

Commissioned officials may only further share FDA information with members of their staff who hold FDA commissions within the same commodity program area, or an official with an Executive Certificate of Commission specifying that they can receive and review official FDA documents. The information may not be copied into state memoranda, emails, or other documents, or discussed with noncommissioned officials. Any requests to further share FDA information received pursuant to a commission beyond that which is authorized should be referred to ORA's Division of Information Disclosure Policy at ORAInfoShare@fda.hhs.gov.

Whenever FDA provides non-public information to commissioned officials, in accordance with the Act and FDA regulations, FDA should indicate the information is non-public by affixing a [transmittal letter](#) which cautions the recipient against further disclosure, marking the documents with a [non-public information coversheet](#), password encrypting electronic files where possible, and adding [E-mail and oral disclaimers](#), as appropriate. When sending documents via non-electronic means, the document's envelope should be identified "To Be Opened By Addressee Only."

3-7-4 Sharing Non-public Information Under 21 CFR § 20.88 (State or Local)

FDA may share certain non-public information pursuant to 21 CFR § 20.88(c) and (d) with state and local officials, as part of cooperative law enforcement or regulatory efforts. This information may be used to inform a state action (i.e., state-level compliance actions, the need for non-contract inspections, etc.). For FDA to share non-public information, there must be a written statement from the state agency establishing that the State government agency has the authority to protect the non-public information from disclosure and a written commitment that the State government agency will not further disclose any such information provided to it. This is called a case-specific 20.88 agreement.

Any documents shared under 21 CFR § 20.88 must have an information disclosure review performed to redact all trade secret information and should not include personal privacy-related information unless there is a demonstrated need by the state agency for the information. When transmitting the records FDA indicates that the information is non-public, e.g., by affixing a [transmittal letter](#) or [disclaimer language in an email](#) which cautions the recipient against further disclosure, marking the documents with a [non-public information coversheet](#), password encrypting electronic files where possible, etc.

To verify an agency is currently covered under a long-term sharing agreement, check the [20.88 Long Term Information Sharing Agreement Database](#) or check with DIDP at ORAInfoShare@fda.hhs.gov. Any records request not covered under a long-term agreement should be forwarded to DIDP for authorization, with a copy to the relevant State Liaison.

For any questions you might have regarding the sharing of non-public information with a state or local entity, please contact DIDP at ORAInfoShare@fda.hhs.gov.

3-7-5 Sharing Non-public Information Under 21 CFR § 20.85 (Federal)

FDA may share certain non-public information with another federal agency under 21 CFR. §20.85 (Disclosure to other federal government departments and agencies). ORA's Division of Information Disclosure Policy (DIDP), Office of Strategic Planning and Operational Policy (OSPOP) manages all 20.85 agreements for the FDA. Any requests for records from a federal agency should be forwarded to the DIDP at ORAInfoShare@fda.hhs.gov with a copy to the relevant State Liaison.

For FDA to share confidential commercial information, pre-decisional information, open investigatory records, and personal privacy information, there must be a written statement from the federal agency establishing that the federal agency has the authority to protect the non-public information from disclosure and a written commitment that the federal agency will not further disclose any such information provided to it. Trade secret information may not be shared under 20.85 agreements. Personal privacy information pertinent or in furtherance of the agency's investigation may be released under a 20.85 authorization.

Any documents shared under a valid 20.85 agreement must have an information disclosure review performed to redact all trade secret information and should not include personal privacy-related information unless there is a demonstrated need by the state agency for the information. When transmitting the records FDA indicates that the information is non-public, e.g., by affixing a [transmittal letter](#) (or use transmittal letter language in an email) which cautions the recipient against further disclosure, marking the documents with a [non-public information coversheet](#), password encrypting electronic files where possible, etc.

For any questions you might have regarding the sharing of non-public information with a federal entity contact DIDP at ORAInfoShare@fda.hhs.gov.

3-7-6 Information Sharing Training

It is imperative that non-public information remains secure and confidential after changing hands. The FDA Information Sharing Training module is designed to

clarify the roles and responsibilities of recipients of various types of non-public information, and it is highly recommended for all of FDA's state and local partners and those FDA employees involved with those partners.

See the [FDA Information Sharing webpage](#)

3-7-7 Privacy Act

The FDA District Office, CTP, Office of Security Operations, and the Office of Partnerships maintain records on individuals who have applied to be commissioned (i.e., photograph, commissioning application package).

Any person may review his or her own file by requesting a copy of it from the Division of Freedom of Information under the Privacy Act. All other questions about Privacy Act records should be addressed to:

Food and Drug Administration
Division of Freedom of Information
Office of the Executive Secretariat, OC
5630 Fishers Lane, Room 1035
Rockville, MD 20857
301-796-3900 (main)
301-827-9267 (fax)
FDAPrivacyOffice@fda.hhs.gov

3-8 COMMISSIONING ADMINISTRATIVE CONSIDERATIONS

3-8-1 Duration

Generally, each state or local commission is issued for a period of five years. At the end of each five-year term, FDA will review the commission and determine whether it should be renewed. For federal commissioned officials, the MOU should include the duration of commission, which might be a term other than five years.

3-8-2 Commissioning Request

A formal request for a commission is considered when a completed application is received by the district for traditional commissioning and CTP for Tobacco.

A Certificate of Commissioning [application packet](#) or [tobacco application packet](#) includes, a completed and signed Basic Information From a Candidate for an FDA Commission and Acceptance of Commission forms. Additional reference materials are distributed with the application packet, i.e., Instructions to

Candidates for an FDA Traditional Commission and The FDA Commission: Granting Federal Authority to State and Local Officials.

3-8-3 Authorities Granted

An individual commissioned by FDA must understand the nature of the federal authority that is granted. It may be used only for the stated purposes when acting on behalf of FDA and does not delegate any federal authority beyond that specified. The authorities granted by an FDA commission are valid **only** for the specific program area(s) for which the candidate applies, up to a maximum of four (4) programs, excluding the Executive Certificate of Commission. The program areas include:

Bioterrorism, Animal Feeds, Biologics, BSE Activity, Cosmetics, Dairy, Drugs, Eggs, Foods, Medical Devices, Produce, Pesticide Residue, Radiological Health, Shellfish, and Tobacco.

An FDA commission confers upon the recipient the authority to perform activities in designated program areas as a federal official within their own state or local jurisdiction. A commission with pocket credentials permits the holder to perform the following activities:

1. Conduct examinations, inspections, and investigations
2. Collect samples
3. Copy and verify records
4. Receive and review FDA documents

Commissioned officials who will be performing activities 1 and 2 above may be requested to show when entering a firm for an inspection. The firm is only required to admit inspectors with up-to-date credentials in an appropriate program area.

A Certificate of Commission and the Executive Certificate of Commission allows the commissioned official to perform activities 3 and 4, listed above. Any records received under activities 1- 4 above should be identified and stored as FDA records.

Additionally, information directly related to an FDA contract can be shared with anyone working on that contract without the need for a commission. Employees receiving non-public information under an FDA contract must be covered under the Single Signature Non-Disclosure Agreement.

3-8-4 Suitability for a Commission

To be considered for an FDA commission, the applicant must be a citizen of the United States or a United States National. Nationals are persons born in an outlying possession of the United States (American Samoa or Swains Island) or born of a parent or parents who are non-citizen nationals who meet certain physical presence or residence requirements. Permanent residents and green card holders are not US nationals and are not eligible for commissioning.

PDDs/DDs are approving authorities for commission requests. Requests must be accompanied by a justification as to why a commission is required in performing work for the FDA. PDDs/DDs are required to provide a justification for all Certificate of Commission approved requests as to why a 20.88 agreement will not suffice for information sharing purposes. The justification must also make clear that the use of the information shared with the commissioned individual won't be used for further work outside of that with FDA.

Prior to issuing a commission, FDA will determine that the candidate is qualified to carry out the duties of a commissioned official. In most cases, the sufficiency of the individual's qualifications will be stipulated by their agency; however, FDA reserves the right to inquire further into the candidate's qualifications. In addition, FDA will conduct a Minimum Background Investigation (MBI) - Level 5 Moderate Risk Public Trust investigation via the Electronic Questionnaires for Investigations Processing (e-QIP) system for all pocket credential requests and, in some cases, certificate of commission requests, if deemed appropriate by the PDD/DD.

Candidates will be required to complete the e-QIP Initiation Form to be given access to the e-QIP system. Candidates will electronically enter data for review and submission to the Office of Personnel Management (OPM). The e-QIP system is part of E-GOV, which is an integral part of the President's Management Agenda (PMA). The MBI will consist of searches of records covering specific areas of an individual's background during the past ten years. Inquiries are sent to current and past employers, schools attended, references and local law enforcement authorities. A credit check and face to face interview with an investigator will also be conducted.

The Office of Personnel Management's (OPM) Federal Investigative Services (FIS) conducts background investigations on federal applicants, employees, contractor personnel, and commissioning candidates for suitability and security determination purposes. A credit search is a routine part of many of these investigations. The subjects of background investigations are requested to sign a release form allowing a check of his or her credit history. Searches are conducted for each name variation a person has used; therefore, there may be more than

one search by OPM showing on a person's credit report. Credit inquiries from OPM investigations are included in the Regular Inquiries portion of a credit record, but these inquiries are "soft" hits and do not have an impact on a person's credit score. Failure to provide FDA with required information within the allotted timeframe will result in a denial for the commission request.

If an individual already possesses a background investigation, the investigation will be reviewed by FDA. If the investigation is compliant with FDA standards, the individual will not need to undergo an additional investigation.

FDA Form 2115s State Credentialing Record is required for all candidates requesting to be commissioned with pocket credentials. A copy of this form is provided to the candidate in the [application packet](#) or [tobacco application packet](#).

3-8-5 Accountability

The commissioning candidate is responsible for contacting FDA when:

- A conflict of interest arises
- An ethical dilemma arises in which a conflict of interest could arise
- Any potential unauthorized or inadvertent release of non-public information
- Any civil, criminal, or illegal activity which could jeopardize the Level 5 MBI obtained by the individual
- When a credential is lost or stolen.
- When a subpoena is received for information that was obtained under a commissioning agreement

FDA reserves the right to deny, administratively hold, suspend, or revoke a commission at any time. In some instances, FDA may pursue civil or criminal charges if the commissioned official is not upholding his or her duties as a commissioned official. Grounds for action may include the following:

- a. Charges of a felony.
- b. Charges of a misdemeanor, excluding minor traffic offenses where the fine is less than \$500.
- c. Pending trial for a felony or misdemeanor charge, excluding minor traffic offenses where the fine is less than \$500.
- d. Pending investigation related to a felony or misdemeanor charge, excluding minor traffic offenses where the fine is less than \$500.
- e. The abuse or misuse of the commission.
- f. The transmittal of confidential information from a commissioned state or local official to individuals who are not employees or commissioned officials of the Department of Health and Human

Services.

- g. A conflict of interest.
- h. Change in criminal or credit history.
- i. Conviction of a crime.
- j. Substance abuse.
- k. Behavior that may discredit the agency.
- l. Inappropriate disclosure of non-public information.
- m. Contract discrepancies.
- n. FDA policy violations.
- o. Programmatic hurdles.

Credentials are considered federal government property. Therefore, the credential must be returned to FDA if the commissioned official leaves the state or local agency or otherwise no longer has a need for the credential. The certificate of commission does not need to be returned to FDA upon its expiration.

3-8-6 Renewal of Commission

1. State or local officials

Commissions of state or local officials are valid for five years. The district will review the commissioned official's record approximately three (3) months prior to expiration of the commission and notify the applicant's supervisor of the impending expiration. This review considers all pertinent aspects of the commission including inspections, collection of samples, consultation extended, cooperation in routine and emergency situations, and any breaches of confidentiality. For state or local officials, a completed application package for traditional commissioning should be sent to the District, from the state or local official, signaling the intent to request a renewal.

Office of Partnerships will work with CTP and State Program Coordinators to renew tobacco retail compliance commissions.

Application packets for tobacco and non-tobacco are specific to those programs.

All renewal applications from the state agency should be entered into the National Commissioning Inventory (NCI) to be routed for approval and processing. ORA has the option to conduct a background investigation at any time during the renewal process, if deemed necessary.

2. Federal officials

For federal officials, the MOU should contain provisions about the duration of the commission and procedures about renewal of a commission.

3-8-7 Non-renewal of Commission

1. *State or local officials*

ORA reserves the right to deny renewal commissioning requests. The PDD/DD will consider the state agency needs, justification, and make a decision based on all pertinent aspects of the commission including inspections, collection of samples, consultation extended, cooperation in routine and emergency situation, non-public document review, and any breaches of confidentiality. FDA will not renew a commission if the holder has changed positions outside of the organization/agency, resigned, or retired. All renewal applications in progress will be withdrawn if the official changes positions outside the organization/agency, resigns, or retires. If the commissioning request is not renewed, the district aided by the NCI with OP's Commissioning Team's signature block or in cases of tobacco, CTP, will send a notification to the applicant and their supervisor advising of the decision.

2. *Federal officials*

For federal officials, the governing MOU may contain provisions about non-renewal of a commission.

3-8-8 Administrative Hold of Commission

1. *General*

ORA may use discretion at any time to administratively hold the commission of such authorized officials on the grounds of violations.

The decision to administratively hold an FDA commission will be communicated within 30 calendar days to both the individual and his/her supervisor.

2. *State or local officials*

For commissioned state or local officials, within ten (10) calendar days after receiving a felony or misdemeanor charge (or pending trial or investigation), or after violation for an administrative hold has occurred, details of the applicable charge or violation must be communicated to their employer, and to the PDD/ DD, deputy director, executive official, director of state programs, or other official specifically charged with oversight of the

commissioning program.

Within five (5) calendar days after receiving details of the charge or violation, the PDD/DD must inform OP's National Commissioning Coordinator at StateCommissioning@fda.hhs.gov. OP's National Commissioning Coordinator will work with Office of Security Operations and OP Senior Management to decide if an administrative hold of the commission is required. After a decision has been reached, the OP National Commissioning Coordinator will recommend the appropriate action, to the PDD/DD specifically charged with oversight of the commissioning official.

If an administrative hold of commission is not required and the PDD/DD concurs, a letter signed by OP's Commissioning Team should be sent to the district to notify the agency head stating that no further action will be taken.

If an administrative hold of commission is required and division concurs, a letter signed by OP's Commissioning Team should be sent to the district for dissemination to the agency head stating the details of the administrative hold and requesting that all commissioning instruments and any documents belonging to FDA be collected and returned to OP. The documents and all additional documentation from the division must then be sent via e-mail to StateCommissioning@fda.hhs.gov.

Once a commission has been administratively held, the FDA will wait for the final verdict of the charge or violation to make its decision on revoking/suspending or reinstating the commission. If the state or local official is not charged with the felony or misdemeanor, or in violation of any of the mentioned scenarios, FDA will use discretion to reinstate their commission. A follow up letter signed by OP's Commissioning Team including the commissioning instruments, should be sent to the district for distribution to the agency head stating the decision to reinstate.

If the state or local official is charged with the felony or misdemeanor, or in violation of any of the mentioned scenarios, their commission will be revoked/suspended immediately. A follow up letter signed by OP's Commissioning Team should be sent to district to notify the agency head stating the decision of revocation/suspensions. Once a commission has been revoked/suspended, that individual is no longer eligible for an FDA commission.

If there is a dissenting opinion between the PDD/DD and another FDA official regarding the administrative hold of an individual's commission, the ACRA, or appropriate senior ORA official, will be consulted for a final

decision.

3-8-9 Suspension of Commission

1. General

ORA may use discretion at any time to suspend the commission of such authorized officials on the grounds of violations.

The decision to revoke or suspend an FDA commission will be communicated within 30 calendar days to both the individual and his/her supervisor.

2. State or local officials

For commissioned state or local officials, within ten (10) calendar days after receiving a felony or misdemeanor charge (or pending trial or investigation), the details of the applicable charge must be communicated to their employer, and to the PDD/ DD, deputy director, executive official, director of state programs, or other official specifically charged with oversight of the commissioning program.

Within five (5) calendar days after receiving details of the charge, the PDD/DD must inform OP's National Commissioning Coordinator at StateCommissioning@fda.hhs.gov. OP's National Commissioning Coordinator will work with Office of Security Operations and OP Senior Management to decide if suspension of the commission is required. After a decision has been reached, the OP National Commissioning Coordinator will recommend the appropriate action, to the PDD/DD specifically charged with oversight of the commissioning official.

If suspension of commission is not required and the PDD/DD concurs, a letter signed by OP's Commissioning Team should be sent to the district to notify the agency head stating that no further action will be taken.

If suspension of commission is required and division concurs, a letter signed by OP's Commissioning Team should be sent to the district for dissemination to the agency head stating the details of the suspension and requesting that all commissioning instruments and any documents belonging to FDA be collected and returned to OP. The documents and all additional documentation from the division must then be sent via e-mail to StateCommissioning@fda.hhs.gov.

Once a commission has been suspended, the FDA will wait for the final verdict of the charge to make its decision on revoking or reinstating the

commission. If the state or local official is not charged with the felony or misdemeanor, FDA will use discretion to reinstate their commission. A follow up letter signed by OP's Commissioning Team including the commissioning instruments, should be sent to the district for distribution to the agency head stating the decision to reinstate.

If the state or local official is charged with the felony or misdemeanor, their commission will be revoked immediately. A follow up letter signed by OP's Commissioning Team should be sent to district to notify the agency head stating the decision of revocation. Once a commission has been revoked, that individual is no longer eligible for an FDA commission.

If there is a dissenting opinion between the PDD/DD and another FDA official regarding the suspension of an individual's commission, the ACRA, or appropriate senior ORA official, will be consulted for a final decision.

3-8-10 Revocation of Commission

1. General

ORA may use discretion at any time to revoke the commission of such authorized officials on the grounds of violations.

The decision to revoke an FDA commission will be communicated in 30 calendar days to both the individual and his/her supervisor.

2. State or local officials

For state or local officials, within ten (10) calendar days after violation for revocation has occurred, details of the violation must be communicated to their place of employment who must then communicate the details to the FDA PDD/DD, deputy director, executive official, director of state programs, or other official specifically charged with oversight of the commissioning program. Within five (5) calendar days after receiving details of the charge, the Division must inform the Office of Partnership's National Commissioning Coordinator.

The Office of Partnership's National Commissioning Coordinator will work with Office of Security and the Office of Partnership's senior management to decide if revocation of commissions is required. After a decision has been reached, the Office of Partnership's National Commissioning Coordinator will recommend the appropriate action to the PDD/DD specifically charged with oversight of the commissioning official.

If the PDD/DD concurs, a letter signed by OP's Commissioning Team

should be sent to district to notify the agency head stating the details of the revocation and requesting that the commissioning instruments, and any documents belonging to FDA be collected and returned to OP. The documents and all additional documentation from the Division office must then be sent via e-mail StateCommissioning@fda.hhs.gov.

Original certificates and credentials should be returned by mail. Once a commission has been revoked, that individual is no longer eligible for an FDA commission. If there is a dissenting opinion between the PDD/DD and another FDA official regarding the revocation of an individual's commission, the ACRA will be consulted for a final decision.

3. *Federal officials*

For federal officials, the MOU may contain provisions about revocation of a commission.

3-8-11 Returning of Pocket Credentials

It is the responsibility of the state agency to return all FDA issued pocket credentials when no longer needed. Examples include expired credentials, individuals that have retired or changed agencies, or when no longer needed to conduct inspections under FDA authority. The expired pocket credentials must be returned to the State Liaison in their respective district office for processing and then forwarded to Office of Partnerships. Tobacco retail compliance credentials should be returned directly to the OP Tobacco Commissioning Coordinator.

3-8-12 Relationship with Commissioned Officials

FDA's relationship with state and local agencies is very important, because close coordination and cooperation provides a high level of consumer protection. State and local officials who hold FDA commissions help FDA enforce its laws and regulations.

To encourage closer ties with cooperating state and local officials who hold FDA commissions, to inform them about FDA, and to let FDA benefit from their knowledge and experience, the PDD/DD should consider the following:

- **Literature and publications**

The manuals listed below are available on the FDA internet and can be accessed at: www.fda.gov. For further assistance please contact OP at StateCommissioning@fda.hhs.gov.

1. [FDA Inspection References](#)

- a. Investigations Operation Manual
- b. FDA Compliance Policy Guides Manual
- c. FDA Regulatory Procedures Manual
2. [Catalog of Courses and Training Materials](#)
3. [Laboratory Information Bulletin](#)
4. [Orange Book: Approved Drug Products With Beneficial Equivalence Evaluations](#)
5. [FDA Information Sharing Course](#)
6. [Section 702\(a\)](#) of the Federal Food, Drug and Cosmetic Act (21 USC 372)
7. [21 CFR §20.88](#) Communications with State and local government officials
8. [SMG 2280.3](#) – FDA Official Credentials and Badges
9. [SMG 3297.4](#) – Implementation of the Privacy Act and the FDA Privacy Program: Overview

3-9 FDA EMPLOYEE ACCEPTING A STATE'S COMMISSION

Rarely, an FDA investigator may find it valuable to exercise state powers. For example, an FDA investigator may wish to obtain a state commission to have the ability to place an embargo in those cases when a state official, who has the authority to do so, is not available. An FDA investigator may hold a state commission provided that:

The commission is offered by a state agency whose agency head holds an FDA Commission.

The commission is not used unless a state official, authorized by the state regulatory agency, has given prior permission to use the state commission in each specific contemplated use. The supervisor of the FDA investigator should agree to the contemplated use of the commission.

3-10 EXHIBITS

Exhibit 3-1: SAMPLE STATE POCKET CREDENTIAL CARD

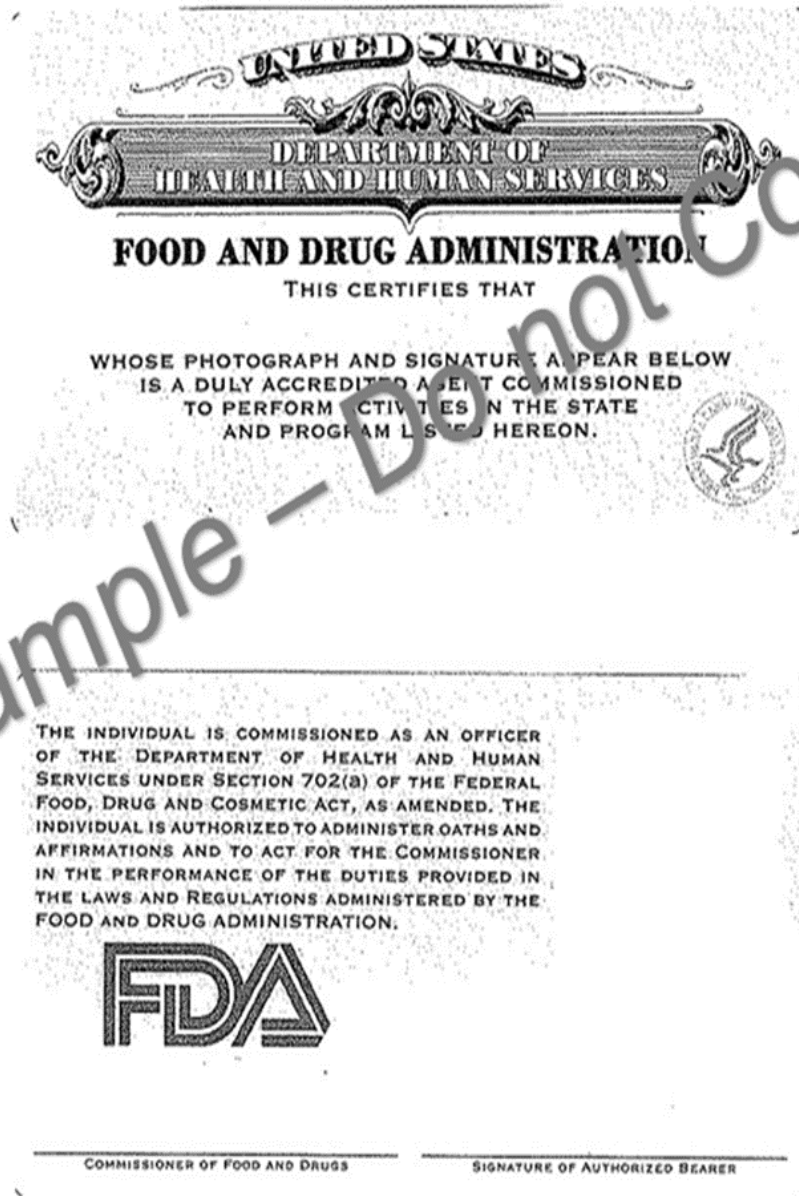


Exhibit 3-2: SAMPLE FORM FDA 3716: CERTIFICATE OF COMMISSION

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

Certificate of Commission

IS COMMISSIONED AS AN OFFICER OF THE DEPARTMENT OF HEALTH
AND HUMAN SERVICES UNDER AUTHORITY CONFERRED BY SECTION
702(a) OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT TO CONDUCT
SPECIFICALLY AUTHORIZED ACTIVITIES IN DESIGNATED PROGRAM
AREAS IN THE FIELD OF _____ FOR THE PURPOSE OF
THE ACT. THIS COMMISSION EXPIRES _____.

COMMISSIONER OF FOOD AND DRUGS

FORM FDA 3716 (5/11)

Regulatory Procedures Manual

Chapter 4: ADVISORY ACTIONS

This chapter defines and establishes uniform guidance and procedures for Warning Letters and Untitled Letters

This chapter includes the following sections:

Section	Topic	Page
4-1	WARNING LETTERS	3
4-1-1.	Warning Letter Procedures	3
4-1-2.	Warning Letters to Government Agencies	5
4-1-3.	Issuing Warning Letters - Factors to Consider	5
1.	General Considerations	6
2.	Ongoing or Promised Corrective Actions	6
3.	Completed Corrective Actions.....	7
4.	Response Letter.....	7
5.	Verification of Corrective Actions	8
4-1-4.	Center Concurrence and Letters Issued by Centers	8
1.	All Centers	8
2.	Center for Drug Evaluation and Research (CDER).....	8
3.	Center for Biologics Evaluation and Research (CBER).....	9
4.	Center for Devices and Radiological Health (CDRH).....	10
5.	Center for Veterinary Medicine (CVM)	11
6.	Center for Food Safety and Applied Nutrition (CFSAN)	12
7.	Center for Tobacco Products	12
4-1-5.	Letters for Illegal Promotional Activities	13
4-1-6.	Multiple Center Review	13
4-1-7.	Time Frames.....	14

4-1-8.	Warning Letter Follow-Up	15
1.	Acknowledgment of Response to a Warning Letter	15
2.	Warning Letter Close-Out Letter	16
3.	Requests to Post Response on Internet.....	17
4.	Follow-Up Enforcement.....	18
5.	Inspection Classification.....	18
4-1-9.	Firm Profile Updates in eNSpect.....	19
4-1-10.	Warning Letter Format.....	19
4-1-11.	Warning Letter Distribution	22
4-1-12.	Warning and Untitled Letters Addressed to Importers, Customs Brokers, and Foreign Firms	22
4-1-13.	Freedom of Information (FOI)	24
4-1-14.	Center for Biologics Evaluation and Research (CBER)	25
4-1-15.	Center for Drug Evaluation and Research (CDER).....	27
4-1-16.	Center for Devices and Radiological Health (CDRH).....	32
4-1-17.	Center for Food Safety and Applied Nutrition (CFSAN) and Center for Veterinary Medicine (CVM).....	35
4-1-18.	Center for Tobacco Products (CTP) Retailer Compliance Check Inspection Program.....	35
4-1-19.	Tracking	36
4-2	UNTITLED LETTERS	37
4-2-1.	Format and Content	37
4-2-2.	Center Concurrence and Letters Issued By Centers.....	37
4-2-3.	Tracking	38
4-3	USE OF STATE EVIDENCE FOR FDA WARNING LETTERS AND UNTITLED LETTERS.....	38
4-4	EXHIBITS	39
	Exhibit 4-1 Procedures for Clearing FDA Warning Letters and Untitled Letters	40
	Exhibit 4-2 Warning Letter Close-Out Letter.....	63

4-1 WARNING LETTERS

4-1-1. Warning Letter Procedures

When it is consistent with the public protection responsibilities of the agency and depending on the nature of the violation, it is the Food and Drug Administration's (FDA's) practice to give individuals and firms an opportunity to take voluntary and prompt corrective action before it initiates an enforcement action. Warning Letters are issued to achieve voluntary compliance and to establish prior notice. (Prior notice is discussed in [Chapter 10 - Other Procedures](#).) The use of Warning Letters and prior notice are based on the expectation that most individuals and firms will voluntarily comply with the law.

The agency position is that Warning Letters are issued only for violations of regulatory significance. Significant violations are those violations that may lead to enforcement action if not promptly and adequately corrected. A Warning Letter is the agency's principal means of achieving prompt voluntary compliance with the Federal Food, Drug, and Cosmetic Act (the Act).

The Warning Letter was developed to correct violations of the statutes or regulations. Also available to the agency are enforcement strategies which are based on the particular set of circumstances at hand and may include sequential or concurrent FDA enforcement actions such as recall, seizure, injunction, administrative detention, civil money penalties and/or prosecution to achieve correction. Despite the significance of the violations, there are some circumstances that may preclude the agency from taking any further enforcement action following the issuance of a Warning Letter. For example, the violation may be serious enough to warrant a Warning Letter and subsequent seizure; however, if the seizable quantity fails to meet the agency's threshold value for seizures, the agency may choose not to pursue a seizure. In this instance, the Warning Letter would document prior warning if adequate corrections are not made and if enforcement action is warranted at a later time.

Responsible officials in positions of authority in regulated firms have a legal duty to implement whatever measures are necessary to ensure that their products, practices, processes, or other activities comply with the law. Under the law such individuals are presumed to be fully aware of their responsibilities. Consequently, responsible individuals should not assume that they would receive a Warning Letter, or other prior notice, before FDA initiates enforcement action.

FDA is under no legal obligation to warn individuals or firms that they or their products are in violation of the law before taking enforcement action, except in a few specifically defined areas. When acting under the authority of Subchapter C - Electronic Product Radiation Control (formerly the Radiation Control for Health and Safety Act of 1968) of Chapter V of the Act, FDA is required by law to provide a written notification to manufacturers when the agency discovers products that fail

to comply with a performance standard or that contain a radiation safety defect. Because of the legal requirements of Subchapter C, minor variations in the procedures may occur.

A Warning Letter is informal and advisory. It communicates the agency's position on a matter, but it does not commit FDA to taking enforcement action. For these reasons, FDA does not consider Warning Letters to be final agency action on which it can be sued.

There are instances when issuing a Warning Letter is not appropriate, and, as previously stated, a Warning Letter is not a prerequisite to taking enforcement action. Examples of situations where the agency will take enforcement action without necessarily issuing a Warning Letter include:

1. The violation reflects a history of repeated or continual conduct of a similar or substantially similar nature during which time the individual and/or firm has been notified of a similar or substantially similar violation;
2. The violation is intentional or flagrant;
3. The violation presents a reasonable possibility of injury or death;
4. The violations, under Title 18 U.S.C. 1001, are intentional and willful acts that once having occurred cannot be retracted. Also, such a felony violation does not require prior notice. Therefore, Title 18 U.S.C. 1001 violations are not suitable for inclusion in Warning Letters; and,
5. When adequate notice has been given by other means and the violations have not been corrected, or are continuing.

See [Chapter 10 - Other Procedures](#), Prior Notice, for other methods of establishing prior notice.

In certain situations, the agency may also take other actions as an alternative to, or concurrently with, the issuance of a Warning Letter. For example:

1. The product is adulterated under Section 402(a)(3) or 402(a)(4) of the Act;
2. There is a violation of current good manufacturing practices (CGMP);
3. The product contains illegal pesticide residues; or
4. The product shows short contents, subpotency, or superpotency.

Additional instructions for Warning Letters in specific product areas are found in [compliance program guidance](#) and in [compliance policy guides](#).

Also, see [Exhibit 4-1](#), the agency's "Procedures for Clearing FDA Warning Letters and Untitled Letters." All agency components responsible for issuing Warning Letters and Untitled Letters must follow these procedures. Developed to facilitate review of all Warning Letters and Untitled Letters by the Office of Chief Counsel

(OCC), the procedures provide instructions for submitting such letters to OCC, and include timeframes and routing information.

4-1-2. Warning Letters to Government Agencies

Government establishments should be held to the same standards as nongovernment establishments. The public health standards are identical; however, the method used to ensure compliance with these standards may vary. FDA believes that government establishments will achieve and maintain a higher rate of voluntary compliance with FDA regulations compared with nongovernment establishments. Efforts to obtain voluntary compliance should be made and documented before recommending the issuance of a Warning Letter. These efforts may include discussing the violations with the responsible government officials by phone or in a meeting, recommending an Untitled Letter, or requesting a written corrective action plan and periodic progress reports. The government establishment's progress should be monitored and a follow-up inspection should be scheduled within a reasonable time consistent with the noted violations to confirm correction of the violations.

Whenever significant violations are observed at a government establishment, or if attempts to achieve compliance have been ineffective, the office (or center) should arrange a meeting with OIO, OCC, and the relevant center to determine a strategy to achieve timely and effective compliance. The meeting should include the Office of Partnerships (OP) if the government establishment is a state or local agency.

Also, see [Exhibit 4-1](#), the agency's "Procedures for Clearing FDA Warning Letters and Untitled Letters." All agency components responsible for issuing Warning Letters and Untitled Letters must follow these procedures.

4-1-3. Issuing Warning Letters - Factors to Consider

The Warning Letter is the agency's principal means of notifying regulated industry of violations and achieving prompt voluntary correction. Warning Letters can be issued at the discretion of the program office director without center concurrence, except in specific program areas that require prior center concurrence. Warning Letters may also be generated through work done at agency headquarters (ORA or centers), processed under appropriate procedures and issued under the authority of a division or office director. (See Center Concurrence and Letters Issued by centers. Also, see [Exhibit 4-1](#), the agency's "Procedures for Clearing FDA Warning Letters and Untitled Letters." All agency components responsible for issuing Warning Letters and Untitled Letters must follow these procedures.)

1. General Considerations

In determining whether to issue a Warning Letter, program office directors and center or other officials with authority to issue should consider whether:

- a. Evidence shows that a firm, product, and/or individual is in violation of the law or regulations and that failure to achieve adequate and prompt correction may result in agency consideration of an enforcement action;
- b. The violation(s) are determined to be of regulatory significance, and the issuance of a Warning Letter is appropriate and consistent with agency policy, as described in Compliance Policy Guides or elsewhere; and
- c. There is a reasonable expectation that the responsible firm and persons will take prompt corrective action.

2. Ongoing or Promised Corrective Actions

Corrective action may be undertaken or promised during an establishment inspection or addressed in correspondence to the agency after an inspection. Ongoing or promised corrective actions generally do not preclude the issuance of a Warning Letter. In addition to being the agency's primary means to achieve prompt, voluntary compliance, Warning Letters remain a primary means to establish prior notice (see [Chapter 10 - Other Procedures](#)) and serve to ensure that the seriousness and scope of the observed violations are understood by top management and that the appropriate resources are allocated to fully correct the violations and to prevent recurrence.

When a firm is in the process of correcting the violations or has made a written promise to take prompt corrective action, a program office or center should consider the following factors when determining whether or not to issue a Warning Letter:

- a. The firm's compliance history, e.g., a history of serious violations, or failure to prevent the recurrence of violations;
- b. The nature of the violation, e.g., a violation that the firm was aware of (was evident or discovered) but failed to correct;
- c. The risk associated with the product and the impact of the violations on such risk;
- d. The overall adequacy of the firm's corrective action and whether the corrective action addresses the specific violations, related violations, related products or facilities, and contains provisions for monitoring and review to ensure effectiveness and prevent recurrence;

- e. Whether documentation of the corrective action was provided to enable the agency to undertake an informed evaluation;
- f. Whether the timeframe for the corrective action is appropriate and whether actual progress has been made in accordance with the timeframe; and,
- g. Whether the corrective action taken ensures sustained compliance with the law or regulations. In the case of Warning Letters being considered for products offered for sale through internet web sites, corrective action to remove claims from or inactivate the website is easily reversible, and should be carefully considered, along with the other factors above, in determining whether or not to issue a Warning Letter. Warning Letters for, or involving, internet web sites should be issued in as close proximity as possible to the time when the claims were last observed, and reference to the date on which the claims were observed should be included in the letter.

If a decision is made not to issue a Warning Letter, see “Response Letter” below. Relying on a firm’s promised corrective actions does not preclude consideration of regulatory action should we later observe that the same or similar violations have not been corrected.

3. Completed Corrective Actions

As a general rule, a Warning Letter should not be issued if the agency concludes that a firm’s corrective actions are adequate and that the violations that would have supported the letter have been corrected. If you believe that an exception is necessary due to the facts or circumstances of the case (e.g., the firm’s compliance history, the nature of the violation, or the risk associated with the product) discuss this background in the Warning Letter referral package and be sure to adapt the language in the proposed letter to fit the circumstances (e.g., recite the history and the consequences if there is a recurrence).

If a decision is made not to issue a Warning Letter, see “Response Letter” below. Relying on a firm’s completed corrective actions does not preclude consideration of regulatory action should we later observe that the same or similar violations have not been corrected.

4. Response Letter

If a decision is made to not issue a Warning Letter because adequate corrective action has been taken, or because corrective action is being taken or has been promised, it is recommended that an alternative form of communication (e.g., a response letter to the firm’s letter promising corrective action) be issued to the responsible individuals at the firm to supplement the record of the violation(s) and reflect the agency’s decision to

rely on the firm's actions and/or promises. The response letter should indicate that the agency is relying on the firm's corrections or commitment regarding corrective actions. Further, the letter may include a statement that should we later observe that these or similar violations have not been corrected; regulatory action (e.g., seizure, injunction and, if appropriate, civil penalties) may be taken without further notice.

5. Verification of Corrective Actions

Verification of the overall completeness and effectiveness of the corrective action should be undertaken during the next inspection, the timing of which may be expedited or routine as determined by the issuing office.

4-1-4. Center Concurrence and Letters Issued by Centers

Center concurrence is required prior to issuing Warning Letters in the areas listed below, or Warning Letters are issued directly by the center.

Also, see [Exhibit 4-1](#), the agency's "Procedures for Clearing FDA Warning Letters and Untitled Letters." All agency components responsible for issuing Warning Letters and Untitled Letters must follow these procedures.

1. All Centers

- a. All labeling violations - except where specific guidance has been provided, e.g., Compliance Programs, Compliance Policy Guides, and Drug Health Fraud Bulletins;
- b. Computer application and software violations;
- c. Bioresearch Monitoring Program violations; and
- d. Product advertising violations.

Note: Only centers issue Warning Letters for violations associated with product advertising, OTC drug monographs, and the Bioresearch Monitoring Program.

2. Center for Drug Evaluation and Research (CDER)

- a. New drug charges - including unapproved changes in processes or formulations and recommendations to withhold approvals of applications or supplements;
- b. Adverse drug experience reporting violations;
- c. Novel and unusual tamper-evident packaging violations;
- d. Prescription Drug Marketing Act violations;
- e. Investigational drug use violations;

- f. CGMP charges involving active pharmaceutical ingredients and other drug component manufacturing deficiencies;
- g. CGMP charges involving all dosage forms, including medical gases;
- h. CGMP charges involving inspections of facilities for therapeutic biologic products regulated by CDER;
- i. CGMP charges involving combination products where CDER is the lead center;
- j. Pharmacy compounding issues; or
- k. Violations related to required postmarketing studies and clinical trials.

The MARCS-Compliance Management System (MARCS-CMS or CMS) is now being used for electronic submission of Warning Letter recommendations from program offices. All recommendations by the program offices must use CMS for submitting the proposed Warning Letter, the FDA 483 supporting alleged violations, the EIR, and any written response by the firm. For any questions, or if you need to submit a document as a hardcopy, the CDER Office of Compliance contact is: [CDER-OC-OMQ-Communications](#).

Also, see [Exhibit 4-1](#), the agency's "Procedures for Clearing FDA Warning Letters and Untitled Letters." All agency components responsible for issuing Warning Letters and Untitled Letters must follow these procedures.

3. Center for Biologics Evaluation and Research (CBER)

- a. Donor re-entry violations (e.g., HBsAg, anti-HIV-1);
- b. Violations relating to drug CGMP* (see below);
- c. CGMP violations involving combination products where CBER is the lead center;
- d. Violative inspections of federal government agencies;
- e. Violative inspections related to licensed biologic drug and device products regulated by CBER;
- f. Viral marker test run deficiencies** (see below);
- g. Violations in areas where specific guidance has not been provided*** (see below);
- h. Violations relating to HIV and HCV lookback; or
- i. Violative inspections of manufacturers of human cell, tissue, and cellular and tissue-based products (HCT/Ps).

*CGMP regulations in Part 211 and blood establishments: CBER concurrence is required for Warning Letters involving deviations from Part

211 that are not associated with provisions in Part 606, such as 21 CFR 211.68(b) or 211.113.

****Viral marker testing violations:** ORA does not need center concurrence regarding viral marker testing violations. However, center concurrence is required for Warning Letters based on invalidation of viral marker test run deficiencies since center guidance on this issue is relatively recent.

*****Violations in areas where specific guidance has not been provided:** In these situations, we encourage the programs to contact the Division of Case Management (DCM) in CBER's Office of Compliance and Biologics Quality (OCBQ) before recommending a Warning Letter to the center.

Also, see [Exhibit 4-1](#), the agency's "Procedures for Clearing FDA Warning Letters and Untitled Letters." All agency components responsible for issuing Warning Letters and Untitled Letters must follow these procedures.

4. Center for Devices and Radiological Health (CDRH)

- a. All 21 U.S.C. 352(j) "dangerous to health" violations;
- b. Medical device reporting violations which cite failure to report malfunctions as defined in 21 CFR 803.3(n). Center medical and technical expertise is necessary for these evaluations;
- c. Restricted device violations;
- d. Radiation Control for Health and Safety Act violations - except for sunlamp products and x-ray assemblers;
- e. Violation of requirements for post market surveillance studies;
- f. Any violation of device tracking regulations other than failure of the firm to implement any form of a tracking system;
- g. All suspected violations of the user reporting regulations;
- h. Failure to submit a premarket notification (510(k)) or premarket approval application (PMA);
- i. Failure to submit a 510(k) or a PMA supplement for a significant modification(s) and/or the addition of a new intended use(s) to a previously cleared or approved device;
- j. All violations arising from pre-approval PMA inspections including supplements to a previously approved PMA application; and,
- k. Mammography Quality Standards Act (MQSA) violations in the following situations, unless superseded by a relevant Compliance Program or other directive:

- l. Where numerous Level 2 or 3 inspection findings were observed, but no single noncompliance constitutes a Level 1 or repeat Level 2 inspection finding; or
- m. Any situations not specifically identified as a Level 1 noncompliance or repeat Level 2 noncompliance; or
- n. CGMP (e.g., 21 CFR Part 211 or Part 820) charges involving combination products where CDRH is the lead center.

Note: For direct reference situations regarding MQSA violations, reference the instructions contained in Part V of the Compliance Program or other directive.

Also, see [Exhibit 4-1](#), the agency's "Procedures for Clearing FDA Warning Letters and Untitled Letters." All agency components responsible for issuing Warning Letters and Untitled Letters must follow these procedures.

5. Center for Veterinary Medicine (CVM)

- a. Product approval violations;
- b. All drug residue violations involving meat, poultry, aquacultured seafood, and other animal-derived products;
- c. Feed contaminant violations where no tolerance has been established;
- d. Adverse drug reaction reporting violations;
- e. Low acid canned pet food violations requiring technical review; and,
- f. CGMP violations for medicated feed [21 CFR Part 225], Type A Medicated Articles [21 CFR Part 226], and dosage form drugs [21 CFR Part 211].

Submit complete recommendation package (recommendation, EIR, CRs, all exhibits, and other supporting documents).

Recommendations, coupled with their supporting evidence, should only be submitted using CMS using CMS, an electronic case submission system. This system is available from the IT Applications page on FDA's intranet site.

Also, see [Exhibit 4-1](#), the agency's "Procedures for Clearing FDA Warning Letters and Untitled Letters." All agency components responsible for issuing Warning Letters and Untitled Letters must follow these procedures.

6. Center for Food Safety and Applied Nutrition (CFSAN)

All violations not covered by direct reference authority, including those issues addressed in a [compliance policy guide](#) or in a [compliance program](#). These letters requiring Center concurrence or Center issuance include, but are not limited to, the following examples:

- a. Any Warning or Untitled Letter involving a novel, controversial, or sensitive legal issue;
- b. Pesticide and chemical contamination violations not covered by direct reference authority;
- c. Dietary supplements, medical foods, and infant formulas, including dietary supplements CGMPs;
- d. Food and color additive violations;
- e. Actions involving environmental microbial contamination;
- f. All situations involving violations of section 402(a)(4) of the Act, including deviations from regulations for bottled water and any other CGMP regulation concerning CFSAN issues; except districts have direct reference for seafood HACCP violations and 21 CFR Part 110 violations that do not include environmental sampling or allergen issues;
- g. Mycotoxins;
- h. Animal drugs in foods (aquaculture chemotherapeutic agents);
- i. Food standards;
- j. Cosmetics; and
- k. Egg rule (21 CFR 118) violations.

Recommendations, coupled with their supporting evidence, should only be submitted using CMS to CFSAN via CMS, an electronic case submission system. This system is available from the IT Applications page on FDA's intranet site.

Also, see [Exhibit 4-1](#), the agency's "Procedures for Clearing FDA Warning Letters and Untitled Letters." All agency components responsible for issuing Warning Letters and Untitled Letters must follow these procedures.

7. Center for Tobacco Products

- a. CTP directly issues Warning Letters for tobacco retailer compliance check violations. Tobacco Retailer Warning Letters are not subject to the time frames established in section 4-1-7 or to the Warning Letter close-out procedures described in section 4-1-8 due to their nature and volume. CTP has developed internal procedures to address time

frames and close-out corresponding WL and close out CTP procedures.

- b. CTP directly issues Warning Letters to regulated industry for all other violations of the Federal Food, Drug, and Cosmetic Act, as amended by the Family Smoking Prevention and Tobacco Act, and implementing regulations.

4-1-5. Letters for Illegal Promotional Activities

Warning Letters, not Untitled Letters, should be issued for promotional activities if the nature of the activity is such that the center would support further regulatory or administrative action. The warning letters are generally initiated by the Centers and may be issued by the Centers or by the Program Offices.

NOTE: For web-based promotion, appropriate further action may involve, e.g., FDA notification of any Internet Service Providers (ISPs) or other related service providers with whom the offending website has a contractual relationship, or FDA notification of the public through consumer or import alerts, rather than the physical (re) inspection of regulated establishments.

The center should alert the program office of the violation and ask that they bring the promotional activity to the attention of the firm on the next scheduled visit. If the inspection reveals additional problems, this violation may be included as part of their regulatory action plan. If the problem is urgent, the district could request a meeting with the firm to discuss the violations.

4-1-6. Multiple Center Review

For issues in a Warning Letter that require review by more than one center, a designation of “lead center”¹ should be made at the earliest possible opportunity. This is necessary to ensure a timely and appropriately coordinated review process. The lead center is responsible for communication with the other involved center(s), the program office, and OCC. The lead center is responsible for shepherding the

¹ Note that a combination product is assigned to a medical product “lead center” (i.e., CBER, CDER, or CDRH) that has primary jurisdiction for the regulation of that specific combination product. The lead center will consult with other centers, as needed, to evaluate inspectional observations for combination products. See SMG 4101 Inter-Center Consult Request Process. Questions on which center is lead for a combination product should be directed to combination@fda.hhs.gov. In most cases, the lead center will coordinate issuance of warning letters for combination products assigned to it. However, there may be cases where a different center issues is responsible for coordination of development and issuance of a warning letter concerning a combination product. For example, if a warning letter is for a facility that manufactures both drug products and device-led combination products and the drug product-related issues are more significant, CDER may be the center that coordinates the warning letter process, though the lead center for the implicated device-led combination products would be CDRH.

Warning Letter through the review process, including the review and incorporation of comments as appropriate from the other involved entities.

For issues in a Warning Letter that require review by more than one center, the program should, prior to submission of the recommendation, communicate with each center and identify which center will serve as the lead. The recommendation should identify the lead center and the other involved center(s). The recommendation should be sent electronically via CMS to the lead center, and the lead center will create a consult task to the other reviewing center(s). The centers should conduct concurrent (not sequential) reviews.

If the program did not identify the need for multiple reviews prior to submission of the recommendation, the center receiving the recommendation should communicate with the program and the other involved center(s) to appropriately designate the lead center. The program should then promptly send a copy of the recommendation to the other involved center(s).

4-1-7. Time Frames

Within fifteen (15) working days after completion of the inspection, sample analysis, or collection of evidence, the program should submit a Warning Letter recommendation to the appropriate reviewing office for concurrence.

Within fifteen (15) working days after receipt of the Warning Letter recommendation, the center should review the Warning Letter and notify the program of its decision. If the Warning Letter is disapproved, the center will notify the program office of its decision within 15 days of receipt, and will issue a memorandum stating its reasons for disapproval within 30 days. The Center will provide notification by e-mail or similar means to the appropriate ORA program office, and to the Office of Policy, Compliance and Enforcement (OPCE) Division of Compliance and Enforcement (DCE) that the memorandum is available in CMS. If the Warning Letter is approved, the center will forward its approval memo and the proposed Warning Letter, as appropriate, for further review and concurrence.

See [Exhibit 4-1](#), the agency's "Procedures for Clearing FDA Warning Letters and Untitled Letters." All agency components responsible for issuing Warning Letters and Untitled Letters must follow these procedures. If a Program or Office enters a formal agreement with another Center, such as a Concept of Operations (CONOPS), the agreement's timelines supercede the procedures in Exhibit 4-1. Recommendations to the Center and Warning Letter time frames for Human Drug Inspections (Surveillance and For-Cause Inspections) which fall under the review of CDER, can be found in [FDA's INTEGRATION OF FDA FACILITY EVALUATION AND INSPECTION PROGRAM FOR HUMAN DRUGS: A CONCEPT OF OPERATIONS](#).

The program compliance officer (or, the center CSO/scientist, if the Warning Letter was center-initiated) assigned to the Warning Letter should diligently pursue and actively monitor the progress of the case through the agency review process to its conclusion (i.e., voluntary compliance or enforcement action). OPCE DCE can assist in situations where significant delays are experienced or assistance is needed to resolve technical, scientific, or policy issues. (Also, see section on *ad hoc* Committees in [Chapter 10 - Other Procedures](#).)

4-1-8. Warning Letter Follow-Up

The issuing program office or center will evaluate the response to the Warning Letter. If the response is inadequate, or if no response is received, the program office or center will begin follow-up action as necessary to achieve correction. If the Warning Letter contains violations that by their nature are not correctable, then no close-out letter will issue. If the recipient of the Warning Letter is verified to be out of business, then no close-out letter will issue. If the recipient of the Warning Letter ceases operation with respect to the issues presented in the Warning Letter but otherwise continues business, FDA may decide not to issue a close-out letter based solely on the recipient's representation that they have ceased the operations related to the issues presented in the Warning Letter.

In the case of Warning Letters issued for products marketed through internet websites, corrective actions such as claim removal or website inactivation are reversible. FDA also may not be able to conduct follow-up inspections of firms or individuals who sell products online without a physical location. FDA will consider whether the information provided or is otherwise available to the agency demonstrates sustained compliance, and may decide not to issue a close-out letter based solely on website corrections.

If the response appears adequate, the program office or center will verify that commitments have been fulfilled and that correction has been achieved, and will notify other appropriate agency units. Usually, the standard for verifying that corrections have been implemented will be a follow-up inspection. Follow-up inspections should be conducted promptly after the agreed upon date of completion of the promised corrections.

1. Acknowledgment of Response to a Warning Letter

The program office or center that issued the Warning Letter should acknowledge, in writing or via electronic mail, receipt of Warning Letter responses. The program office or center should save a PDF copy of the issued correspondence under the Final Outcome tab in CMS, identified as doc type = "courtesy acknowledgment correspondence."

Warning Letter responses regarding CTP Retailer Compliance Check Inspections are acknowledged with "Reply to Warning Letter Response"

letters when necessary, in accordance with internal procedures. CTP should save a PDF copy of the issued Reply letter under the “POST Action Mgt” tab in CMS, identified as doc type = “Letter of FDA’s review of firm’s response.”

2. Warning Letter Close-Out Letter

A Warning Letter close-out letter (“close-out letter”) will not be issued based on representations that some action will or has been taken. The corrective actions must actually have been made and verified by FDA.

The program office or center that issued the Warning Letter should issue a close-out letter for Warning Letters issued on or after September 1, 2009, if the violations in the Warning Letter have been adequately addressed, and the following conditions have been met:

- a. The firm replied to the Warning Letter with sufficient information to demonstrate that any listed violations have been adequately corrected; or

A follow-up inspection shows that implementation of the corrective actions was adequate, or,

based on other verified, appropriate and reliable information, FDA determines that the follow-up inspection is not needed;

and

- b. The follow-up inspection (or other appropriate and reliable information) does not reveal other significant violations.

The issuing office will evaluate the firm’s response to the Warning Letter. Where the program office is the issuing office, the following procedure should be followed prior to issuance of a close-out letter:

If the program office performs an inspection to verify correction, the program office may, but need not, ask the center whether it has a comment or objection prior to issuing a close-out letter. If the program office decides not to inspect to verify correction, and the Warning Letter required center concurrence, the program office will ask the center, via CMS, whether it has a comment or objection prior to issuing a close-out letter. The center will enter any comments or objections to the issuance of a close-out letter (i.e., FDA’s conclusion that the firm’s corrective actions are adequate to address the violations contained in the Warning Letter), via the center documents tab in CMS within 30 working days. If the center requests more time, an additional 30 working days should be granted. At the end of the 30 (or 60) working day period, the program office will review the center’s comments or objections, if any, providing deference to the center in areas of the center’s

expertise, and, where the center has provided comments or objections, will issue the close-out letter only if consensus is reached with the center.

The Program office may also ask other program offices whether they have any comments or objections prior to issuing a close-out letter if the other program office has a potential or open case for the same individual or firm.

Program offices or centers should issue close-out letters within a total of 65 working days of having the necessary information upon which to make a decision. Use the model “close-out letter” in [Exhibit 4-2](#). The issuing program office or center is responsible for ensuring that a PDF copy of the final, signed close-out letter is added into CMS.

A close-out letter does not relieve recipients from their responsibility to take all necessary steps to assure sustained compliance with the Act, and all other applicable requirements. If a subsequent inspection reveals problems with the adequacy or sustainability of the corrections that were taken in response to the Warning Letter, such violations would be considered serious. If FDA observes violations during subsequent inspections or through other means, we may take enforcement action without further notice.

The issuing program office or center will ensure that FDA posts a notice on [FDA Warning and Close-Out Letters webpage](#) when a close-out letter is issued.

3. Requests to Post Response on Internet

Warning Letters are posted publicly on [fda.gov](#). FDA does not remove Warning Letters from its Internet site unless the Agency rescinds or amends the letter. A recipient, however, may submit a request to post and make available to the public their response to the Warning Letter.

When a recipient of a Warning Letter requests that their response to that Warning Letter be posted on FDA’s internet site and provides the response electronically in a word processing format or legible pdf format, the agency will post that response. The agency has reserved the right not to post certain responses, such as when posting likely would mislead the public about the safety or efficacy of a regulated product. Note: CTP is not required to post Tobacco Retailer Warning Letter responses on the internet.

ORA DIDP or center must redact the response to the extent permitted by the Freedom of Information Act, and send a redacted copy of the response to FDA’s Division of Freedom of Information (DFOI), Office of the Executive Secretariat, and DFOI will then post the response to the above-referenced website. See 4-1-13 for more information.

4. Follow-Up Enforcement

If a firm has been issued a Warning Letter and has been unable or unwilling to correct the violations, program offices and centers should consider further administrative and/or regulatory actions. When considering further action, one factor to evaluate is prior notice (see RPM [Chapter 10 - Other Procedures](#)). This evaluation is particularly relevant for firms operating multiple facilities and producing a variety of products when administrative and/or regulatory action involving more than one location is being considered. Although a second Warning Letter to the same firm should not be issued for the same or similar violations, ensuring prior notice through issuance of a second Warning Letter in some situations may best support the agency's objectives.

In determining whether to issue a second Warning Letter, program directors and center issuing officials should consider whether:

- a. The products, processes, and/or significant violations are different, taking into account that systems-based inspectional observations may transcend individual products and processes and may, thereby, provide prior notice without an additional Warning Letter;
- b. The responsible individual(s) is (are) different; or,
- c. The Warning Letter will support the agency's objectives (e.g., letters sent to different facilities within a corporation to achieve correction of corporate-wide problems).

Whether or not a second Warning Letter is issued, any proposed administrative or regulatory action must be supported by adequate evidence (inspectional or other). OPCE DCE and center office of compliance contacts can assist program offices in evaluating the evidence, the prior notice, and in developing a regulatory approach when multiple facilities are involved. (Also, see section on Ad hoc Committees in [Chapter 10 - Other Procedures](#).)

Program offices and centers also have the option of conducting a meeting with firm's management prior to pursuing an administrative or regulatory action. Such meetings also serve as further prior notice. (See sections on Prior Notice and Regulatory Meetings in [Chapter 10 - Other Procedures](#).)

5. Inspection Classification

A Warning Letter constitutes official but not final agency action. Inspections will be classified Official Action Indicated (OAI) whenever a Warning Letter is issued. This procedure provides greater consistency and uniformity in the classification system and regulatory policy.

For further information on classification of inspections see Field Management Directive No. 86, [Establishment Inspection Report Conclusions and Decisions](#).

4-1-9. Firm Profile Updates in eNSpect

When a profilable firm (i.e., domestic or foreign drug, biologics, medical device, or combination product facility) undergoes a CGMP or Quality System (QS) inspection, the inspected profile classes should be updated by the action office at each stage in the review process. When an inspection is final classified OAI, the date and type of letter should be entered in the Remarks field for the relevant profile classes, and these profile classes should be changed to unacceptable. When a Warning Letter close-out letter is issued, the final profile for the relevant profile classes should be changed to acceptable. For profile procedures, see IOM Exhibit 5-14.

4-1-10. Warning Letter Format

Warning Letters can vary in form, style, and content to provide the flexibility needed to accurately and effectively state the nature of the violation(s) found and the response expected. However, the elements listed below are common to Warning Letters:

1. Title: "WARNING LETTER."
2. Delivery: Sent to ensure overnight delivery or sent electronically, and receipt of delivery (e.g., signature required (carrier), email response) is documented.
3. Addressed to the highest known official in the corporation that includes the facility that was inspected, and a copy sent to the highest known official at the facility that was inspected. If you are requesting a separate response from other officials, they would be included as addressees. A suitable notation (e.g., cc, or copy sent to) in the letter would be included, and each person would be identified by name, title, and, if appropriate, address. The letter to each addressee and each person who is identified as having received a copy of the letter would be issued separately as warranted (e.g., when sent via carrier) and in accordance with the delivery instructions above. Ensure the recipients of a cc or copy sent electronically are entitled to receive the unredacted Warning Letter.

Tobacco Retailer Warning Letters are addressed to the legal entity or to the sole owner at the retail establishment that was inspected. The legal entity or sole owner is copied if the entity's business address is different than the inspected retail establishment.

4. The dates of the inspection and a description of the violative condition, practice, or product in brief but sufficient detail to provide the respondent the

opportunity to take corrective action. The citation of the section of the law and, where applicable, the regulation violated would be included, and the violations of the law using the appropriate section(s) of both the FD&C Act and the U.S. Code, e.g., Section 501(a)(2)(B) of the Act, 21 U.S.C. 351(a)(2)(B) would be cited. Violations of other laws (e.g., the Public Health Service Act) would be cited in the same manner.

5. Citations to the appropriate application number, post marketing requirements (PMR) reference number (if appropriate) and the date that the applicant was notified of the PMR for Warning Letters not based on inspections and citing violations of statutory requirements for studies such as PMRs and clinical trials.
6. Appropriate acknowledgement of corrections promised during the inspection, annotated on the 483, or provided to the FDA in a written response. It would reply as to the apparent adequacy of the firm's corrective actions set forth in the response.
7. A request for correction and a written response within a specific period of time after the date of receipt of the letter, usually fifteen (15) working days. At the program office's discretion, the recipient may be offered an opportunity to discuss the letter with program office officials or, when appropriate, with center officials.
8. A warning statement indicating that failure to adequately address the issues that are the subject of the letter may result in regulatory or legal action. Examples of such actions may be cited.
9. In most cases, language to the effect that, if the recipient believes that it or its product is not in violation of the FD&C Act or other laws (e.g. the Public Health Service Act) or FDA regulations, it should provide FDA with its reasoning and any supporting evidence or information for FDA's consideration within a specified period of time.
10. Where appropriate, language to the effect that the recipient should investigate and determine the causes of any violations and take prompt actions to correct any violations and bring products into compliance.
11. Where appropriate, language to the effect that other federal agencies may take the recipient's compliance history into account when considering the award of federal contracts.
12. CTP Retailer Warning Letters (except those issued to online tobacco product retailers) would include language to the effect that, if the recipient believes that the Warning Letter was issued in error, they should preserve any relevant evidence or information in the event FDA initiates regulatory action at a later date.
13. Drug Warning Letters (except those issued to IRBs, clinical investigators, sponsors, and monitors involved in clinical trials) that cite CGMP violations would include a statement to the effect that violations may be the cause for

FDA to withhold issuance of Export Certificates. Where appropriate, these letters would also include language indicating that any violations may be cause for FDA to withhold approval of new applications or supplements listing the recipient as a manufacturer.

14. Device Warning Letters (except those issued to IRBs, clinical investigators, sponsors, and monitors involved in clinical trials) would include language to the effect that, should FDA determine that devices, or other articles as appropriate, or facilities do not meet the requirements of the FD&C Act, requests for Certificates to Foreign Governments (CFG) may not be granted. Device Warning Letters concerning PMAs would include language to the effect that if FDA determines that there has been a specific violation and those violations are not addressed, the PMA may be subject to withdrawal.

Device Warning Letters that include CGMP violations would include language to the effect that if FDA determines that there are Quality System regulation violations that are reasonably related to premarket approval applications for Class III devices, such devices would not be approved until the violations have been corrected. Where appropriate, these letters may also include language to the effect that failure to address violations of a statutory or regulatory citation may result in the withdrawal of a PMA.

15. A statement in letters that pertain to imported products to the effect that products that appear to be adulterated or misbranded or that appear to be violation of section 505 or another specified violation listed in 801 may be detained or refused admission.
16. Warning Letters may request the recipient cease any violative conduct.
17. Instructions, as appropriate, that the response include:
- a. each step that has been or will be taken to completely correct the current violations and to prevent similar violations;
 - b. the time within which correction will be completed;
 - c. any reason the corrective action has not been completed within the response time; and,
 - d. any documentation necessary to show that correction has been achieved.
18. A designated program or center official to whom the response should be addressed.
19. "Issued by" the program office director, division director, or higher agency official.

Some program areas will require center concurrence before issuance.

4-1-11. Warning Letter Distribution

Warning Letter distribution is as follows:

1. Original – Addressee(s)
2. Copy to each person identified in the Warning Letter
3. Blind copy (bcc) to the following:
 - a. MARCS-CMS case file. The final, unredacted signed letter should be added to the MARCS-CMS case file under the Final Outcome tab with the file type identified as PDF VERSION Non-Redacted Issued Violation Letter. Once added, this copy becomes available to the full text DOC search within MARCS-CMS. It also serves as an internal copy for FDA that is available through the system to anyone who may need a copy of the issued letter.
 - b. Division of Freedom of Information (DFOI) – For more information, see Section 4-1-13 – Freedom of Information (FOI) and the operating instructions within the FOI User’s Guide hyperlink in MARCS-CMS located under the User’s Guides/Training hyperlink.
4. If the Warning Letter is to a foreign food facility, contact the U.S. agent for the foreign facility by email, phone, facsimile, or regular mail within 5 business days and inform the agent that a redacted letter is available on the [Warning Letter page](#).
5. Also provide copies to Local Distribution, factory file, WL file, the appropriate program office, and appropriate federal and state agencies.
6. Provide one redacted copy of Warning Letters regarding Dietary Supplements to:

Associate Director
Division of Advertising Practices ([link](#))
Federal Trade Commission
600 Pennsylvania Avenue, N.W. Washington, D.C. 20580
(Or, send a redacted e-copy to: mengle@ftc.gov).

4-1-12. Warning and Untitled Letters Addressed to Importers, Customs Brokers, and Foreign Firms

See [Exhibit 4-1](#), the agency’s “Procedures for Clearing FDA Warning Letters and Untitled Letters.” All agency components responsible for issuing Warning Letters and Untitled Letters must follow these procedures.

Warning Letters should be addressed to the party responsible for the violation. Therefore, before issuing either a Warning Letter or an Untitled Letter, the issuing office must determine the identity and role of the “responsible party.” OIO may

make this determination by examining the entry documents or the electronic entry data submitted to FDA's OASIS via the Automated Commercial System (ACS) of Customs of Customs and Border Protection (CBP). The ACS is used by CBP to track, control, and process all goods imported into the United States. A key component of ACS is the Automated Broker Interface ABI/ACS, which allows qualified participants to electronically file required import data with CPB. OIO may also examine other supporting records.

It is particularly important to determine whether the firm identified as the importer-of-record is the actual importer, that is, importing for its own account, or whether the importer-of-record is a customs broker acting as the agent for the actual importer. Generally, customs brokers are merely agents for actual importers and therefore are not the responsible parties to whom Warning Letters should be addressed. For more information, see "Customs Brokers" below. Contact OIO, Division of Import Operations (DIO) and Division of Import Program Development (DIPD) for assistance in issuing a Warning or Untitled Letter to an importer, consignee, owner, or broker of imported goods. Use the OIO contact information on the OIO intranet page.

1. Importers

FDA may issue Warning Letters and Untitled Letters to importers, owners, or consignees of FDA-regulated imports when they engage in practices that violate the Act.

2. Customs Brokers

Generally, it is not appropriate to issue a Warning Letter or Untitled Letter to a customs broker unless that broker also is the owner, consignee, or importer responsible for the imported goods. In cases where a customs broker also is the owner, consignee, or importer, that is, the party initiating the importation, or if the broker has authority over the product through prior arrangement with the importer, it may be appropriate to issue a Warning Letter or Untitled Letter to that broker.

In all cases, authorized FDA officials should ensure that Warning Letters and Untitled Letters are addressed to the party responsible for the violation.

3. Foreign Firms

A Warning Letter or Untitled Letter may be appropriate if FDA has regulatory authority over the company and is prepared to exercise that authority. Firms may be placed on detention without physical examination (DWPE) because of repeatedly offering violative products for import. Unless the foreign firm is under the regulatory purview of FDA, issuing Warning Letters and Untitled Letters should be discussed with OCC. Authorized FDA officials may issue Warning Letters to foreign producers of FDA-regulated products based on establishment inspections or other information. For CBER regulated products,

administrative actions may also be considered for licensed foreign establishments.

4-1-13. Freedom of Information (FOI)

1. When submitting redaction requests to ORA DIDP for posting firm Warning Letter responses, ORA-issued Untitled Letters and Pharmacy Compounding (483's, 483 responses, State Hand-Off Letters, and State Referral Letters) create a linked [CMS Work Activity](#), "DIDP Redaction Request." Select "ORA DIDP FOIA" and do not assign to a specific individual. For Warning Letters see below.

2. Internet Posting of Warning Letters

DFOI will obtain the Redacted Warning Letters for posting using - CMS. When the Action Taken Date (i.e., date on the letter) is entered into CMS, an FOI section in the electronic case file for the Warning Letter opens.

- a. Before selecting redaction office and FOIA officer, upload the warning letter confirmation of delivery receipt to the firm under the "Final Outcome" tab in Documents with the "Confirmation of Delivery" document type.
- b. Select the redaction office and the FOIA officer that will be redacting the letter.
- c. For **ORA-issued warning letters only**:
 - 1) When submitting redaction requests to ORA DIDP follow the [Warning Letter FOI process in CMS](#). Select "ORA DIDP FOIA" as the redaction office and leave the redaction officer "blank" as the FOIA officer will be assigned by Division of Information Disclosure Policy management. The FOIA officer will confirm there is a "Confirmation of Delivery Receipt" included before proceeding with redactions.
 - 2) For expedited redaction related to high profile posting, concurrent with a press release, send an e-mail to ORA's DIDP management at oraospopfoiainfodiscpolicydivmgmt@fda.hhs.gov with the subject line "Expedited Redaction" include the name of firm, FEI # and CMS case number in the body of the e-mail. to process.
- d. The FOI Officer redacts the letter and uploads a redacted Adobe PDF version of the letter into CMS under the "Final Outcome" tab and sets the status to "FOI Office Review" to notify DFOI it is ready for their review prior to posting.

NOTE: Do not include "bcc" information, or the "credit page" related to drafting sequence, etc., on the redacted copies.

For more information, see the operating instructions within the FOI User's Guide hyperlink in MARCS-CMS under User Guides/Training.

3. FOI Requests for Warning Letters

All FDA-issued Warning Letters (redacted) should be posted on FDA's Warning Letters internet page and thus the public can obtain a copy directly without the need to submit a formal FOIA request. If FDA has not yet posted the Warning Letter on the Warning Letter internet page, the requester should fax the request for a copy of the Warning Letter to DFOI to answer. By following this procedure, the agency will comply with its "first in, first out" policy. Do not disclose the existence of a Warning Letter or release a copy of a Warning Letter to the public unless your office receives the response to the FOIA request through DFOI.

DFOI will obtain the issued letter from within MARCS-CMS, or DFOI will notify OPCE DCE if the final letter is not contained in the MARCS-CMS case file per established regulatory procedures.

Refer the public to FDA's procedures in the agency's webpage for submitting a Freedom of Information Act (FOIA) request at: [How to Make a FOIA Request](#). The webpage includes DFOI's mailing address and fax number. Generally, do not accept electronic or telephone requests for records, including Warning Letters.

CTP Retailer Compliance Check Inspection Warning Letters are posted to the [Tobacco Retailer Warning Letters](#) webpage.

4-1-14. Center for Biologics Evaluation and Research (CBER)

The compliance programs for CBER regulated products are located at: <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInform> the page for [Compliance Programs \(CBER\)](#). Evaluate violations to decide if they are of regulatory significance. To help in this determination, refer to Part V of each Compliance Program, which provides information on deviations that may warrant action.

The organizational unit in the CBER Office of Compliance and Biologics Quality (OCBQ) that handles warning letter recommendations is the Division of Case Management (DCM). The office can be reached at the contact information on the CBER OCBQ intranet page, or at 240-402-9155.

1. CBER Program Warning Letters

- a. All correspondence to licensed establishments should be addressed to the most responsible person. A copy of the correspondence should also be sent to the authorized official. For unlicensed establishments,

correspondence should be addressed to the most responsible individual, e.g., blood bank director or hospital administrator.

- b. The lists of deviations (those that may lead to enforcement action if not promptly and adequately corrected) serve as guides for determining the recommended course of action. Any significant deviation, whether repetitive or an isolated occurrence, may warrant the issuance of a Warning Letter.
- c. The specific areas that require CBER concurrence for program office directors to issue a Warning Letter are listed above in “Center Concurrence and Letters Issued by Centers.” In addition, program offices do not have direct reference authority to issue a Warning Letter to other federal agencies. Once the appropriate reviews are completed, Warning Letters are issued directly by the program office.

Also, see [Exhibit 4-1](#), the agency’s “Procedures for Clearing FDA Warning Letters and Untitled Letters.” All agency components responsible for issuing Warning Letters and Untitled Letters must follow these procedures.

- d. Schedule a follow-up inspection approximately 30 days after the response to the Warning Letter is received to determine the adequacy of the reported corrective actions. When corrective action has not been made or the firm has failed to respond, the program office should consider suitable follow-up.
- e. Send copies of all Warning Letters to OCBQ DCM.
- f. Program offices should routinely provide copies of Warning Letters to the appropriate state agency or agencies. If the state regulatory office for these products is not known, contact ORA, OP using the contact information available on ORA OP’s intranet page. The letter should be redacted to protect confidential commercial information unless the state officials are commissioned or the sharing is authorized by law. See Chapter 3 for commissioning procedures.

2. Federal-State Relations For Blood Bank Inspections

Currently, the agency has no formal cooperative program with state or local jurisdictions for the inspection or regulation of blood banks. Cooperation with these authorities is encouraged especially if a state or local jurisdiction has a regulatory program for blood banks. Exchange of information should occur with all levels of state government whenever possible.

3. Advertising and Promotional Labeling Branch Procedural Guide

The Advertising and Promotional Labeling Branch (APLB) in DCM, OCBQ may initiate regulatory action if the advertising and promotional labeling are not consistent with the approved labeling (package insert), clinical data used

to approve the product, or applicable sections of the Act and regulations for labeling and advertising by notifying the manufacturer in writing of the violations.

Also, see [Exhibit 4-1](#), the agency's "Procedures for Clearing FDA Warning Letters and Untitled Letters." All agency components responsible for issuing Warning Letters and Untitled Letters must follow these procedures.

4. Warning Letter Recommendations

Send Warning Letter recommendations to CBER's Office of Compliance and Biologics Quality

1. For Blood, Plasma and HCT/Ps:

Chief, Blood and Tissue Compliance Branch
Division of Case Management

2. For Biological Drugs and Devices:

Chief, Biological Drug and Device Compliance Branch
Division of Case Management, (except for therapeutic biological drugs, which are submitted to CDER for concurrence.)

Direct CBER Warning Letter questions to the Division of Case Management, 240-402-9155.

Also, see Exhibit 4-1, the agency's "Procedures for Clearing FDA Warning Letters and Untitled Letters." All agency components responsible for issuing Warning Letters and Untitled Letters must follow these procedures.

4-1-15. Center for Drug Evaluation and Research (CDER)

1. Preapproval Inspections/Pending Applications - Withhold Approval

Warning Letters are not to be recommended by the program offices as a follow-up to a preapproval inspection for pending drug or device applications (ANDAs, NDAs, BLAs) if no other FDA regulated products are marketed by the firm.

Warning Letters may be recommended by the program offices for preapproval inspections of drug and device firms if other FDA regulated products are marketed by the firm and the issue(s) affect marketed products or the inspection has extended to marketed products which are included on the FDA 483. These letters should include the following statement: "Due to the deficiencies listed on the attached FDA-483 we are recommending to the center that approval of the "..." application be withheld."

2. Surveillance Inspections For Assessing Conformance With Adulteration Provisions of the Act, Including CGMP

Warning Letters may be recommended by the program offices based on findings from surveillance inspections made to assess conformance of a manufacturing site with the adulteration provisions of the Act, including CGMP. See Standard Charge i, in Section 3, below. The lists of deviations (those that may lead to enforcement action if not promptly and adequately corrected) serve as guides for determining the recommended course of action. Any significant deviation, whether repetitive or an isolated occurrence, may warrant the issuance of a Warning Letter. In therapeutic biologic drugs, operations to assess their conformance to the adulteration provisions, including CGMP, will be conducted by appropriately trained investigators. Therapeutic biologic drugs will be subject to the same regulatory procedures and actions as other drugs regulated by CDER. If there is a question of which center presides over a therapeutic biologic drug, contact the Office of Compliance, CDER, via email using the following email link [CDER-OC-OMQ-Communications](#).

3. Standard CDER Charges

- a. Grandfather New Drug Charge: The charge for drugs that claim to have been on the market before 1938 or before 1962:

505(a), 21 U.S.C. 355(a) - The articles are new drugs within the meaning of Section 201(p) of the Act, 21 U.S.C. 321(p), and approval of an application filed under Section 505(b) of the Act, 21 U.S.C. 355(b), is not effective for such drugs and a Notice of Claimed Investigational Exemption under Section 505(i) of the Act, 21 U.S.C. 355(j), and 21 CFR Part 312 is not on file for such drugs, and documentation in support of such drugs, and "grandfather" exemption has not been submitted per 21 CFR 314.200(e)(2) which constitutes a waiver of such claims.

- b. Back Door New Drug Charge: When the new drug charge (505) cannot be used because of lack of interstate movement of the article to be seized but there is documentation of the interstate movement of a component as a 301(k) sample then the charge is that the product was misbranded while held for sale:

502(f)(1), 21 U.S.C. 352(f)(1) - The article of drug, (DRUG NAME), is misbranded in that its labeling fails to bear adequate directions for the use for which the article is represented or suggested (as described above), and it is not exempt from this requirement under regulation 21 CFR 201.115, since the article is a new drug within the meaning of Section 201(p) of the Act, 21 U.S.C. 321(p), and no approval

of an application filed pursuant to Sections 505(b) and 505(j) of the Act, 21 U.S.C. 355(b) and (j), is effective for this drug.

A 502(f)(1) charge is appropriate for OTC drugs for which the directions are “inadequate in fact.” These are drugs which:

- a) have no directions;
- b) have directions that deviate from those required by a final monograph; or
- c) have directions, but those directions lack information which is necessary for the drug to be used safely, such as dosage or frequency of administration.

(See 21 CFR 201.5.) However, a 502(f)(1) charge should not be used if “adequate directions for common uses thereof are known to the ordinary individual.” (See 21 CFR 201.116.)

A 502(f)(1) charge is appropriate for all prescription drugs that are unapproved new drugs. This includes a drug with an indication that is generally not amenable to lay diagnosis, even if the drug would not ordinarily be thought of as a prescription drug (e.g., shark fin cartilage for the treatment of cancer.)

- c. When the product is not a new drug, the simple misbranding charge should read:

502(f)(1), 21 U.S.C. 352(f)(1) - The article of drug, (Drug Name) is misbranded in that its labeling fails to bear adequate directions for use for which the article is represented or suggested.

- d. Prescription Drug Where There Is No Labeling Bearing Directions for Use The charge is as follows:

502(f)(1), 21 U.S.C. 352(f)(1) - The article(s), (DRUG NAME), is subject to the provisions of Section 503(b)(1) of the Act, 21 U.S.C. 353(b)(1), and it is not exempt from Section 502(f)(1) of the Act, 21 U.S.C. 352(f)(1), in that its labeling fails to bear information required by regulation 21 CFR 201.100, providing adequate directions for use under which a practitioner licensed by law can use the drug safely and for the purposes for which it is intended, including indications; effects, dosages, routes, methods, frequency and duration of administration, relevant hazards; contraindications, side effects, and precautions.

e. Drug Registration and Listing

The charge is misbranding under section 502(o) of the Act but the violation is failure to register and list:

502(o), 21 U.S.C. 352(o) - The articles, (DRUG NAMES), are misbranded in that they were manufactured, prepared, propagated, compounded, or processed in an establishment not duly registered under Section 510 of the Act, 21 U.S.C. 360, and the articles have not been listed as required by Section 510(j) of the Act, 21 U.S.C. 360(j).

f. Prescription and OTC Drugs

Section 503(b)(1) provides criteria for determining if the article is a prescription drug. Section 503(b)(1) is not a violation charge:

503(b)(1) 21 U.S.C. 353(b)(1) - The article, (DRUG NAME), because of its toxicity or other potential for harmful effect, or the method of use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drug, and is misbranded because it is not dispensed upon prescription by a licensed practitioner.

The charge is:

i. For a prescription drug:

503(b)(4)(A), 21 U.S.C. 353(b)(4)(A) - The article of drug, (DRUG NAME), is subject to Section 503(b)(1) of the Act, 21 U.S.C. 353(b)(1), and is misbranded in that its label fails to bear the symbol, "Rx only."

ii. For an OTC drug that is not to bear the symbol, "Rx only":

503(b)(4)(B), 21 U.S.C. 353(b)(4)(B) - The article of drug, (Drug name), is not subject to Section 503(b)(1) of the Act, 21 U.S.C. 353(b)(1), and is misbranded in that its label bears the symbol, "Rx only" and it is not entitled to bear such symbol.

g. The following straight UNAPPROVED NEW DRUG charge may be used when there is interstate movement of the finished, labeled drug product.

505(a), 21 U.S.C. 355(a) - The article of drug, (DRUG NAME), is a drug within the meaning of Section 201(g) of the Act, 21 U.S.C. 321(g), which may not be introduced or delivered for introduction into interstate commerce under Section 505(a) of the Act, 21 U.S.C. 355(a), since it is a new drug within the meaning of Section 201(p) of the Act, 21 U.S.C. 321(p), and

no approval of an application filed pursuant to Section 505(b) of the Act, 21 U.S.C. 355(b), is effective for such drug.

- h. For information regarding health fraud issues, contact OPCE DCE, Health Fraud Branch using the information on the DCE Staff Contacts page.
- i. For information regarding pharmacy compounding issues, contact the Pharmacy Compounding Team at (301) 796-3409.
- j. Combination product CGMP charges (violations of 21 CFR part 820 and 21 CFR part 210 and 211):
 - i. The products you manufacture at this facility are combination products under section 503(g) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. 353(g) as your products include [drug, device, biological product] constituent parts.
 - ii. This warning letter summarizes significant violations of current good manufacturing practice (CGMP) requirements for combination products. See 21 CFR part 4, 21 CFR parts 210 and 211 (drug CGMP), and 21 CFR part 820 (Quality System or QS Regulation).
 - iii. Because your methods, facilities, or controls for manufacturing, processing, packing, or holding do not conform to drug CGMP requirements, 21 CFR parts 210 and 211, your combination products are adulterated within the meaning of section 501(a)(2)(B) of the FD&C Act, 21 U.S.C. 351 (a)(2)(B). In addition, your combination products are adulterated within the meaning of section 501(h) of the FD&C Act, 21 U.S.C. 351(h), in that the methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation are not in conformity with applicable CGMP provisions of the Quality System regulation (21 CFR part 820).
- k. Adulteration Due To Inadequate Conformance with CGMP.

The charge is as follows:

501(a)(2)(B), 21 U.S.C. 351(a)(2)(B) - The article(s), (DRUG NAME), is (are) adulterated within the meaning of Section 501(a)(2)(B) of the Act, 21 U.S.C. 351(a)(2)(B), in that the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding fails to conform to, or is not operated or administered in conformity with, CGMP regulations [21 CFR 210, 211].

I. Adverse Drug Experience Reporting Violations and NDA Field Alerts Reporting Violations

The charge is as follows:

505(k)(1), 21 U.S.C. 355(k)(1) – Your firm failed to establish and maintain records and report data relating to clinical experience, along with other data or information for drugs for which an approved application is in effect, as required by Section 505(k)(1) of the Act, 21 U.S.C. 355(k)(1). Failure to comply with Section 505(k) is a prohibited act under Section 301(e) of the Act, 21 U.S.C. 331(e).

If CDER would like to include a charge related to a violation of 505(o)(3) in a Warning Letter, they should consult with OCC.

Also, see [Exhibit 4-1](#), the agency's "Procedures for Clearing FDA Warning Letters and Untitled Letters." All agency components responsible for issuing Warning Letters and Untitled Letters must follow these procedures.

4-1-16. Center for Devices and Radiological Health (CDRH)

1. Violations Under The Mammography Quality Standards Act (MQSA)

For routine Level 1 or repeat Level 2 noncompliances found during MQSA inspections, programs will not need CDRH concurrence before sending Warning Letters. Also, programs may send a Warning Letter without CDRH concurrence when a facility has performed mammography without a certificate. Under other circumstances, where inspections show numerous Level 2 and 3 noncompliances but no Level 1 or repeat Level 2 noncompliances, programs will need CDRH concurrence before sending a Warning Letter. For any of the situations mentioned above where CDRH concurrence is needed for an MQSA Warning Letter, the program should send the draft Warning Letter to the Division of Mammography Quality and Radiation Programs. (See Part V of the Compliance Program.)

Most Level 1 and repeat Level 2 inspection observations will not result in Warning Letters (see Part V of the Compliance Program).

Also, see [Exhibit 4-1](#), the agency's "Procedures for Clearing FDA Warning Letters and Untitled Letters." All agency components responsible for issuing Warning Letters and Untitled Letters must follow these procedures.

2. Sample Wording For Charges

a. Adulteration Charges

- i. Section 501(f)(1)(B), 21 U.S.C. 351(f)(1)(B), in that it is a Class III device under Section 513(f), 21 U.S.C. 360c(f), and

does not have an approved application for premarket approval in effect pursuant to Section 515(a), 21 U.S.C. 360e(a), or an approved application for an investigational device exemption under Section 520(g), 21 U.S.C. 360j(g).

- ii. Section 501(c), 21 U.S.C. 351(c), in that its strength, purity, or quality falls below that which it purports or is represented to possess.
- iii. Section 501(h), 21 U.S.C. 351(h), in that the methods used in, or the facilities or controls used for, the manufacture, packing, storage, or installation are not in conformance with the CGMP requirements for medical devices which are set forth in the Quality System regulation, as specified in Title 21, Code of Federal
- iv. Section 501(i), 21 U.S.C. 351(i), in that it is a device for which an exemption has been granted under section 520(g), 21 U.S.C. 360j(g), for investigational use and the person who was granted such exemption or an investigator who has used the device under such exemption has failed to comply with a requirement imposed by or under such section.

b. Misbranding Charges

- i. Section 502(a), 21 U.S.C. 352(a), in that the labeling for the device represents or suggests that the device is adequate and effective for (.....), which representations or suggestions are false or misleading or otherwise contrary to fact because the device is not adequate or effective for such purposes.
- ii. Section 502(b), 21 U.S.C. 352(b), in that the device is in package form and its label fails to contain: (1) the name and place of business of the manufacturer, packer, or distributor; and (2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count.
- iii. Section 502(f)(1), 21 U.S.C. 352(f)(1), in that the labeling for the device fails to bear adequate directions for the purposes for which it is intended, because adequate directions cannot be written for (e.g., such purposes, etc.)
- iv. Section 502(f)(1), 21 U.S.C. 352(f)(1), in that the labeling for the device fails to bear adequate directions for use because the labeling does not contain an expiration date based upon the stated storage instructions, as required by 21 CFR 809.10.
- v. Section 502(o), 21 U.S.C. 352(o), in that the device was manufactured, prepared, propagated, compounded, or processed in an establishment not duly registered under Section 510, 21 U.S.C. 360, was not included in a list required

by Section 510(j), 21 U.S.C. 360(j), and a notice or other information respecting the device was not provided to FDA as required by Section 510(k), 21 U.S.C. 360(k).

- vi. Section 502(o), 21 U.S.C. 352(o), in that a notice or other information respecting the device was not provided to FDA as required by 21 CFR 807.81(a)(3)(i), when the device was significantly changed or modified by (describe change).

For examples of model Quality System regulation/MDR Warning Letters, see [Medical Device Compliance Program 7382.845 - Inspection of Medical Device Manufacturers](#).

CDRH has established a separate mailbox for electronic submission of device Warning Letters from program offices. The address is [CDRHOCWarningLetterResponses](#).

3. Letters To X-Ray Assemblers

Letters issued to assemblers of diagnostic x-ray systems as a result of routine compliance field testing which uncover Class B Violations (see [CP 7386.003, Field Compliance Testing of Diagnostic Medical X-Ray Equipment](#)) will be issued as Untitled Letters. Letters issued for more serious radiation hazard violations (Class A Violations) which require immediate corrective action will be issued as Warning Letters. Warning Letters may also issue to x-ray assemblers for “pattern of violations” situations where the agency is prepared to take enforcement action if the violations continue and/or if failure to correct violations continues. Subchapter C - Electronic Product Radiation Control (formerly the Radiation Control for Health and Safety Act of 1968) of Chapter V of the Act requires the Secretary to notify the assembler/manufacture concerning noncompliant or defective radiation emitting devices and solicit follow-up corrective action by the assembler/manufacture whether or not the agency is prepared to take follow-up enforcement action. If there are specific cases to discuss or a need for further information on this subject, contact CDRH, [Office of In Vitro Diagnostics and Radiological Health](#), Division of Radiological Health, Diagnostic X-Ray Devices Systems Branch at the contact information provided on the office’s Intranet page.

Also, see [Exhibit 4-1](#), the agency’s “Procedures for Clearing FDA Warning Letters and Untitled Letters.” All agency components responsible for issuing Warning Letters and Untitled Letters must follow these procedures.

4. Combination product CGMP charges (violations of 21 CFR part 820 and 21 CFR part 210 and 211):

- i. The products you manufacture at this facility are combination products under section 503(g) of the Federal Food, Drug, and

Cosmetic Act (FD&C Act), 21 U.S.C. 353(g) as your products include [drug, device, biological product] constituent parts.

- ii. This warning letter summarizes significant violations of current good manufacturing practice (CGMP) requirements for combination products. See 21 CFR part 4, 21 CFR parts 210 and 211 (drug CGMP), and 21 CFR part 820 (Quality System or QS Regulation).
- iii. Because your methods, facilities, or controls for manufacturing, processing, packing, or holding do not conform to drug CGMP requirements, 21 CFR parts 210 and 211, your combination products are adulterated within the meaning of section 501(a)(2)(B) of the FD&C Act, 21 U.S.C. 351 (a)(2)(B). In addition, your combination products are adulterated within the meaning of section 501(h) of the FD&C Act, 21 U.S.C. 351(h), in that the methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation are not in conformity with applicable CGMP provisions of the Quality System regulation (21 CFR part 820).

4-1-17. Center for Food Safety and Applied Nutrition (CFSAN) and Center for Veterinary Medicine (CVM)

CFSAN and CVM will provide instructions for priority areas to be covered in Warning Letters in Compliance Programs.

Recommendations, coupled with their supporting evidence, should only be submitted using CMS, to CFSAN or CVM via CMS. This system is available from the IT Applications page on FDA's intranet site.

4-1-18. Center for Tobacco Products (CTP) Retailer Compliance Check Inspection Program

The Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (Public Law 111-31; 123 Stat. 1776) was enacted on June 22, 2009, amending the Federal Food, Drug, and Cosmetic Act (the Act) and providing FDA with the authority to regulate tobacco products. As required by section 102 of the Tobacco Control Act, FDA published a final rule regarding sales and distribution of cigarettes and smokeless tobacco. This final rule was identical in its provisions to the regulation issued by FDA in 1996 (61 FR 44396, August 28, 1996), with certain specified exceptions. The rule at 21 CFR Part 1140, has two main sections:

1. Access provisions, which consist of restrictions on the sale of cigarettes, smokeless tobacco products, and cigarette tobacco; and

2. Restrictions on advertising, marketing, and promotion of cigarettes and smokeless tobacco products.

The Tobacco Control Act also amended the Act to require that the agency contract with States, where feasible, to carry out inspections of retailers within that State to enforce applicable provisions of the Act and its implementing regulations.

Therefore, compliance check inspections of retailers are carried out in accordance with each contract and pursuant with agency authority.

FDA's State Tobacco Compliance Check Inspections of retailers are completed by FDA –commissioned state inspectors. Inspections that result in violations are reviewed by the State Programs Group within the Office of Compliance and Enforcement (OCE) of the Center for Tobacco Products. If it is determined that there has been a violation, OCE initiates appropriate action in the form of a Warning Letter or enforcement action. The program offices are not involved in retailer compliance check inspections or the issuance of related Warning Letters.

Standard tobacco retailer violation charges include:

1. Misbranded tobacco products within the meaning of section 903(a)(7)(B) of the FD&C Act, 21 U.S.C. § 387c(a)(7)(B), in that they are sold or distributed in violation of 21 C.F.R. Part 1140.
2. Adulterated cigarettes with certain characterizing flavors within the meaning of section 907(a)(1)(A) of the FD&C Act, 21 U.S.C. § 387g(a)(1)(A).
3. Violative modified risk tobacco products within the meaning of section 911(b)(2) of the FD&C Act, 21 U.S.C. § 387k(b)(2).

Tobacco Retailer Warning Letters are not subject to the time frames laid out in section 4-1-7 or the issuing of Warning Letter Close-Out Letters in 4-1-8 due to their nature and volume. Additionally, Tobacco Retailer Warning Letters are not routinely acknowledged as stated in 4-1-8. CTP internal procedures to address time frames, acknowledgment of responses, and close-out procedures.

4-1-19. Tracking

1. Identification Of Warning Letters

All Warning Letters must be entered into the Compliance Management System (CMS); whether they are generated by a program office or center, and whether they are approved and issued or not. Every Warning Letter that is issued should bear the CMS-assigned number or a sequential code number assigned by the issuing program office or center. If a program office or center assigned number is used, this number should be recorded in CMS to facilitate tracking.

2. Updating Firm Profile Status in eNSpect

When a violation letter is the result of a CGMP or QS inspection of a domestic or foreign drug, biologics, or medical device facility, the firm's profile status information in eNSpect is to be appropriately updated at each stage in the review process. The action office (i.e., the program office or center initiating the recommendation) is responsible for entering the status of the violation letter into eNSpect. (See ["Firm Profile Updates in eNSpect"](#) in this chapter and [Exhibit 4-1](#) for more information.)"

4-2 UNTITLED LETTERS

4-2-1. Format and Content

An Untitled Letter cites violations that do not meet the threshold for significance of regulatory significance for a Warning Letter. Therefore, the format and content of an Untitled Letter should clearly distinguish it from a Warning Letter. For example:

1. The letter is not titled.
2. The letter does not include a statement that FDA will advise other federal agencies of the issuance of the letter so that they may take this information into account when considering the awarding of contracts.
3. The letter does not include a warning statement that failure to take prompt correction may result in enforcement action.
4. The letter does not evoke a mandated follow-up.
5. The letter requests (rather than requires) a written response from the firm within a reasonable amount of time (e.g., "Please respond within 30 days"), unless more specific instructions are provided in a relevant Compliance Program.

Any appropriate agency compliance official may issue an Untitled Letter.

Also, see [Exhibit 4-1](#), the agency's "Procedures for Clearing FDA Warning Letters and Untitled Letters." All agency components responsible for issuing Warning Letters and Untitled Letters must follow these procedures.

4-2-2. Center Concurrence and Letters Issued By Centers

Center concurrence is required prior to issuing Untitled Letters unless direct reference has been granted.

Also, see [Exhibit 4-1](#), the agency's "Procedures for Clearing FDA Warning Letters and Untitled Letters." All agency components responsible for issuing Warning Letters and Untitled Letters must follow these procedures.

4-2-3. Tracking

1. Identification Of Untitled Letters

All Untitled Letters must be entered into CMS; whether they are generated by a program office or center, and whether they are approved and issued or not. Every Untitled Letter that is issued should bear the CMS-assigned number or a sequential code number assigned by the issuing program office or center. If a program office or center assigned number is used, this number should be recorded in CMS to facilitate tracking.

2. Updating Firm Profile Status in eNSpect

When a profilable firm (i.e., domestic or foreign drug, biologics, or medical device facility) undergoes a CGMP or QS inspection, the inspected profile classes should be updated by the action office at each stage in the review process. When an Untitled Letter is issued as a result of the inspection, the date and type of letter issued should be entered in the Remarks field for the relevant profile classes. For profile procedures, see IOM Exhibit 5-14 or the [Government-Wide Quality Assurance Program \(GWQAP\) intranet page](#).

4-3 USE OF STATE EVIDENCE FOR FDA WARNING LETTERS AND UNTITLED LETTERS

Evidence obtained by state personnel may be sufficient to support the issuance of Warning Letters and Untitled Letters if the standards and criteria used by state personnel provide reliable support for regulatory actions the agency may take consistent with the agency's guidance on regulatory actions and laboratory procedures.

1. If state evidence involves inspectional observations made solely by state personnel, factors that indicate that the standards and criteria used are reliable for these purposes include, but are not limited to, the following:
 - a. The state inspector made the inspectional observations during an inspection conducted pursuant to an agency contract inspection program or a joint inspection program in which FDA participates; or
 - b. The state inspector made the inspectional observations after receiving training in relevant law and any specific requirements applicable to the inspection and the establishment or commodity being inspected; or
 - c. The state inspector received an "acceptable" rating if audited by a qualified FDA or state auditor under [FMD 76, "State Contracts – Evaluation of Inspectional Performance"](#) (or other applicable audit program); or

- d. The state inspector detected and documented the observations in the manner set forth in FDA's inspectional procedures, such as the Investigations Operations Manual, guides to inspections, or comparable inspectional approaches.
2. If state evidence involves laboratory data, factors that indicate that the laboratory data and the methods and procedures used to collect and analyze the sample are valid and reliable include the following:
 - a. The procedures involved in the sample collection have been analyzed and found to be reliable in that the sample was collected, handled, and analyzed using procedures that assure sample integrity and chain of custody and a sample size and test method the Director, Office of Regulatory Science (ORS), determines to be appropriate; or
 - b. The Director, ORS, designates that the laboratory data from state facilities meet the criteria and standards appropriate for compliance decision-making; or
 - c. The Director, ORS, has reviewed and endorsed the state laboratory findings through an evaluation of the laboratory operations, methods, sampling, and evidence documentation.
3. Except for state inspections of retailers to determine compliance with the provisions of the Family Smoking and Tobacco Control Act and its implementing regulations, the program office must review and endorse the state evidence as meeting the criteria for the issuance of a Warning Letter or Untitled Letter in accordance with FDA procedures and agency compliance policy. Warning Letters and Untitled Letters relating exclusively to state inspections of retailers to determine compliance with the provisions of the Family Smoking and Tobacco Control Act and its implementing regulations will be drafted by the Center for Tobacco Products based on sufficient evidence collected and documented by state personnel.
4. The FDA product center with primary jurisdiction over the establishment or commodities inspected and the Office of Chief Counsel concurs with the use of the evidence obtained by state personnel.
5. This section is not applicable where a proposal for a Warning Letter or Untitled Letter is based on FDA-developed evidence to demonstrate the current condition of the commodity or establishment, and evidence obtained by state personnel is used to solely demonstrate prior compliance history.

4-4 EXHIBITS

Exhibit 4-1 Procedures for Clearing FDA Warning Letters and Untitled Letters

Exhibit 4-2 Warning Letter Close-Out Letter

Exhibit 4-1 Procedures for Clearing FDA Warning Letters and Untitled Letters

Contents

1. Purpose
2. Scope
3. Background
4. Definitions
5. Responsibilities
6. Procedures
 - a. Timeframes
 - b. Procedures for the Review of Agency Warning and Untitled Letters
 - c. Licensed Products Letters
 - d. Enforcement Correspondence under an Audit Review

1. Purpose

To facilitate the review by the Office of Chief Counsel (OCC) of certain types of Warning Letters and Untitled Letters, prior to their issuance, for legal sufficiency and consistency with Agency policy.

2. Scope

These procedures apply to all of the agency components that are responsible for recommending, evaluating or issuing Warning Letters and Untitled Letters. Therefore, the applicability of these procedures is not limited to ORA and the Centers' offices of compliance.

The OCC review provisions in these procedures apply only to Warning and Untitled Letters described below:

a. CFSAN

- i. Any Warning or Untitled Letter involving a novel, controversial, or sensitive legal issue.
- ii. Warning Letters involving medical foods.
- iii. Warning Letters involving section 502(f)(1) drug misbranding charges.
- iv. Warning Letters involving section 403(a) false or misleading food labeling.

- v. Warning Letters involving section 403 (r) (1) (A) (unauthorized nutrient content claim) or section 403 (r) (1) (B) (unauthorized health claims) charges.
- vi. Warning Letters for dietary supplements with a new drug charge based in whole or in part on promotional use of scientific studies to market the product for disease uses.
- vii. Warning Letters with violations of the general CGMP regulations.
- viii. Warning and Untitled Letters with violations of the dietary supplement CGMP regulations.
- ix. Warning Letters with adulteration and/or misbranding charges related to cosmetics.

In addition, cyber letters (letters resulting from web sites promoting dietary supplements with drug claims) will be reviewed under the audit review program in 6.4 with OCC reviewing every 10th letter.

b. CDRH

- i. Any warning or untitled letter involving a novel, controversial, or sensitive legal issue.
- ii. Advertising/promotion warning/untitled letters.
- iii. Warning/untitled letters with unapproved device charges under section 501(f)(1)(B) if the firm contests that the product is a device or any other warning/untitled letter in which the firm contests that the product is a device.²
- iv. Warning/untitled letters with section 502(a) charge-labeling of the device is false or misleading.
- v. Warning/untitled letters with 502(j) charge-device is dangerous to health when used in the manner or with the frequency or duration prescribed, recommended or suggested in the labeling thereof.
- vi. Warning/untitled letters with section 502(o) charge-notice/information of modification of the device not provided to FDA.
- vii. Warning/untitled letters with section 502(o) charge-notice/information of new intended use of the device not provided to FDA.

² The term "contests" in this list means that FDA has had prior contact with the firm, e.g., through an inspection, a 483 response, a prior issuance of an untitled letter, email, or telephone, and the firm has asserted that its product is not a "device."

- viii. Warning/untitled letters with section 502(t) (3)-firm has failed or refused to comply with a requirement under section 522.
 - ix. Warning and untitled letters involving bioresearch monitoring not covered by the December 8, 2005 agreement between OCC and CDRH's Office of Compliance.
- c. CVM
- i. Any Warning or Untitled Letter involving a novel, controversial, or sensitive legal issue.
 - ii. Warning Letters involving bioresearch monitoring.
 - iii. Warning Letters with violations of 21 CFR 589.2000 (ruminant feed ban) and/or 21 CFR 589.2001 (new animal feed ban).
 - iv. Warning and Untitled Letters involving advertising and promotion.
 - v. Warning Letters with section 502(a) false or misleading labeling drug misbranding charges.
 - vi. Warning Letters related to turtles.
 - vii. Warning and Untitled Letters involving new animal drug compounding.
- d. CBER
- i. Any Warning or Untitled Letter involving a novel, controversial, or sensitive legal issue.
 - ii. Warning Letters and notice of initiation of disqualification proceedings and opportunity to explain (or "NIDPOEs") involving clinical investigators and IRBs.
 - iii. Warning Letters involving advertising or promotion, except for those involving only straightforward omission of risk (e.g., no risk information whatsoever).
 - iv. Warning and Untitled Letters involving product jurisdiction.
 - v. Warning and Untitled Letters involving unregistered or unlicensed blood banks.
- e. CDER
- i. Any Warning or Untitled Letter involving a novel, controversial, or sensitive legal issue.
 - ii. Warning Letters involving clinical investigators and IRBs.
 - iii. Warning Letters involving advertising or promotion, except for those involving only straightforward omission of risk (e.g., no risk information whatsoever).

- iv. Warning and Untitled Letters involving compounding.
 - v. Warning and Untitled Letters involving unapproved new drugs, except health fraud, over-the-counter drugs subject to final monographs, and Warning Letters that contain both GMP and unapproved new drug charges.
- f. ORA

Any Warning or Untitled Letter involving a novel, controversial, or sensitive legal issue.

3. Background

On November 29, 2001, then Deputy Secretary of the Department of Health and Human Services directed "...the Food and Drug Administration (FDA) to submit all Warning Letters and Untitled Letters to FDA's OCC prior to their issuance so that they can be reviewed for legal sufficiency and consistency with Agency policy." To implement this directive, a cross-agency working group established procedures to integrate OCC review into the agency's existing procedures for the review of enforcement correspondence. These procedures were implemented in March 2002. In August/September of 2009, the OCC review provisions of these procedures were modified, on an interim basis, to apply only to the Warning and Untitled Letters described in section "2. Scope." The 2009 interim procedures were evaluated as described in section 5.1 and finalized in December 2010.

4. Definitions

For the purpose of these procedures:

- a. A Warning Letter is a correspondence that notifies regulated industry about violations that FDA has documented during its inspections or investigations. Typically, a Warning Letter notifies a responsible individual or firm that the Agency considers one or more products, practices, processes, or other activities to be in violation of the Federal Food, Drug, and Cosmetic Act (the Act), its implementing regulations and other federal statutes. Warning Letters should only be issued for violations of regulatory significance, i.e., those that may actually lead to an enforcement action if the documented violations are not promptly and adequately corrected. A Warning Letter is one of the Agency's principal means of achieving prompt voluntary compliance with the Act.
- b. An Untitled Letter is an initial correspondence with regulated industry that cites violations that do not meet the threshold of a Warning Letter. Untitled Letters are intended to cover those circumstances where the Agency has a need to communicate with regulated industry about violations that do not meet the threshold of regulatory significance as described above. The three types of letters related to

licensed products that are issued by CBER and CDER, pursuant to subsection 6.3 of Exhibit 4-1 do not necessarily fall within this definition of an Untitled Letter; however, they are still Untitled Letters that are covered by the scope of these procedures.

5. Responsibilities

- a. FDA's Office of Policy, Planning, Legislation and Analysis conducted a qualitative and quantitative evaluation of the OCC review provisions in the 2009 interim procedures. OCC, in coordination with other agency components, reviewed the results of this evaluation and concluded that the interim procedures should be finalized.

Any refinements to these procedures that become identified through periodic evaluation or otherwise, that may facilitate the review, streamline or focus the process, or enable better management of the workload, while maintaining the overall intent, are implemented through established, internal agency review procedures. In addition, FDA will monitor the timeframes to determine whether they need to be modified based on the agency's experience with these procedures.

- b. Each Office involved in implementing these procedures is responsible for documenting additional internal procedures as needed.
- c. Violation letters are tracked using MARC-CMS (or CMS). CMS provides the capability to enter and track Warning and Untitled Letters through the approval process. The action office (i.e., the Program office or Center initiating the recommendation) is responsible for entering all violation letters into CMS; as well as updating data related to their submissions. The issuing office of the violation letter is also responsible for ensuring that a PDF copy of the final, signed violation letter is added into CMS.

Instructions for using CMS are available in the User's Guide link within the application and further information is available within the link to Frequently Asked Questions.

- d. When a violation letter is the result of a CGMP or QS inspection of a domestic or foreign drug, biologics, or medical device facility, the firm's profile status information in eNSpect is to be appropriately updated at each stage in the review process. The action office (i.e., the Program office or Center initiating the recommendation) is responsible for entering the Final Profile Status in eNSpect. (See Chapter 4 "Firm Profile Updates in eNSpect" for more information.)

6. Procedures

a. Timeframes

i. Warning Letters

The agency did not establish new timeframes for ORA and the Centers. In these procedures, the agency recommits to the established timeframes at each level of review. To ensure the applicability of evidence to the present situation, the agency will strive to issue Warning Letters within four months from the appropriate reference date. Examples of the appropriate reference date are: the last day of the inspection, the date of sample analysis, or the date of evidence collection.

If a Program or Office enters a formal agreement with another Center, such as a Concept of Operations (CONOPS), the agreement's timelines supercede this procedure. Recommendations to the Center and Warning Letter time frames for Human Drug Inspections (Surveillance and For-Cause Inspections) which fall under the review of CDER, can be found in [FDA's INTEGRATION OF FDA FACILITY EVALUATION AND INSPECTION PROGRAM FOR HUMAN DRUGS: A CONCEPT OF OPERATIONS](#). If the agency anticipates pursuing further enforcement action after issuance of the Warning Letter but prior to a follow-up inspection or other verification activities, an expedited timeframe for Warning Letter issuance may be warranted to ensure applicability of the evidence to the present situation (i.e., within four months from the appropriate reference date).

The timeframe for OCC review, when OCC review is required, is fifteen (15) working days. If OCC does not respond to Direct Reference Warning Letters and those issued pursuant to foreign inspections within this timeframe, the Program office or Center can presume concurrence and may send the letter out without additional input. All other categories of letters requiring OCC review should await an OCC decision prior to being issued. For all categories of Warning Letters receiving a decision by OCC, OCC will either concur, concur with changes, not concur with written reasons, or flag the letter because it raises significant issues and questions, e.g., jurisdictional issues or insufficient evidentiary support.

The period for OCC review officially begins once OCC has received the full packet of materials that serve as support for the agency's issuance of the Warning Letter. If the basic elements of the case are not provided (the basic elements are identified in the Program office and center responsibility sections of these procedures), OCC will return the materials to the originator. If, as a part of their review, OCC asks for an exhibit or attachment that accompanied the Establishment Inspection

Report (EIR) or Form FDA 483 response, a copy of the document should be sent to OCC electronically, via fax or by mail.

ii. Warning Letter Responses

When OCC review of the Warning Letter was required, and it is reasonably clear from the Warning Letter response that the individual or firm is going to contest the findings as set out in the Warning Letter, OCC should be consulted and provided with the relevant documents. This is not necessary when the disputed issues are scientific or technical.

iii. Untitled Letters

There are no agency timeframes for the issuance of Untitled Letters. However, pursuant to these procedures, the working group established timeframes for the review of Untitled Letters. In most cases, the timeframes for Warning Letters are tripled for the review of Untitled Letters. The exceptions to this rule are the letters for licensed products that are issued by CBER or CDER pursuant to subsection 6.3 of this exhibit. To ensure the applicability of evidence to the present situation, the agency will strive to issue Untitled Letters within six months from the last day of the inspection, the date of sample analysis, or the date of evidence collection.

When OCC's review of an Untitled Letter is required, OCC will either concur, concur with changes, not concur with written reasons, or flag the letter because it raises significant issues and questions, e.g., jurisdictional issues or insufficient evidentiary support. However, the default provisions do not apply to Direct Reference Untitled Letters and Untitled Letters issued pursuant to a foreign inspection. The period for OCC review officially begins once OCC has received the full packet of materials that serve as support for the agency's issuance of the Untitled Letter. If the basic elements of the case are not provided (the basic elements are identified in the Program office and Center responsibility sections of these procedures), OCC will return the materials to the originator. If, as a part of their review, OCC asks for an exhibit or attachment that accompanied the EIR or Form FDA 483 response, a copy of the document should be sent to OCC electronically, via fax or by mail.

b. Procedures for the Review of Agency Warning and Untitled Letters

All Warning Letters and Untitled Letters must be entered into CMS, where they are available for review.

- i. General Procedures for Direct Reference Warning and Untitled Letters
 - a. Program office Responsibilities
 1. When OCC review of a Warning or Untitled Letter is required:
 - Submit a draft “final” Warning Letter via CMS to OCC for concurrence, within 15 working days after the completion of an inspection, the sample analysis, or date of evidence collection.
 - Submit a draft “final” Untitled Letter via CMS to OCC for concurrence within 45 working days after the completion of an inspection, the sample analysis, or date of evidence collection.
 - To facilitate OCC’s review of the Warning or Untitled Letters, ensure that the violation letter documents within CMS include the Form FDA 483, the endorsement page of the EIR or the eNSpect coversheet, the narrative portion of the EIR, and, if applicable, the summary of any sample analysis.
 - If there is no Form FDA 483 or EIR, send the evidence to OCC that supports the issuance of the letter.
 - If the Program office receives the Form FDA 483 response prior to submitting the draft “final” Warning or Untitled Letter to OCC, a copy of the Form FDA 483 response (without the exhibits or the attachments) and the Program office’s assessment of the response should accompany the draft “final” Warning or Untitled Letter.
 - If the Program office receives the Form FDA 483 response while OCC is reviewing the draft “final” Warning or Untitled Letter, the Program office should notify the attorney that is conducting the review. A copy of the Form FDA 483 response (without the exhibits or the attachments) and the Program office’s assessment of the response (including whether the response has changed the Program office’s view on whether to issue the letter) should also be submitted to the assigned attorney electronically, via fax, or by mail and also added into the case file for the proposed action within CMS. The review clock will stop when OCC is notified and

restart upon OCC's receipt of the Form FDA 483 response and the Program office's assessment. Any changes to the proposed letter as a result of the FDA-483 response will be discussed with the initiating office.

- If OCC concurs, or if OCC does not review the draft "final" Warning Letter within 15 working days, issue the letter.
- If OCC concurs with the draft "final" Untitled Letter, issue the letter.
- If the Program office receives the Form FDA 483 response after OCC has concurred with the issuance of the draft "final" Warning or Untitled Letter, you should issue the letter.

In the case of nonconcurrence or the letter is flagged because it raises significant issues, the Program Office will work with OCC as necessary to quickly address OCC's concerns.

2. Upon issuance, add a PDF signed copy of the Warning or Untitled Letter into the Final Outcome tab for the action within CMS. Distribute additional copies in accordance with any applicable Compliance Program and RPM Chapter 4.

b. OCC Responsibilities

1. Review any draft "final" Warning Letter and Untitled Letter requiring OCC review within 15 working days.
2. If concurrence, send concurrence to the Director of the Compliance Branch and the compliance officer who proposed the action, along with a copy of the draft "final" letter with any edits (the Program office can then issue the letter).
3. If nonconcurrence or the letter is flagged because it raises significant issues, contact the Program office, and state in writing the reason for nonconcurrence.

c. OPCE DCE Responsibilities

DCE will facilitate the discussion to quickly address significant issues, policy misalignment, novel, political, appearance or other controversial issues when notified by the Program office, Center or OCC.

- ii. General Procedures for Warning and Untitled Letters Pursuant to a Foreign Inspection
 - a. Center Responsibilities
 1. Within 15 working days after the receipt of the EIR, the Center will determine if a Warning Letter is appropriate.
 2. Within 45 working days after the receipt of the EIR, the Center will determine if an Untitled Letter is appropriate.
 3. When OCC review of a Warning or Untitled Letter is required:
 - Send a copy of the draft “final” letter via CMS to OCC for concurrence.
 - To facilitate OCC’s review of the Warning or Untitled Letters, ensure that the violation letter documents within CMS include the Form FDA 483, the endorsement page of the EIR or the eNSpect coversheet, the narrative portion of the EIR, and, if applicable, the summary of any sample analysis.
 - If there is no Form FDA 483 or EIR, send the evidence to OCC that supports the issuance of the letter.
 - If the agency receives the Form FDA 483 response prior to submitting the draft “final” Warning or Untitled Letter to OCC, a copy of the Form FDA 483 response (without the exhibits or the attachments) and the agency’s assessment of the response should accompany the draft “final” Warning or Untitled Letter.
 - If the agency receives the Form FDA 483 response while OCC is reviewing the draft “final” Warning or Untitled Letter, the Center should notify the attorney that is conducting the review. A copy of the Form FDA 483 response (without the exhibits or the attachments) and the agency’s assessment of the response (including whether the response has changed the agency’s view on whether to issue the letter) should also be submitted to the assigned attorney electronically, via fax, or by mail, and should also be added into the case file for the proposed action within CMS. The review clock will

stop when OCC is notified and restart upon OCC's receipt of the Form FDA 483 response and the agency's assessment. Any changes to the proposed letter as a result of the FDA-483 response will be discussed with the initiating office.

- If OCC concurs, or if OCC does not review the draft "final" Warning Letter within 15 working days, issue the letter.
- If OCC concurs with the draft "final" Untitled Letter, issue the letter.
- If the agency receives the Form FDA 483 response after OCC has concurred with the issuance of the draft "final" Warning or Untitled Letter, the letter should be issued.
- In the case of nonconcurrence or the letter is flagged because it raises significant issues, the Center will work with OCC and the programs and divisions in ORA as necessary to quickly address OCC's concerns.

4. Upon issuance, add a PDF signed copy of the Warning or Untitled Letter into the Final Outcome tab for the action within CMS.

b. OCC Responsibilities

1. Review any draft "final" Warning Letter and Untitled Letter requiring OCC review within 15 working days.
2. If concurrence, send concurrence to the Center along with a copy of the draft "final" letter with any edits (the Center can then issue the letter).
3. If nonconcurrence or the letter is flagged because it raises significant issues, contact the Center, and state in writing the reason for nonconcurrence.

c. OPCE DCE Responsibilities

DCE will facilitate the discussion to quickly address significant issues, policy misalignment, novel, political, appearance or other controversial issues when notified by the Program office, Center or OCC.

iii. Warning and Untitled Letters that Require Center Concurrence

a. Program office Responsibilities

1. Within 15 working days after the completion of the inspection, the sample analysis, or collection of evidence, submits a recommendation and a draft “final” Warning Letter to the Center through CMS.
2. Within 45 working days after the completion of the inspection, the sample analysis, or collection of evidence, submit a recommendation and a draft “final” Untitled Letter to the Center through CMS.
3. To the extent that this information is not included in the recommendation, and to facilitate the Center’s review of the Warning or Untitled Letters, ensure that the violation letter documents within CMS include all evidence necessary to support issuance of the letter or other relevant information. For example, the Form FDA 483, the endorsement page of the EIR or the eNSpect coversheet, the narrative portion of the EIR, the relevant exhibits, product labels and labeling, and, if applicable, the summary of any sample analysis.
4. If the Program office receives the Form FDA 483 response prior to submitting the draft “final” Warning or Untitled Letter recommendation, a copy of the Form FDA 483 response (without the exhibits or the attachments) and the Program office’s assessment of the response should accompany the draft “final” Warning or Untitled Letter.
5. If the Program office receives the Form FDA 483 response while the draft “final” Warning or Untitled Letter is being reviewed, the Program office should notify the Center and, for letters requiring OCC review, the attorney that is conducting the review, as appropriate. The review clock will stop when OCC is notified and restart upon OCC’s receipt of the Form FDA 483 response and the agency’s assessment. A copy of the Form FDA 483 response (without the exhibits or the attachments) and the Program office’s assessment of the response (including whether the response has changed the Program office’s view on whether to issue the letter) should also be submitted to the appropriate reviewer(s) electronically, via fax, or by mail and also added into the case file for the proposed action within CMS. The review clock will stop when OCC is notified and restart upon OCC’s receipt of the Form FDA 483 response and the agency’s assessment. Any changes to the proposed letter as a

result of the FDA-483 response will be discussed with the initiating office.

6. If the Center approves the recommendation and OCC review is not required, issue the letter.
 7. When OCC review of a Warning or Untitled Letter is required:
 - If OCC concurs, issue the letter.
 - If the agency receives the Form FDA 483 response after OCC has concurred with the issuance of the draft “final” Warning or Untitled Letter, the letter should be issued.
 - In the case of nonconcurrence or the letter is flagged because it raises significant issues, the Center will work with OCC and the programs and divisions in ORA as necessary to quickly address OCC’s concerns.
 8. Upon issuance, add a PDF signed copy of the Warning or Untitled Letter into the Final Outcome tab for the action within CMS. Distribute additional copies in accordance with any applicable Compliance Program and RPM Chapter 4.
- b. Center Responsibilities
1. Within 15 working days after the receipt of the recommendation, the accompanying documents, and the draft “final” Warning Letter, the Center should review and approve or nonconcur with the issuance of the letter. The Center will issue the approval memo within the 15 working day timeframe and add a copy of the Center decision document for the violation letter into the Center documents tab in CMS.
 2. Within 45 working days after the receipt of the recommendation, the accompanying documents, and the draft “final” Untitled Letter, the Center should review and approve or nonconcur with the issuance of the letter. The Center will issue the approval memo within the 45 working day timeframe and add a copy of the Center decision document for the violation letter into the Center documents tab in CMS.
 3. When OCC review of a Warning or Untitled Letter is required:

- If the recommendation is approved, the Center will send its concurrence and the draft “final” letter with any edits to OCC for concurrence. The Center’s “final” letter with any edits should be added to the Center documents tab in CMS and should clearly identify via the document description any letter that require OCC review and concurrence. For instance, the description field within CMS should indicate “FOR OCC REVIEW.”
 - To facilitate OCC’s review of the Warning or Untitled Letters, ensure that the violation letter documents within CMS include the Form FDA 483, the endorsement page of the EIR or the eNSpect coversheet, the narrative portion of the EIR, and, if applicable, the summary of any sample analysis.
 - If there is no Form FDA 483 or EIR, send the evidence to OCC that supports the issuance of the letter.
4. If the Warning Letter recommendation is not approved, the Center will notify the Director of the Compliance Branch and OCC if the letter required OCC review, of its decision within 15 working days. The Center will also issue a memorandum to the Director of the Compliance Branch that states its reasons for nonconcurrence within 30 working days, or as soon as possible. The Center will add a copy of its Center decision memorandum for the violation letter into the Center documents tab in CMS.
 5. If the Untitled Letter recommendation is not approved, the Center will notify the Director of the Compliance Branch, and OCC if the letter required OCC review, of its decision within 45 working days. The Center will also issue a memorandum to the Director of the Compliance Branch that states its reasons for nonconcurrence within 60 working days, or as soon as possible. The Center will add a copy of its Center decision memorandum for the violation letter into the Center documents tab in CMS.
- c. OCC Responsibilities
1. Once the Center has approved the recommendation, review any draft “final” Warning Letter requiring OCC review within 15 working days.

2. Once the Center has approved the recommendation, review any draft “final” Untitled Letter requiring OCC review within 45 working days.
3. If concurrence, send concurrence to the Director of the Compliance Branch and the program office’s compliance officer who proposed the action, along with a copy of the draft “final” letter with any edits (the Program office can then issue the letter).
4. If nonconcurrence or the letter is flagged because it raises significant issues, contact the Center involved and the Program office, and state in writing the reason for nonconcurrence.

d. OPCE DCE Responsibilities

DCE will facilitate the discussion to quickly address significant issues, policy misalignment, novel, political, appearance or other controversial issues when notified by the Program office, Center or OCC.

iv. Warning and Untitled Letters that Issue Directly from the Center

a. Center Responsibilities

1. Make the decision to issue a Warning Letter or an Untitled Letter
2. When OCC review of a Warning or Untitled Letter is required:
 - Submit a draft “final” Warning Letter or Untitled Letter via CMS to OCC.
 - To facilitate OCC’s review, ensure that the violation letter documents within CMS include the Form FDA 483, the endorsement page of the EIR or the eNSpect coversheet, the narrative portion of the EIR, and, if applicable, the summary of any sample analysis.
 - If there is no Form FDA 483 or EIR, send the evidence to OCC that supports the issuance of the letter.
 - If the agency receives the Form FDA 483 response prior to submitting the draft “final” Warning or Untitled Letter to OCC, a copy of the Form FDA 483 response (without the exhibits or the attachments) and the agency’s assessment of the response

should accompany the draft “final” Warning or Untitled Letter.

- If the agency receives the Form FDA 483 response while OCC is reviewing the draft “final” Warning or Untitled Letter, the Center should notify the attorney that is conducting the review. A copy of the Form FDA 483 response (without the exhibits or the attachments) and the agency’s assessment of the response (including whether the response has changed the agency’s view on whether to issue the letter) should also be submitted to the assigned attorney electronically, via fax, or by mail, and also added into the case file for the proposed action within CMS. The review clock will stop when OCC is notified and restart upon OCC’s receipt of the Form FDA 483 response and the agency’s assessment. Any changes to the proposed letter as a result of the FDA-483 response will be discussed with the initiating office.
 - If OCC concurs, the Center can issue the letter.
 - If the agency receives the Form FDA 483 response after OCC has concurred with the issuance of the draft “final” Warning or Untitled Letter, the letter should be issued.
 - In the case of nonconcurrence or the letter is flagged because it raises significant issues, the Center will work with OCC as necessary to quickly address OCC’s concerns.
3. Upon issuance, add a PDF signed copy of the Warning or Untitled Letter into the Final Outcome tab for the action within CMS. Send a copy to the Compliance Branch where the recipient of the letter is located and distribute additional copies in accordance with any applicable Compliance Program and RPM Chapter 4.
- b. OCC Responsibilities
1. Review any draft “final” Warning Letter requiring OCC review within 15 working days.
 2. Review any draft “final” Untitled Letter requiring OCC review within 45 working days.

3. If concurrence, send concurrence to the Center along with a copy of the draft “final” letter with any edits (the Center can then issue the letter).
 4. If nonconcurrence or the letter is flagged because it raises significant issues, contact the Center, and state in writing the reason for nonconcurrence.
- v. Letters that Issue Directly from the Centers Promotion and Advertising Staffs
- a. Center Responsibilities
 1. Make the decision to issue a Warning Letter or an Untitled Letter.
 2. When OCC review of a Warning or Untitled Letter is required:
 - Send a copy of the draft “final” letter via CMS to OCC for concurrence.
 - To facilitate OCC’s review, ensure that the violation letter documents within CMS include the evidence that supports the issuance of the letter.
 - If OCC concurs, issue the letter.
 - In the case of nonconcurrence by OCC or the letter is flagged by OCC because it raises significant issues, the Center will work with OCC to quickly address OCC’s concerns.
 3. Upon issuance, add a PDF signed copy of the Warning or Untitled Letter into the Final Outcome tab for the action within CMS. Distribute additional copies in accordance with any applicable Compliance Program and RPM Chapter 4.
 - b. OCC Responsibilities
 1. Review any draft “final” Warning Letter requiring OCC review within 15 working days.
 2. Review any draft “final” Untitled Letter requiring OCC review within 45 working days.
 3. If concurrence, send concurrence to the Center along with a copy of the draft “final” letter with any edits (the Center can then issue the letter).
 4. If nonconcurrence or the letter is flagged because it raises significant issues, contact the Center and state in writing the reasons for nonconcurrence.

c. Licensed Products Letters

Violation Letters associated with licensed biological therapeutic drugs may fall under CBER or CDER responsibility. Contact the Centers if the jurisdiction is not clear.

Recommendations and other correspondence related to 6.3.1 – 6.3.3 (below) that are associated with CDER products should be forwarded to CDER, Office of Compliance, and Office of Manufacturing Quality. Recommendations and correspondence related to CBER products should be referred to CBER, OCBQ, DCM.

i. License Suspension

a. Center Responsibilities

1. Within three (3) working days after receiving information that a danger to health exists, the Center will gather the pertinent evidence, convene a Health Hazard Evaluation meeting with the applicable product office, and draft a Letter of Suspension.
2. If the determination is made that a danger to health exists, a draft “final” Letter of Suspension will be submitted by the Center via CMS to OCC within the 3 working day period.
 - To facilitate OCC’s review, ensure that the documents within CMS include the Health Hazard Evaluation and the pertinent evidence that establishes that a danger to health exists.
 - If OCC concurs, the Center’s Office of Compliance and the Office of the Center Director will process and issue the letter.
 - In the case of nonconcurrence or the letter is flagged because it raises significant issues, the Center will work with OCC to quickly address OCC’s concerns.
3. Upon issuance, add a PDF signed copy of the letter into the Final Outcome tab for the action within CMS. Distribute additional copies in accordance with any applicable Compliance Program and RPM Chapter 4.

b. OCC Responsibilities

1. Review the draft “final” letter within 5 working days.

2. If concurrence, send concurrence to the appropriate Center along with a copy of the draft “final” letter with any edits.
3. If nonconcurrence or the letter is flagged because it raises significant issues, contact the Center, and state in writing the reason for nonconcurrence.

c. OPCE DCE Responsibilities

DCE will facilitate the discussion to quickly address significant issues, policy misalignment, novel, political, appearance or other controversial issues when notified by the Program office, Center or OCC.

ii. License Revocation (For Cause)

a. Center Responsibilities

1. Within 30 working days after receipt of a Recommendation for a License Revocation, the Center will evaluate the recommendation to determine whether the issuance of a letter requesting the revocation of a license is appropriate.
2. If the issuance of a letter is appropriate, submit a draft “final” letter via CMS to OCC for their concurrence.
3. To facilitate OCC’s review of the letter, ensure that the documents within CMS include the recommendation and any additional supporting documents.
4. If OCC concurs, issue the letter.
5. In the case of nonconcurrence or the letter is flagged because it raises significant issues, the Center will work with OCC to quickly address OCC’s concerns.
6. Upon issuance, add a PDF signed copy of the letter into the Final Outcome tab for the action within CMS.

b. OCC Responsibilities

1. Review the draft “final” letter within 30 working days.
2. If concurrence, send concurrence to the Center along with a copy of the draft “final” letter with any edits.
3. If nonconcurrence or the letter is flagged because it raises significant issues, contact the Center, and state in writing the reason for nonconcurrence.

c. OPCE DCE Responsibilities

DCE will facilitate the discussion to quickly address significant issues, policy misalignment, novel, political, appearance or other controversial issues when notified by the Program office, Center or OCC.

iii. Notice of Intent to Revoke

a. Center Responsibilities

1. Within 30 working days after the receipt of a Recommendation for a Notice of Intent to Revoke (NOIR), the Center will evaluate the recommendation to determine whether the issuance of a (NOIR) letter is appropriate.
2. If the issuance of a NOIR is appropriate, submit a draft “final” NOIR letter and any accompanying documentation via CMS to OCC for their concurrence.
 - If OCC concurs, issue the letter.
 - In the case of nonconcurrence or the letter is flagged because it raises significant issues, the Center will work with OCC.
3. Upon issuance, add a PDF signed copy of the letter into the Final Outcome tab for the action within CMS.

b. OCC Responsibilities

1. Review the draft “final” letter within 30 working days.
2. If concurrence, send concurrence to the Center, along with a copy of the draft “final” NOIR letter with any edits.
3. If nonconcurrence or the letter is flagged because it raises significant issues, contact the Center and state in writing the reason for nonconcurrence.

c. OPCE DCE Responsibilities

DCE will facilitate the discussion to quickly address significant issues, policy misalignment, novel, political, appearance or other controversial issues when notified by the Program office, Center or OCC.

d. Enforcement Correspondence Under an Audit Review

Periodically, the agency may determine, through the periodic evaluations or otherwise, that certain Untitled and Warning Letters may be reviewed by OCC on an audit basis rather than a letter-by-letter review. The

agency may institute such an audit review under those circumstances in which policy is clear and well established, and model letters have been developed and cleared through OCC for use by the originating organization. Specific areas and criteria for audit review will be developed for the relevant letters.

If, during the evaluation or otherwise, any problems are identified in the use of the models, quality of issued letters, conformance with the audit requirements or other criteria in this procedure, audit review may revert back to full letter-by-letter review.

i. Introduction

Audit letters are automatically identified by CMS, using the audit schedules in 6.4.1 based on the nationwide count of that category of letter. The system will automatically indicate those letters subject to OCC review while the remaining letters in that audit category may be issued without such review. The model letters must be followed for all letters under this audit review program issued on or after the associated effective date.

If the same model is used for both Warning Letters and Untitled Letters, the audit schedule must be followed for each type of letter. This means that Untitled Letters and Warning Letters are to be counted separately to identify the audit letter to be submitted for OCC review using the procedures in this document.

At the discretion of the issuing office, letters that represent unique circumstances that warrant OCC review may continue to be submitted for review through the routine procedures in this document, in addition to the required submission of audit letters.

ii. Program office Responsibilities

Use the relevant model letter for all letters to be issued under the audit program. Once the action is added into CMS, the program office must identify the OCC audit program under which the letter falls in order to determine whether the letter is subject to audit submission to OCC. For letters that require Center concurrence, the program office should likewise identify that the proposed action letter falls within one of the OCC audit programs and follow the routine procedures in this document. For direct reference letters, submit audit letters to OCC for review using the procedures in this document. The other letters may issue without OCC review but must still be added into CMS in order for the agency to keep accurate accounting for the issuance of the letter.

Program offices must continue to be diligent to ensure the high quality and timeliness of any letters that are issued and must otherwise follow the appropriate procedures in the RPM, Compliance Programs, or elsewhere.

Conformance with these procedures and use of the model letter is required. Audit review can be rescinded if warranted.

iii. Center Responsibilities

Use the relevant model letter for all letters to be issued under the audit program. Once the action is added into CMS, the Center must identify the OCC audit program under which the letter falls in order to determine whether the letter is subject to audit submission to OCC. In most instances, this information should be completed by the recommending program office; however, Centers will review as well to ensure an audit program is identified when appropriate. For letters for which the Center is responsible for obtaining OCC concurrence, submit audit letters to OCC for review using the procedures in this document. The other letters may issue without OCC review.

When a Center submits an “audit letter” to OCC for review, the transmittal memo approving the recommendation will contain the notation “Audit Letter – OCC concurrence is required” under the heading “Warning Letter –Approved.” This identifies the letter as one that requires OCC review and concurrence under the audit review program before it can be issued.

Centers must continue to be diligent to ensure the high quality and timeliness of any letters that are issued and must otherwise follow the appropriate procedures in the RPM, Compliance Programs, or elsewhere.

Conformance with these procedures and use of the model letter is required. Audit review can be rescinded if warranted.

iv. OCC Responsibilities

Review Untitled Letter and Warning Letter recommendations submitted by a Program office or Center, representing the audit letters of that type to be issued by that Program office or Center on or after the effective date of the model (shown below) in accordance with the routine procedures in this document. Determine conformity with the model letter. Report any perceived problems to OPCE DCE.

v. OPCE DCE Responsibilities

DCE will facilitate the discussion to quickly address significant issues, policy misalignment, novel, political, appearance or other controversial issues when notified by the Program office, Center or OCC.

vi. Model Letters and Audit Schedules

The following model letters and audit schedules have been approved for use under this audit review program. The links to these letters can be found in the Warning Letter page on the ORA's intranet page.

Center	Type of Letter	Audit Schedule
CFSAN	CFSAN Dietary Supplement Cyber Letters (resulting from web sites promoting dietary supplements with drug claims) with: Disease Claims Disease and Structure-Function Claims The effective date for use of these letters is August 6, 2009.	Every Tenth Letter

Exhibit 4-2 Warning Letter Close-Out Letter

Mr. John Doe,
President J.D. Laboratories, Inc.
Somewhere, USA

Dear Mr. Doe:

The Food and Drug Administration has completed evaluation of (your /your firm's) corrective actions in response to our Warning Letter [insert WL # and Date]. Based on our evaluation, it appears that you have addressed the violation(s) contained in this Warning Letter. Future FDA inspections and regulatory activities will further assess the adequacy and sustainability of these corrections.

This letter does not relieve you or your firm from the responsibility of taking all necessary steps to assure sustained compliance with the Federal Food, Drug, and Cosmetic Act and its implementing regulations or with other relevant legal authority. The Agency expects you and your firm to maintain compliance and will continue to monitor your state of compliance. This letter will not preclude any future regulatory action should violations be observed during a subsequent inspection or through other means.

Sincerely,

Official [issuing program/office]

bcc: Establishment File

Home District of Corporate HQ (or of receiving firm if issued by a Center) FOI
Office for Posting (typically no redaction needed; electronic through CMS)

CMS case file (electronic copy)

Regulatory Procedures Manual

Chapter 5 – ADMINISTRATIVE ACTIONS

NOTE: The compliance officer (or, the center CSO/Scientist, if the action was center-initiated) assigned to the administrative action should diligently pursue and actively monitor the progress of the case through the Agency review process to its conclusion. The Office of Strategic Planning and Operational Policy (OSPOP), Division of Enforcement (DE) can assist in situations where significant delays are experienced or assistance is needed to resolve technical, scientific, or policy issues. See also section on **Ad Hoc** Committees in Chapter 10.

For actions resulting from a Current Good Manufacturing Practice (CGMP) or Quality System (QS) inspection of a domestic or foreign drug, biologics, or medical device facility, the firm's profile status information in the Field Accomplishment and Compliance Tracking System (FACTS) should be appropriately updated at each stage in the review process. See "Firm Profile Updates in FACTS" in Chapter 4 for more information.

This chapter contains the following sections.

Section	Topic	
5-1	CITATIONS	4
5-1-1	Purpose	4
5-1-2	Legal Authority	4
5-1-3	Citation Under Multiple Laws	4
5-1-4	Criteria For Citation.....	4
5-1-5	Determining The Need For Citation	5
5-1-6	Time Frames.....	6
5-1-7	Citation Procedures.....	6
5-1-8	Determination Of Citees	8
5-1-9	Setting Date For Meeting	8
5-1-10	Preparation Of Citation Documents.....	9
5-1-11	Distribution Of Citation Documents.....	11
5-1-12	Transfer of Meeting	12
5-1-13	Correspondence With Attorneys	13
5-1-14	Drug Advertising Citations	13
5-2	SECTION 305 MEETING	14

5-2-1	Purpose	14
5-2-2	Authority	14
5-2-3	Preparation	14
5-2-4	Respondents' Request For Special Information.....	15
5-2-5	Conducting The 305 Meeting.....	15
5-2-6	Procedures After Meeting.....	23
5-3	ADMINISTRATIVE DETENTION OF FOODS.....	24
5-3-1	Purpose	24
5-3-2	Background	24
5-3-3	Issuing and Terminating Detention Orders.....	26
5-3-4	Appeal of a Detention Order.....	36
5-3-5	Informal Hearing on Appeal of a Detention Order	43
5-3-6	Issuing the Decision on an Appeal	46
5-3-7	Administrative Record and FOIA Requests	48
5-4	DETENTION OF FOODS – OTHER STATUTORY AUTHORITY.....	48
5-4-1	Purpose	48
5-4-2	Authority	49
5-4-3	Criteria For Effecting And Terminating Detentions	50
5-5	ADMINISTRATIVE DETENTION OF DRUGS.....	51
5-5-1	Purpose	51
5-5-2	Background	51
5-5-3	Issuing and Terminating Detention Orders.....	53
5-5-4	Appeal of a Detention Order.....	63
5-5-5	Informal Hearing on Appeal of a Detention Order	69
5-5-6	Issuing the Decision on an Appeal	72
5-5-7	Administrative Record and FOIA Requests	73
5-6	ADMINISTRATIVE DETENTION OF DEVICES.....	74
5-6-1	Purpose	74
5-6-2	Detention of Devices.....	74
5-6-3	Appeal Of A Detention Order.....	81
5-6-4	Informal Hearing On Appeal Of A Detention Order.....	84
5-6-5	Requirements After A Hearing On Appeal Of A Detention Order	87
5-7	LICENSE REVOCATION OR SUSPENSION	89
5-7-1	Purpose	89
5-7-2	General.....	89

5-7-3	General Considerations for Revocation	90
5-7-4	Issues Not Supporting License Revocation	91
5-7-5	Revocation Procedures	92
5-7-6	General Considerations For Suspension	94
5-7-7	Suspension Procedures	95
5-8	ORDERS OF RETENTION, RECALL, DESTRUCTION AND CESSATION OF MANUFACTURING RELATED TO HUMAN CELL, TISSUE AND CELLULAR AND TISSUE-BASED PRODUCTS (HCT/Ps)	97
5-8-1	Purpose	97
5-8-2	Background	97
5-8-3	General Considerations.....	99
5-8-4	Procedures for Orders of Retention, Recall, or Destruction of HCT/Ps	99
5-8-5	Follow-Up to Orders of Retention, Recall, or Destruction	101
5-8-6	Procedures for Orders of Cessation of Manufacturing.....	102
5-8-7	Follow Up to Orders of Cessation of Manufacturing	104
5-8-8	Part 16 Hearing	104
5-9	CIVIL MONEY PENALTIES AND NO-TOBACCO-SALE ORDERS	105
5-9-1	Civil Money Penalty Authorities.....	105
5-9-2	Reduction Of Civil Money Penalties For Small Entities	112
5-9-3	Civil Money Penalty Recommendations	112
5-10	DISQUALIFICATION OF CLINICAL INVESTIGATORS	113
5-10-1	Purpose	113
5-10-2	Criteria for Initiating Disqualification Proceedings	114
5-10-3	Initiating the Disqualification Process.....	114
5-10-4	Notice of Initiation of Disqualification Proceedings and Opportunity to Explain (NIDPOE) 115	
5-10-5	Consent Agreements.....	116
5-10-6	Informal Conference with the Clinical Investigator	116
5-10-7	The Notice of Opportunity for Hearing (NOOH)	117
5-11	EXHIBITS	120

5-1 CITATIONS

5-1-1 Purpose

This section describes the Food and Drug Administration's (FDA) procedures for issuing Section 305 Notices (21 USC 335).

5-1-2 Legal Authority

FDA issues Citations under Section 305 of the [Federal Food, Drug, and Cosmetic Act](#) (the Act or the FFDCA), which states:

"Before any violation of this Act is reported by the Secretary to any United States attorney for institution of a criminal proceeding, the person against whom such proceeding is contemplated shall be given appropriate notice and an opportunity to present his views, either orally or in writing, with regard to such contemplated proceeding."

21 CFR 7.84 provides requirements about the issuance of such notice and opportunity.

NOTE: Citation is to be used only when a prosecution recommendation is contemplated. Do not use a Citation for warning purposes.

5-1-3 Citation Under Multiple Laws

On occasion, the same or related conduct that violates the Act may also constitute a violation of one or more other federal laws, such as the licensing provisions for biologics under the [Public Health Service Act](#) (42 U.S.C. Section 262), [18 U.S.C. Section 1001](#) (Fraud and False Statements), and [18 U.S.C. Section 371](#) (Conspiracy to commit offense or to defraud United States).

In such a case, identify the section of each law under which action is contemplated, and the specific actions considered to violate that law.

5-1-4 Criteria For Citation

The basic criteria for consideration of citation are as follows:

- A violation of the law has been established and the Agency has evidence in its possession to support the case in court.
- The violation is significant in terms of consumer protection.

Except in cases involving a health hazard, fraud, or extremely gross violations, prior warning must have been given to the firm and each individual involved. This prior warning may be in the form of conferences, previous meetings, letters, or discussions of FDA 483s at the conclusion of inspections or previous court actions. See RPM [Chapter](#)

[10](#) for a discussion of Prior Notice. In instances where the prior warning was in the form of letters or a Section 305 Notice involving past violations, copies must have been directed to each individual to be cited.

NOTE: Additional, more specific criteria in many areas may be found in [Compliance Policy Guides](#) (CPGs) and the [Compliance Program Guidance Manual](#) (CPGM).

5-1-5 Determining The Need For Citation

The division compliance branch is responsible for deciding whether citation is warranted. The compliance officer assigned to the case should ensure that all samples and other evidence have been considered. The search for other samples and evidence may include:

1. Searching the Field Accomplishments and Compliance Tracking System (FACTS) for further information on the firm;
2. Checking with the laboratory to find out if there are other samples that are in-process and need to be analyzed;
3. Checking the collection report (C/R) on the initial sample to ensure that all related samples are attached; and,
4. Checking outstanding sample assignments in FACTS.

If there are other samples to be analyzed or the establishment inspection report has not been completed, and seizure has not yet been considered, you may wish to defer action until the entire case can be considered at one time. In such instances, discuss the matter with investigations branch and/or the laboratory to expedite processing of the report or the samples.

Conduct a thorough review of the evidence. For example, review the firm's regulatory history to determine who was responsible for the violations and whether prior warning has been given. Review inspection reports to ensure that any inspectional observations that are inconsistent with analytical results are addressed. Ensure that reserve samples are available, where required. In labeling violations, search the file to determine whether the firm has revised the labeling since the shipment of the samples in question.

A citation may be based solely on establishment inspection evidence. A minimum of two documentary samples covering violative products is desirable.

NOTE: Under normal circumstances, notice and an opportunity to present information and views will always be given before violations are reported for criminal prosecution. However, there are certain circumstances under which notice and opportunity need not be provided. Notice and opportunity need not be given when there is reason to believe that alerting the prospective defendants by a Section 305 Notice may result in the destruction of evidence or cause the proposed defendants to flee to avoid prosecution.

(21 CFR 7.84(a)(2)). In addition, notice and opportunity need not be given when further investigation by the Department of Justice is contemplated. (21 CFR 7.84(a)(3)).

Such situations are infrequent and should be approved on a case-by-case basis. Submit the facts to the center and request concurrence from the center, Office of Strategic Planning and Operational Policy (OSPOP), and the Office of Chief Counsel (OCC) when you do not believe providing notice and an opportunity for presentation of views is appropriate.

5-1-6 Time Frames

All timeframes are in calendar days unless specified otherwise.

The following time frames apply to citations:

1. Division: fifteen (15) working days after analysis of most recent sample involved in case.
2. Center: fifteen (15) working days after receipt of the recommendation.

There may be good reasons for exceeding these timeframes in a particular case. For example, analytical procedures may be lengthy, or there may be a need to obtain assistance from other divisions to establish responsibility. Document the reasons for delays in the case file.

5-1-7 Citation Procedures

1. Prior Consultation with the Office of Criminal Investigations (OCI)

The [Office of Criminal Investigations](#) (OCI) is responsible for reviewing all matters in FDA for which a criminal investigation is recommended, and is the focal point for all criminal matters.

FDA personnel must refer all criminal matters, regardless of their complexity or breadth, to OCI. This includes criminal search warrants, misdemeanor prosecutions, and citations.

Division management must communicate with its [local OCI office](#) before pursuing any criminal matter. This communication is absolutely essential to preclude potential interference with other on-going criminal investigations and to prevent confusion among the components of OCC and the Department of Justice that are responsible for handling FDA's criminal cases. During this communication, OCI is to be provided with all the facts of the potential case and any additional information that is relevant to, or could impact, the case in any way. OCI will decide promptly whether or not it is interested in pursuing the case and will communicate that decision to the division.

If OCI chooses not to pursue a criminal matter, the division office, after considering the reasons for the declination, is at liberty to proceed with the case in accordance with the procedures in this chapter.

2. Authorization To Cite

Citation may issue either on a direct basis or after the submission of a recommendation to the appropriate center and receipt of concurrence to issue the Section 305 Notice.

It is incumbent upon the office issuing the Section 305 Notice to ensure that the firm and each individual to be cited have received prior warning, unless such warning is not required.

a. Direct Citation

CPGs give division offices authority to issue Section 305 Notices in cases where specific criteria are met. Most of these guidelines involve filth violations or noncompliance with standards. Check the [CPG manual](#) each time the division office believes citation is the action of choice to preclude submitting unnecessary recommendations to a center.

b. Citation Recommendation

Where the division office does not have direct citation authority, it should submit a citation recommendation to the appropriate center for approval.

The recommendation should include:

- the full background of the case,
- the history of notification,
- the facts supporting the violation(s) for which prosecution is being considered,
- the names and responsibilities of each individual to be cited,
- the proposed charges,
- the supporting samples,
- any labels, worksheets, and pertinent inspection reports, and
- any issues, concerns, discrepancies, or other problems with the case.

The recommendation package should be well-organized, tabbed, and indexed. The recommendation should identify the location of supporting information it discusses. Interstate (IS) documentation remains the responsibility of the divisions and need not be submitted. However, the center may request IS documentation if there is a special need to review it.

c. Citation Recommendation After or Concurrently with Seizure

When the division follows a seizure action with a citation recommendation based on the same underlying violations, it is acceptable to submit a memorandum that references information in the seizure recommendation, provided that the center has all of the labeling and other documents necessary to consider the citation.

When the division office is recommending citation at the same time it is recommending seizure, flag the recommendation memorandum as "Seizure and Citation Recommendation."

5-1-8 Determination Of Citees

1. Corporations, Partnerships, and Associations

Corporations, partnerships, and associations are "persons" under the Act, and may be prosecuted as separate legal entities. They should always be included in the citation.

2. Individuals

In every case, carefully consider citing individuals. Prior warning is a prerequisite except where the violation involves a danger to health, fraud, or where the violation is extremely gross.

It is FDA procedure to cite officers of corporations and members of partnerships and associations, when the available evidence establishes that the individual stood in a "responsible relationship" to the violation. As the U.S. Supreme Court stated in *U.S. v. Park*: "The Act imposes not only a positive duty to seek out and remedy violations when they occur but also, and primarily, a duty to implement measures that will insure that violations will not occur."

Persons who have the power and authority, and therefore the responsibility, to carry out these duties and fail to do so are logical candidates for citation. Obtain the type of information needed to demonstrate responsibility from observations reported by the investigators, through correspondence and/or memoranda of conferences with the individuals, or through other means. In addition, if there is a need, obtain information from officers and individuals located at a parent plant, as well as persons at the inspected plant.

5-1-9 Setting Date For Meeting

If the firm and individuals to be cited are located within a reasonable proximity of the office in which the meeting is to be held, schedule the meeting for approximately ten (10) days after issuing the Section 305 Notice. If the citees must travel extensive

distances or wish to have a corporate attorney in attendance, or the violations involved are complex, schedule the meeting approximately twenty (20) days after issuing the Section 305 Notice.

When there are multiple citees, schedule a separate meeting for any citee who requests one in writing. The meeting may be held at a separate time on the same date or on a separate date. The citee must submit the request to the office that issued the Section 305 Notice, and the request must be received at least three (3) working days before the date set in the notice.

5-1-10 Preparation Of Citation Documents

1. Section 305 Notice ([Exhibit 5-1](#))

Insert the division address under the printed heading "Food and Drug Administration." Under the caption at the right, "In reply refer to," insert the key or file reference sample number for the action, and "et. al." if there are several samples involved. If there is only one product or class of products, such as "drugs," bakery products," etc., identify the product directly below the reference sample number. The complete list of samples will appear on the Charge Sheet along with the respective products. See [Exhibits 5-2 and 5-3](#) for examples of charge sheets.

Enter the date that Notice issues directly above the rectangle on "Section 305 Notice" or centered under the city and state of the division's address.

In the space for addressee, insert the name and address of the firm or sole owner cited (primary citee). When the citation also names responsible individuals, address it in the following manner:

Standard Pharmaceutical Co.
and Mr. Henry Jones
and Mr. John Doe
125 Main Street
Canton, Ohio 28531

(Do not show titles of individuals listed as citees.)

In the body of the Notice, following the phrase "with respect to the following," enter clear, concise statements identifying the specific interstate shipment and product for each sample on which citation is issuing. In each statement include

- the name of the product,
- sufficient quotation from the label to identify the brand, size, etc.,
- the date of shipment,
- where the shipment originated, and
- where and to whom it was consigned.

When there is more than one sample, show sample numbers in parenthesis following the description of each shipment. If there is insufficient space on the form to enter the samples and shipments involved, enter the notation "See Page 2" conspicuously in the body of the Notice and continue the additional information regarding the samples on a separate page captioned as follows: "Page 2 - Section 305 Notice".

NOTE: When charging violations involving items other than shipments, include a concise factual statement of the violations. See [Exhibits](#).

Following the words, "A meeting has been scheduled for," insert the day, date, specific time and location of the meeting. Add any other information that may facilitate the citee's appearance in parentheses following this statement (e.g., availability of parking near the building).

Type the name of the Compliance Officer who will conduct the meeting at the bottom of the form and have that individual sign the copies mailed to the firm and each individual cited.

If individuals have been cited along with the firm, show distribution on all copies of the Notice under the parenthetical statement: "(IMPORTANT: NOTE ALL ENCLOSURES CAREFULLY)" such as: 1 cc to Mr. John Doe and to Mr. Robert Roe each with Charge Sheet and Information Sheet.

2. Charge Sheet (Form FDA 1854) ([Exhibit 5-2](#))

Use Form FDA 1854 (Model Charge Sheet [Exhibit 5-2](#)). Under the title, list each sample and product in ascending numerical order. If the list of samples is long, arrange it in two columns.

Under the heading "PROHIBITED ACT" state the section(s) of the law(s) violated and the statutory description from the law. In charges involving Title 18 or Title 42, cite those laws.

At the left of the sheet, following the above paragraph type the word "CHARGES". If only one sample and charge are involved, enter the statement "The article is violative in that" followed by the non-legal description of the violation. In the case of multiple charges, enter the statement: "The article is violative in the following respects:" and list each charge separately, numbered as "1," "2," "3," etc.

When a number of samples and charges are involved, use the statement "The articles are violative in the following respects:" and list the charges as described above. Show the sample numbers involved at the left of each charge.

State the charges in "lay language." There is no need to reference specific sections of the Act (other than the "Prohibited Act") or the regulations. Exhibit 5-3 contains examples of charges.

3. Legal Status Sheet (Form FDA 454) ([Exhibit 5-4](#))

Use Form FDA 454. [Exhibit 5-4 Legal Status Sheet](#). Enter the sample numbers involved in the citation in the upper right hand side of the form following the caption "Sample No."; and the date(s) of the alleged violations over the "(Date)" caption following line "A." If more than two dates are involved, show the earliest and latest dates only; for example, "3/3/94 thru 4/12/94." The division office makes no other entries.

4. Information Sheet (Form FDA 466a) ([Exhibit 5-5](#))

Use Form FDA 466 ([Exhibit 5-5 Information Sheet](#)) This form describes the purpose and nature of the meeting. It is not necessary to type any information on the form; however, it is mandatory that this form accompany the Section 305 Notice sent to each individual cited.

5-1-11 Distribution Of Citation Documents

1. Distribute the Section 305 Notice, Charge Sheet, Legal Status Sheet, and Information Sheet as follows:
 - a. Send a signed, original copy of the Section 305 Notice, a Charge Sheet, an Information Sheet, and a Legal Status Sheet to the primary citee (generally the firm).
 - b. Send a signed copy of the Section 305 Notice, a copy of the Charge Sheet, and an Information Sheet, to each of the other citees, if it is a joint citation.
 - c. Forward one copy of the Section 305 Notice, together with one copy of the Charge Sheet, to the factory file, the reading file, and, if applicable, to the division resident post.
 - d. Retain three copies of the Section 305 Notice and the Charge Sheet in the Division Sample File for use when making a recommendation for disposition of the charges.

2. Mailing Instructions

Mail the Section 305 Notice in a regular, letter size envelope with the typed name and address of the citee. Do not use window envelopes. When individuals are cited along with a firm, circle or underline their names on their respective copies and mail each citee's copy in a separate envelope. Where the interests of the individual citees may be at odds, you may send the individual notices to the home addresses of the citees.

Send the Section 305 Notice by certified mail with return receipt requested or by other method with proof of receipt.

3. Postponement of Meetings

Divisions may grant a reasonable postponement of a meeting upon written request by a citee or person representing a citee (see exception below). The length of the postponement will depend on particular circumstances but should avoid excessive delay. Confirm the new date by a letter to the citee or representative who requested the postponement. Provide an information file copy to the center.

Exception: If an office in headquarters directed that the meeting be scheduled within a certain time frame, do not agree to postponements without first consulting with that office.

5-1-12 Transfer of Meeting

Occasionally citees will request a transfer of the scheduled meeting to another city in the division area, to another division office, or to Washington headquarters. The citee also has the option of answering by other means when personal appearance at the division headquarters is impractical.

1. Transfer Within Division Area

Do not grant requests for transfer of the meeting to another city in the division area. The cost to the public of holding the meeting in another city outweighs any benefit or convenience to the citee.

2. Transfer to Another Division

A request to transfer a meeting to another division may be granted if reasonable grounds are presented, the request is addressed to the office that issued the Section 305 Notice, and the request is received in that office at least three (3) working days prior to the date set in the notice. See 21 CFR 7.84(e). However, before granting the request to transfer the meeting, check with the division involved to make sure it agrees to the meeting.

Once the request is granted, verify the transfer by letter to the citee. Send copies of the letter to the new division with these attachments:

- a. complete file on the samples involved
- b. pertinent Establishment Inspection Reports (EIRs)
- c. a FACTS printout of firm's record, if pertinent to the case

The home division should establish a temporary jacket as a record of the transfer. The transferee division will reschedule the meeting promptly and advise accordingly. This may be done by letter with reference to the original

Section 305 Notice and to the letter approving transfer from the original division. Forward copies to the home division.

After the meeting, send the Record and any exhibits to the home division along with the original files.

Prepare a skeleton sample jacket or electronic file containing a copy of the Record, transcripts (if any), and copies of any collateral correspondence that may have issued on the case.

3. Transfer to Headquarters

Discourage requests by citees, before or during the meeting, to transfer the meeting to headquarters.

If, however, the citee insists that the meeting be held at headquarters, refer the request to the center involved. If granted, the center will inform the citee and home division of the new date set for the meeting. The division should then promptly forward the case file to the center for review and use during the meeting. The center will return the case file with the Record to the home division for disposition of the charges.

5-1-13 Correspondence With Attorneys

Attorneys representing clients who received a Section 305 Notice will often correspond with the division compliance officer regarding the Section 305 Notice. Because the issuance of a Section 305 Notice is confidential and generally not releasable to the public until all potential criminal matters are resolved, division compliance officers are responsible for ensuring that representatives of the citee provide appropriate documentation regarding their authorization. See 21 CFR 7.84(g).

It is not necessary to send citees copies of correspondence from their attorneys. However, when a citee is identified as having received a copy of the citee's attorney's correspondence, and we have responded to that correspondence, you may wish to send the citee a copy of our response.

5-1-14 Drug Advertising Citations

Due to the specialized nature of medical advertising, the [Office of Prescription Drug Promotion](#) (OPDP), Center for Drug Evaluation and Research (CDER) is the primary reviewer of drug advertisements. With few exceptions, OPDP will initiate citations based on violative drug advertisements.

After determining that an advertisement is violative and that citation is warranted, OPDP may initiate a request for samples to support an action. Samples that are obtained are routed to the home division of the responsible firm.

OPDP will prepare citation instructions for issuance by the appropriate division. The instructions will specify whether the meeting is to be held at the division office or at headquarters. In most cases, meetings are held at headquarters.

The division will issue the Section 305 Notice in the normal manner, with a copy to OPDP. Following the meeting, OPDP will make a decision on the disposition of the charges and notify the division of that decision.

5-2 SECTION 305 MEETING

5-2-1 Purpose

This section summarizes the authority and procedures pertaining to the opportunity, under Section 305 of the Act, for a person to present their views before criminal prosecution is recommended to a United States Attorney.

5-2-2 Authority

The Secretary of Health and Human Services delegates broad authority to the Commissioner of Food and Drugs, and, unless specifically prohibited, gives the Commissioner the authority to redelegate this authority. Division Directors, Program Directors, and Directors and Deputy Directors of the centers, are authorized under the redelegations to designate officials to hold hearings under section 305 of the Act.¹ A Compliance Officer has authority to hold Section 305 meetings by such designation.

21 CFR 7.85 provides requirements about the conduct of such meetings.

5-2-3 Preparation

Except in unusual circumstances, the Compliance Officer who holds the meeting is the individual who issued the Section 305 Notice. As there is normally a time lapse between the issuance of the Section 305 Notice and the meeting date, the Compliance Officer should review the case immediately prior to the meeting. The Compliance Officer will need to be completely familiar with the charges, the law and regulations, and fully understand any analytical results and methodology that are part of the case (if necessary, through discussion with the analyst).

The Compliance Officer should assemble any necessary references, such as the Act, regulations, official compendia, etc. The Compliance Officer may also wish to mark or photocopy pertinent information in the files to avoid searches for data during the meeting. Such information may include records relating to samples, EIRs, and FDA

¹ Delegation of authority information is available on the Internet at www.fda.gov/aboutfda/reportsmanualsforms/staffmanualguides.

483s, and documents relating to prior warnings to the firm or individuals in the form of citations, seizures, prosecutions, office interviews, letters, etc. To avoid the need to reread all of the material, it is best to organize this information at the time of the initial review, when preparing the Section 305 Notice.

5-2-4 Respondents' Request For Special Information

Respondents, their attorneys, and others occasionally attempt to obtain detailed information concerning the government's case. Such requests constitute requests for information under the Freedom of Information Act (FOIA). Point out that under the FOIA, they must submit requests in writing to the Director of FDA's Division of FOI. Refer the requester to FDA's [Freedom of Information](#) page and mention that the request must be processed according to law and FDA's procedures. For example, FDA's Associate Commissioner for External Affairs might determine that some or all of the information about FDA's case may be withheld from disclosure under 21 CFR 20.62 (pre-decisional information, attorney work product, etc.) and/or 21 CFR. 20.64 (open investigatory, personal privacy, confidential source, etc.).

NOTE: If a respondent requests a portion of a sample, follow the procedures set forth in 21 CFR 2.10(d) and 2.10(c).

5-2-5 Conducting The 305 Meeting

Respondents are occasionally quite upset due to the receipt of the Section 305 Notice and may tend to be discourteous or argumentative. The 305 meeting is not a debate and nothing can be gained by the Compliance Officer losing objectivity or by the respondent becoming abusive. The Compliance Officer should politely point out that the proceedings are not a trial but rather an opportunity for the respondents to give their side of the story and discuss any mitigating circumstances, corrective actions taken or planned, etc., and that FDA will consider this information when deciding whether or not to forward the case to the Department of Justice for the institution of criminal proceedings.

Do not make an unofficial audio or video recording of the meeting or permit any attendee to make an audio or video recording, without obtaining documentation from OCC that it is permissible. If an official transcript is desired, see 11(c) below.

The Compliance Officer should strive for continuity and relevancy. Some respondents may digress into time-consuming, irrelevant or repetitious discussion unless there is a diplomatic effort to focus upon relevant matters. Listed below is a suggested routine format for achieving orderly progress during the meeting:

1. Identification of Respondents

After the respondents have been introduced and seated, make notes showing the name, address, position, and business connection of each respondent.

The notes are for ready reference during the meeting and useful during the dictation of the record.

2. Failure of Respondent To Appear

Frequently, a cited individual does not attend the meeting. Determine if anyone present purports to represent such respondent and enter any responses into the record.

Designated representative(s) must have a signed written statement of authorization for each respondent for whom he/she has authority to act. If a representative appears without written authorization, the meeting may proceed with respect to any respondent for whom the representative appears, only if the Compliance Officer first verifies by telephone, or other appropriate means, the authenticity of the representative's authority. See 21 CFR 7.84(g).

3. Attendance by Individuals Not Cited

Occasionally, an individual who was not named in the Section 305 Notice will appear and, during the course of the meeting, it will become apparent that the person shares the responsibility for the violation. In such instances, request a short delay and have the legal clerk prepare a supplemental Section 305 Notice including the individual's name, present it to him/her, and proceed with the meeting.

Respondents may arrive at a meeting accompanied by adherents. When this situation occurs, the Compliance Officer should have each person identify themselves by name, state their relationship to the respondent, and, for the record, state that they are attending on behalf of the respondent.

The Compliance Officer should then announce to the group that the meeting is not open to the public, that it concerns only the respondent, and that the only legitimate business other persons have in being there is that they are there at the request of, and on behalf of, the respondent; otherwise, they may not be present.

Afterwards, the Compliance Officer will hear comments from all persons remaining present.

If these actions are not taken, the respondent may claim that FDA deprived him/her of his/her rights to fully respond and explain.

4. More Than One Respondent

Requests for separate meetings should be in writing and should be received at least three (3) working days before the date set in the notice. 21 CFR

7.84(e). However, if there is more than one respondent, advise the respondents in advance that they are entitled to separate meetings if they so wish.

5. Legal Status Sheet, Form FDA 454 ([Exhibit 5-4](#))

Ask for the Legal Status Sheet. The respondent may complete the sheet before or at the meeting. However, you may not demand completion or submittal of the sheet since there is no legal requirement that respondents furnish the sheet.

6. Explain The Purpose Of The Meeting And The Charges

Although the Information Sheet ([Exhibit 5-5](#)), which accompanies the Section 305 Notice and Charge Sheet, contains information concerning the reason for the notice, the Compliance Officer should reiterate the purpose of the notice prior to the discussion of the charges and advise the respondents that:

- a. The meeting is being held in accordance with Section 305 of the Act to give them an opportunity to present any facts they believe are relevant prior to the FDA making its decision whether to recommend prosecution to the Department of Justice; and
- b. The purpose of the meeting is not to resolve conclusively whether violations occurred, and therefore FDA will not present either witnesses or evidence at the meeting.

The Compliance Officer should briefly state the information in the FDA's possession, which indicates that violations of the Act (and other laws, if pertinent) occurred and that the individuals listed in the Section 305 Notice were responsible, either through their actions or their failure to take action. This may be by reference to the pertinent inspections, FDA 483s, warning letters etc., to provide a brief summary of the relevant time and acts. Request that the respondents follow their copies of the Section 305 Notice and Charge Sheet as the Compliance Officer either reads verbatim or summarizes the pertinent information concerning the shipment or receipt of each product and the charges pertaining to it, or the acts that constitute violations.

The Compliance Officer should ask the respondents whether they understand the charges. If the response is negative, answer any questions to ensure that the respondent understands the basis of the allegations. If the respondent indicates that the shipping or receiving dates are incorrect, clarify the discrepancies. If they indicate that they will make no admissions with regard to the shipment or receipt of the products, do not pursue the matter.

7. Miranda Warning

In the past, there were questions regarding whether the Compliance Officer needs to give the "Miranda Warnings" prior to conducting a Section 305 meeting. They are not to be given.

In *Miranda v. Arizona*, the court ruled that when an individual is taken into custody or otherwise deprived of his freedom and subjected to questioning, the person must be notified of his right to remain silent, that anything he says may be used against him, and that he has the right to an attorney. This warning does not apply to Section 305 meetings because a respondent to a Section 305 Notice is not "taken into custody or otherwise deprived of his freedom." In addition, even though not required, FDA notifies the respondents ([Exhibit 5-5](#)) that they are not compelled to answer and that an attorney may represent them. In 1976, in *Beckwith v. United States*, the Supreme Court held that even when the investigation has "focused" on an individual, he is not entitled to Miranda warnings unless he is in custody. In *Oregon v. Mathiason*, decided in January 1977, the Supreme Court held that a meeting at which the individual was free to leave did not require Miranda warnings.

8. Respondents' Statement

After discussing the purpose for the meeting and the charges, the Compliance Officer should invite the respondents to state their views with respect to the alleged violations. Take notes regarding the various points covered by the respondents to ensure that pertinent comments are not inadvertently omitted when the summary is dictated.

Occasionally respondents appearing at a meeting present a prepared written response. In such instances the Compliance Officer should, if practical, read the written response aloud while the respondents follow their copies. The Compliance Officer should ask questions regarding any points that need clarification. In the dictation of the meeting summary, refer to the written response, which will be attached to the record as an exhibit, indicate that it was read aloud in the presence of the respondents, and include in the dictation only information concerning the points discussed for clarification.

Each respondent may present any information bearing upon the issues. This may consist of proposed or revised labeling, letters, laboratory data, sanitation contracts, etc. Identify each exhibit submitted by respondents at the meeting with the related sample number, date received, and the Compliance Officer's initials. Place the identification at the top right hand corner of the exhibit, if it is possible to do so without obscuring any material.

Respondents may request that the Compliance Officer comment on the adequacy of the proposed corrections. Unless headquarters provided specific

instruction, refrain from commenting, and explain that comments may be provided after careful consideration of the submitted material and that it may involve headquarters review. Advise the respondents that the information will be included in the record as an exhibit.

9. Ensure Scope of Respondents' Responsibility

Usually respondents demonstrate their responsibilities while expressing their views with respect to the alleged violations. Normally, they express responsibilities in the form of comments such as "I hired extra men for sanitation" or "I ordered the destruction of the merchandise" etc.

If there are any doubts about the responsibility of any of the respondents, ask questions to ensure that you are not including individuals in a criminal proceeding who lack the authority to detect, prevent or correct violations. For example, ask who had the authority to change pest control firms or consulting laboratories, who hires or discharges employees for sanitation or quality control work, who directs labeling changes, and who expends monies for structural repairs and the purchase of new equipment, etc.

In addition to the responsibility of those who appear, the Compliance Officer may need to make inquiries regarding the responsibilities of an individual listed in the Section 305 Notice who does not appear. This could be particularly important in cases where officials of a company at a location other than the one inspected have been cited, but do not appear at the meeting.

10. Guaranties

Unless a respondent voluntarily includes as part of his presentation a guaranty related to the violations, explore thoroughly the question of whether one exists. Otherwise, the respondent may overlook the fact that he/she had a guaranty, until he/she or his/her attorney eventually presents it as a defense at trial.

If a respondent requests information regarding guaranties so that he/she may obtain them in the future, furnish a copy of 21 CFR 7.13.

If the respondent presents a guaranty at the meeting, do not comment upon its validity. Tell the respondents that the validity of the guarantee will be reviewed after the meeting.

11. Summary

At the conclusion of the meeting, the Compliance Officer will create an accurate summary of the meeting in the presence of the respondents, or at

their option, immediately after their departure. The respondents, for a variety of reasons, may wish to leave the meeting before the summary is completed, and should be afforded that option. In that event, a draft copy of the summary should be forwarded to the respondents, requesting their comments within ten (10) days, and explaining that without benefit of comment the record will stand as drafted. In the event respondents remain, they should be offered an opportunity to provide additional comments or corrections. Inform the respondents that if they disagree with, or wish to clarify, any of the statements they may do so after completion of the summary.

If respondents undertake to have long or irrelevant statements included in the summary, tactfully suggest that they may wish to submit a statement after the meeting, and that the statement will be included as an attachment to the Record. 21 CFR 7.85(g).

a. Required Statements

The Summary should always contain statements to the effect that:

- i. The purpose of the meeting was discussed with the respondents and they understood that it was being held pursuant to Section 305 of the Act;
- ii. The charges were discussed with the respondents and they understood them;
- iii. The respondents indicated that the shipments had been made, or received, as alleged. (If not admitted, or they have reservations, this information should be included);
- iv. Information concerning the statements each respondent made concerning his scope of authority (responsibility) at the firm;
- v. The respondents were asked if they had any corrections or comments to make (followed by their statements or a comment in the record that they had none);
- vi. Copies of the Summary will be forwarded to the respondents; and,
- vii. (In the final section of the record) that the Summary was dictated in the presence of the respondents and when asked if they felt that it accurately and fairly summarized the discussion they indicated that it did (or did not in the following respect). If the respondents elected not to remain for the finalization of the summary, the final section of the draft should reflect that fact.

A copy of the typed summary should be provided to each respondent, and should be accompanied by a cover letter, which states that the firm and individuals have an opportunity to make any additions or corrections in writing within ten (10) days after receipt.

b. Addendum to the Summary

Occasionally after the respondents have left the premises, the Compliance Officer will realize that significant information was omitted from the Summary. In such a case, an addendum to the Summary should be created and mailed to the respondents along with the Summary created in their presence. A cover letter should accompany the Summary and addendum pointing out the inadvertent omission. Request a letter from the respondents within ten (10) days indicating that the additional information had been discussed as recorded in the addendum.

A respondent may request that the meeting be reopened in order to submit new information for the record. Such a request must be timely, in writing, state the nature of the new information, the reason it was not previously available at the time of the original meeting and why the information cannot be submitted in documentary form. If the division concludes that the meeting should be reopened to receive the new information, it may do so.

On occasion, respondents will request an additional meeting at headquarters to discuss the matter further. Such meetings are an extension of the Section 305 meeting and are governed by the procedures of this chapter.

c. Verbatim Transcript of Meeting

The respondent has the right to a verbatim transcript, at his expense. If exercising this right, the respondent must provide the necessary person or equipment to make the transcript. The respondent must submit a copy of such transcription to the division at no cost with an opportunity to make corrections and obtain agreement as to its accuracy. Under these circumstances, the Compliance Officer need dictate only a brief in-house summary after departure of the respondents, explaining the circumstances under which the verbatim transcript was made, who was present, etc. In this case, FDA does not prepare a "Summary".

The Compliance Officer may also order the meeting transcribed at FDA's expense. In this case, a copy of the transcription is provided to each respondent See 21 CFR 7.85(e).

d. Handling of Electronic Recording

If the meeting statement has been recorded, after transcribing, appropriately identify the recording medium with the date of the meeting, the name of firm cited, the sample numbers, and the transcriber's name. File the recording in the lead sample jacket and retain it until the ten

(10) -day period for review by the respondent has expired, then remove and destroy, or erase the recording.

e. Preparation of Summary

i. Method of Preparation

- Prepare the summary as a separate document, using the format in [Exhibit 5-6](#) as an example.
- Include the following statement at the bottom of the copy provided to each respondent: "Copy of this Summary (or transcript) furnished to (respondent)."
- Include the transmittal letter advising respondents of the ten (10) -day period for additions or corrections.

ii. Number of Copies - Make sufficient copies for the following distribution:

- Original + 1 copy for center (hold for submission with case)
- One copy for division case file
- One copy for division establishment file on firm
- One copy for Resident Investigator, if desired
- One copy for division reading file
- One copy for each respondent

12. Multi-Session Meetings

The intent of the regulations is to limit multi-session meetings. Requests for changes in time and place of the meeting must be made in accordance with 21 CFR 7.84(e). New evidence may be submitted in accordance with 21 CFR 7.85(g). Nevertheless, a respondent may appear for a meeting, but claim he/she has further evidence to submit. If the request is reasonable, recess the meeting until a mutually agreeable date. Prepare only one Record covering both meetings.

When the respondent merely requests an opportunity to submit supplemental documentary evidence without further personal appearance, he/she may do as provided in 21 CFR 7.85(g). Mark additional information and/or documentation that is received within ten (10) calendar days after respondents received their copy of the summary or transcription of the meeting as an exhibit and add it to the Record.

13. Response By Mail

Frequently, respondents elect to respond in writing in lieu of making a personal appearance. It is not necessary to acknowledge receipt of a written response. However, it may be desirable to acknowledge a written response

when you also need to clarify some point of misunderstanding or oversight on the part of the respondent.

Hold correspondence to a minimum to avoid "holding a meeting by mail."

5-2-6 Procedures After Meeting

After the meeting (or written response, if any), a decision must be made as to disposition of the charges for each sample involved. The charges are disposed of by one or a combination of the following actions: Permanent Abeyance, Temporary Abeyance, or Prosecution.

1. Reporting Permanent Abeyance And Temporary Abeyance Cases

The division should process cases designated as in abeyance within seven (7) days after the meeting, with notification to the appropriate center, as described below.

a. Permanent Abeyance

Prepare a memorandum to the appropriate center(s) compliance office, headed "PA after CITATION" which provides the reason for placing the case in permanent abeyance (PA) and the planned division follow-up. Attachments should include a copy of the Section 305 Notice endorsed "PA (date and initials)", a copy of the Charge Sheet, a copy of the Summary, and any relevant information. Hold all copies the above documents in the division case file.

Forward a copy of the memorandum to the center(s), an endorsed "PA (date and initials)" copy of the Section 305 Notice, and a copy of the Charge Sheet to the division establishment file.

The Home Division's Compliance Branch should update the Sample Disposition record(s) in FACTS with the appropriate information about the status of the samples.

a. Temporary Abeyance

Prepare assignments for necessary follow-up and forward copies to the appropriate center(s) compliance office. Hold the file in the Division Compliance Branch. A case in TA is not considered closed.

2. Notification Of Non-Prosecution

When the Agency makes a final determination that prosecution will not be recommended for any of the persons named in a notice (i.e., the case is closed), the division that issued the 305 Notice will advise each person in writing of that fact. 21 CFR 7.85(h)(1).

After the Agency decides to decline prosecution, that decision must be communicated to the office (generally a division office) that originated the citation recommendation to ensure that notification of non-prosecution issues in accordance with regulations. The FDA unit to which the recommendation was made, e.g., center, OSPOP/DE, OCC, is responsible for issuance of the declination to the originating office/division. Upon receipt of the declination, and absent a request for reconsideration of the recommendation, the originating office/division should issue the notification of non-prosecution within ten (10) working days.

When it is determined that one of several persons named in a notice will not be included in a recommendation for criminal prosecution, OCC will determine when that person will be notified (21 CFR 7.85(h)(2)). OCC will notify the division of this fact, and the district will issue the letter. The latter procedure applies when the Department of Justice declines to proceed with the entire case (21 CFR 7.85(h)(3)) or declines to proceed against an individual (21 CFR 7.85(h)(4)). See Exhibit 5-7 for the model letter to use.

5-3 ADMINISTRATIVE DETENTION OF FOODS

5-3-1 Purpose

This section provides procedures for the administrative detention of articles of food.

5-3-2 Background

The [Public Health Security and Bioterrorism Preparedness and Response Act of 2002](#) provided FDA with the authority to administratively detain articles of food and made it a prohibited act to move a detained article or to remove or alter any mark or label required by a detention order. In 2011, the [FDA Food Safety Modernization Act](#) amended the criteria for administrative detention to provide that an article of food may be detained when FDA has reason to believe that the article of food is adulterated or misbranded.

Further, administrative detention protects the public by preventing movement of an article of food while FDA institutes appropriate action, which may include seizure under section 304(a) of the Act, injunction under section 302 of the Act, or other administrative actions, such as emergency permit control, mandatory recall, or food facility registration suspension. Administrative detention is implemented to gain immediate control over food when there is reason to believe the food is adulterated or misbranded. Administrative detention is designed for swift and immediate action to ensure that adulterated or misbranded products do not enter commerce or, if they are already in commerce, to stop them from reaching consumers. As such, administrative

detention is a tool that can be used to achieve immediate public health protection. FDA's administrative detention authority applies to articles of food in interstate and intrastate commerce, and food that is outside a United States Department of Agriculture regulated facility. See the [Investigations Operations Manual](#) (IOM), Section 2.7 for further information on detention of food authorities under the FD&C Act and under the [Federal Meat Inspection Act](#), the [Poultry Products Inspection Act](#), or the [Egg Products Inspection Act](#).

Administrative detention of food requires prior approval by the Division Director of the Division where the detained article of food is located or an official senior to the Division Director (hereinafter referred to as the Division Director) (21 CFR 1.391). When ordering an administrative detention, the Division will need to act quickly to protect the public health. However, in situations where FDA has reason to believe the food is adulterated within the meaning of section 402(a)(4) of the FD&C Act (e.g., failure to have and implement a seafood or juice HACCP plan when required, or other critical violations of risk-based preventive control standards), the Division should immediately initiate a preliminary assessment (PA) call to consult with and obtain the concurrence of the appropriate Center compliance office, OCC, and OSPOP/DE prior to issuing an administrative detention order. In most situations of misbranding, the Division should immediately initiate a PA call, as well.

The period of the detention must be for a reasonable period, not to exceed twenty (20) calendar days. However, the period of detention may be extended up to a total of thirty (30) calendar days, if necessary to provide sufficient time to institute a seizure, injunction or other administrative enforcement action.

Any person, who would be entitled to claim the detained article of food, if seized, may appeal the administrative detention and may also request a hearing on the appeal. The appeal and request for a hearing must be submitted to the Division Director that issued the detention order. If requested by the individual entitled to claim the detained article of food and granted by the presiding officer, the hearing must be held within two (2) calendar days after the appeal is filed. The presiding officer's decision to affirm or revoke the detention must be made within five (5) calendar days after the appeal is filed.

Articles of food offered for import into the U.S. can be administratively detained. As with food generally, administrative detention will provide further assurance that the article of food will not be distributed in domestic commerce.

Articles of food offered for import into the U.S. and subject to an administrative detention order under section 304(h) of the FD&C Act should be held in import status pending the outcome of the administrative detention process.

1. References

The regulatory authority for administrative detention of foods appears in section 304(h) of the FD&C Act and in 21 CFR 1.377-1.406, and associated regulatory authority and operations appear in 201(x) of the FD&C Act, 21 CFR Part 16, 21 CFR 10.19, and 21 CFR 10.45. [IOM](#) Subchapter 2.7 Detention Activities also contains instructions for implementing the administrative detention authority.

5-3-3 Issuing and Terminating Detention Orders

Section 304(h) of the Act gives FDA the authority to administratively detain an article of food when it has reason to believe that the food is adulterated or misbranded. An administrative detention order temporarily prevents the potentially adulterated or misbranded food from being distributed in commerce while FDA determines the appropriate legal or other administrative enforcement action (e.g., Emergency Permit Control, food facility registration suspension, mandatory recall order) against the food or persons. Consistent with FDA's mission to protect the public health, FDA will implement a risk-based approach in its use of administrative detention of food. The Division Director should consider the viability of legal action under sections 304(a) or 302 of the FD&C Act or other administrative enforcement action while considering whether to order administrative detention.

Divisions should focus on, but are not limited to, food that poses either of the following food safety risks in establishing priorities for administrative detention:

- Reasonable probability that the use of, or exposure to, an adulterated or misbranded food will cause serious adverse health consequences or death (i.e., Class I recall and reportable food situations)
- Use of, or exposure to, an adulterated or misbranded food product that may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote (i.e., Class II recall situations).

The timing of the detention should be taken into consideration as much as possible without impacting public health to ensure it doesn't impact on the available resources within the agency and other supporting agencies. Communicating the intent to order a detention to parties impacted by the order should be occurring as soon as possible for planning resources necessary to support the detention and subsequent seizure action.

1. Basis for Detention

An FDA employee, or state or local officer or employee commissioned by FDA as an officer of the Department, may order a detention, with appropriate FDA Division Director approval as described in this subsection (5-3-3, item #2, below), as part of his/her function of inspecting, examining, or investigating an article of food when FDA has reason to believe that the

article of food is adulterated or misbranded. See section 304(h) of the [FD&C Act](#) and 21 CFR 1.378.

2. *Approval of Detention Order by the Division Director*

The FDA Division Director in whose Division the article of food is located must approve the detention order. If prior written approval is not feasible, prior oral approval must be obtained and confirmed in writing as soon as possible. See 21 CFR 1.391.

Prior to approving the detention order, the Division Director should verify that there is reason to believe that the article of food is adulterated or misbranded. When FDA has reason to believe an article of food is adulterated or misbranded the Division will need to act quickly to protect the public health. However, in situations where the food is adulterated within the meaning of section 402(a)(4) of the FD&C Act (e.g., failure to have and implement a seafood or juice HACCP plan when required, or other critical violations of risk-based preventive control standards), the Division should immediately initiate a PA call to consult with and obtain the concurrence of the appropriate Center compliance office, OCC, and OSPOP/DE prior to issuing an administrative detention order. Appropriate supporting documentation should be provided before the PA call. A PA call initiates a collaborative process between the Divisions, Programs, OSPOP/DE, appropriate Centers (CFSAN or CVM) and OCC regarding possible Agency enforcement actions. PA calls are identified in Chapter 6 of the [RPM](#) for instructions on seizures and injunctions.

3. *Notification*

If the article of food presents a threat of serious adverse health consequences or death to humans or animals, the Division should also notify FDA's Emergency Operations Center (EOC) at 1-866-300-4347. EOC will coordinate any emergency response activities associated with the food and will notify the appropriate office(s) (OFVM, CFSAN, CVM and ORA offices), either orally or in writing.

4. *Issuing the Detention Order*

The detention order must be issued in writing, in the form of a Detention Order See [Form FDA 2289](#). The ADO form must be issued in its entirety with no pages missing to ensure the firm has adequate notice. The detention order must be signed and dated by the FDA employee (usually an investigator) or commissioned officer who has reason to believe that the article of food is adulterated or misbranded. FDA must issue the detention order to the custodian (i.e., the owner, operator, or agent in charge of the place where the article of food is located). If this individual is not the owner of the article of food, FDA must provide a copy of the detention order to the owner of the article, if the

owner's identity can be readily determined. See 21 CFR 1.392(a). Copies that cannot be hand delivered by an investigator must be sent as soon as possible via overnight delivery, with documentation of receipt of delivery.

If the article of food is detained in a vehicle or other carrier used to transport the detained article, FDA must provide a copy of the detention order to the shipper of record, importer of record (if applicable), the owner and operator of the vehicle or carrier, and the owner of the food, if their identities can be readily determined. Copies that cannot be hand delivered by an investigator must be sent as soon as possible via overnight delivery, with documentation of receipt of delivery.

5. Detention Order and Detention Tags – Forms

Section 2.7.2.3 of the [IOM](#) provides instructions for completing the Detention Order ([Form FDA 2289](#)). Section 2.7.2.4 provides instructions for completing the Detention Tag ([Form FDA 2290](#)), which should be affixed to the article of food subject to the detention order. If necessary, a label other than the Detention Tag may be used to identify the detained article of food, provided the label includes the information required in 21 CFR 1.382.

The detention order frames the issues for any appeal, including any informal hearing that may result from the detention. Therefore, the information on the order concerning the reason for detention is important. Provide clear direction to the plaintiff regarding the mechanism (courier, mail, email, fax) and to whom (DD) should they respond to the ADO.

The detention order must provide a brief, general statement of the reason(s) for the detention. There is no requirement that the order include all of the reasons for believing that the article of food is adulterated or misbranded. As such, the reasons outlined in the detention order do not limit the charges that may be included in a subsequent legal action. If the detention is based on classified information, this information must not be provided in the detention order.

6. Length of Detention

The article of food initially should be detained for twenty (20) calendar days, unless the Division believes that additional time will be required to institute a seizure or injunction. In such cases, the detention should be made for thirty (30) calendar days at the time the order is issued.

If the article of food is detained for twenty (20) days and a seizure, injunction or other administrative action cannot be instituted against the article of food within that time frame, the detention can be extended to a total of thirty (30) days. If a detention is extended from twenty (20) to thirty (30) days, FDA will issue

another detention order and place new tags or labels on the product. The entire detention period may not exceed thirty (30) days.

7. *Movement of a Detained Article of Food*

An article of food offered for import into the U.S. and also subject to a detention order may not be delivered under the conditions of a bond held with U.S. Customs and Border Protection. Notwithstanding section 801(b) of the FD&C Act, any article of food subject to a detention order under section 304(h) of the FD&C Act may not be further delivered to any of its importers, owners, or consignees. However, this does not preclude the movement of the detained articles of food, at FDA's direction, to a secure facility under an appropriate Customs' bond when that bond is required by Customs' law and regulation as described below.

The detained article of food must be held in the location and under the conditions specified by FDA in the detention order. The movement of an article of food in violation of a detention order is a prohibited act under section 301(bb) of the FD&C Act.

Except as noted below, no person may transfer a detained article of food within or from the place where it has been ordered detained, or from the place to which it was removed, until the detention order is terminated by the Division Director or the detention period expires, whichever occurs first.

The Division Director may approve, in writing, a request to modify a detention order to permit movement of a detained article of food for any of the following purposes under 21 CFR 1.381(c):

- i. To destroy the article of food;
- ii. To move the detained article of food to a secure facility under the terms of a detention order (see below);
- iii. To maintain or preserve the integrity or quality of the article of food; or
- iv. For any other purpose that the Division Director believes is appropriate in the case.

The required tags or labels must accompany the detained article of food during and after movement and must remain with the article of food until FDA terminates the detention order or the detention period expires, whichever occurs first, unless otherwise permitted by the Division Director who approves the modification of a detention order. 21 CFR 1.381(f).

The Division Director's letter approving a request to modify a detention order to allow the article of food to be moved should state (21 CFR 1.381(e)):

- i. That the detained article of food remains under detention before, during, and after the transfer; and
- ii. That FDA must supervise the transfer OR
- iii. That FDA has declined to supervise the transfer and that the person who received the detention order, or his representative, must immediately notify the Division Director of the specific location to which the article of food was moved. Such notification must be sent to the Division Director who approved the order by fax, e-mail, or other written form as agreed to by the Division Director.

8. Movement to a Secure Facility at FDA's Request

If, after a food is detained, FDA determines that removal to a secure facility is necessary, the article of food must be removed to a secure facility at the expense of the owner or claimant. Prior to moving the food to a secure facility, the owner or claimant must receive a modification of the detention order (21 CFR 1.380(c)). The investigator who issued the initial detention order or other qualified official will issue a modified detention order, indicating:

- i. The location to where the article of food must be moved;
- ii. That the detained article of food remains under administrative detention before, during, and after movement to a secure facility; and
- i. The conditions of transportation applicable to the detained article of food.

As noted above in this subsection, item # 7, the detained article of food must not be moved to the secure facility until FDA modifies the detention order.

9. Legal Actions against Detained Food, Including Perishable Food

- Legal action - The Division should expedite the preparation of a legal action against the detained food or its owner, to obtain control over the temporarily (i.e., twenty (20) to thirty (30) calendar days) detained food, particularly perishable food. This will most often be through a seizure action.

NOTE: The timelines for perishable foods are significantly shorter than the general timelines provided in [RPM Chapter 6 - Judicial Actions](#).

If FDA initiates a seizure action against a detained perishable food as defined in 21 CFR 1.377, **we are required under 21 CFR 1.383 to send the seizure recommendation to the Department of Justice (DOJ) within four (4) calendar days of issuing the detention order against perishable food,**

unless there are extenuating circumstances. Extenuating circumstances include, but are not limited to, instances where the results of confirmatory testing or other evidentiary development requires more than four (4) calendar days to complete. If the fourth (4th) calendar day is not a working day, OCC should advise DOJ on the last working day before the deadline of its plans to recommend a seizure and will send the seizure as soon as practicable on the first working day after the non-work day.

All recommendations for legal action against a detained article of food must be flagged to indicate the action involves product that is under administrative detention, must include the date the detention expires (and, for perishable food, the deadline for sending the recommendation to DOJ). For procedures on the approval process for seizures and injunctions, refer to the approval process in [RPM Chapter 6 section 6-1-5](#). The Center, Division of Enforcement (DE), and OCC will concurrently review the case initiation memorandum (CIM) and supporting evidence. The Center compliance office, DE, and OCC should expedite their reviews to ensure that the legal action is to be instituted prior to expiration of the detention. A final, signed inspection report is preferred for seizure actions; however, a final narrative inspection report may not be necessary in all situations. For instance, seizure actions have been implemented on the basis of the FDA Form 483 accompanied by supporting evidence (e.g., photographs, official samples, copies of records, affidavits) documenting the violations. Divisions should be mindful that perishable food seizure actions must go to DOJ **within four (4) calendar days** after issuing the detention order. Decisions on suitability of the available evidence will be made on a case-by-case basis among the reviewing coordinators with final determination by OCC. Logistics should be discussed during the PA calls for both the administrative detention and the seizure action.

When the action is a seizure, the Division is responsible for coordination with the U.S. Attorney's office and the U.S. Marshals Service, to facilitate the prompt filing of the complaint and seizure of the food. The Division also is responsible for immediately providing oral or e-mail notice of the accomplishment of the seizure to the appropriate Center compliance office, DE, OCC, and the presiding officer of any in-process appeal of a detention order. CMS should be promptly updated with legal documentation including dates actions take place.

When a seizure or injunction action is filed regarding the article of food involved in the detention order, the process for the appeal of a detention order terminates 21 CFR 1.402(c).

- Administrative Action – Divisions should initiate other administrative actions (i.e., emergency permit control, mandatory recall order, or food facility registration suspension), if appropriate and possible, during the period of detention. An administrative detention is in effect for at least twenty (20)

calendar days and will terminate if the detention period is not extended. If more time is necessary to enable FDA to institute an administrative action, the administrative detention can be extended, if necessary, for up to ten (10) calendar days, for a total of thirty (30) calendar days.

Administrative detention may be used in conjunction with other administrative actions, as necessary to control movement of the food while instituting that enforcement action. Please note that, administrative detention is distinct from, and not a prerequisite for, other administrative actions. Administrative detention does not alter the processes or timeframes established for other administrative actions. However, when multiple regulatory actions relating to the detained food or the implicated firm are initiated, the respective actions should be coordinated to the extent necessary and appropriate to control the movement and disposition of the detained food.

10. Termination or Expiration of Detention Orders

If FDA terminates a detention order, the Division Director will issue a detention termination notice releasing the article of food to any person who received the detention order or that person's representative and will remove, or authorize in writing the removal of, the required tags or labels. See 21 CFR 1.384. While the regulation does not give a time frame for FDA to issue the termination notice, we expect that we will normally issue the termination notice to the person who received the detention order **within one (1) calendar day** of the decision to terminate the detention order.

FDA will terminate a detention order when one of the following occurs:

- i. FDA determines that the food is not adulterated or misbranded;
- ii. FDA approves voluntary destruction and the destruction is accomplished;
- iii. The detention order is appealed with or without an informal hearing and the presiding officer revokes the detention order; or
- iv. A seizure action under section 304(a) of the FD&C Act has been instituted in court and the goods have been seized by the U.S. Marshals pursuant to a court-issued warrant, or an injunction action under section 302 of the FD&C Act has been instituted in court.

The Division Director issues a Detention Termination Notice ([Form FDA 2291](#)) to the person(s) who received the Detention Order, or his representative(s) and, if movement of the article of food occurred pursuant to a modification of the detention order prior to the termination, to the person possessing the article of food. The notice may be issued in person or by mail. If the termination notice is issued by mail, request that the Detention Tags ([Form FDA 2290](#)) be returned. If

the termination notice is issued in person, see Section 2.7.2.5 of the [IOM](#) for instructions.

Once the detention period expires, the detention automatically terminates. In general, the Division Director will acknowledge the expiration and the release of the article of food, using the [Form FDA 2291](#) Detention Termination Notice and the procedures described in this subsection.

11. Responsibilities For Issuing And Terminating Detention Orders

FDA responsibilities for issuing and terminating a detention order are as follows. Note, all components should identify alternate personnel to include in case activities should the assigned individual become unavailable or unable to remain on the case.

- a. Division Responsibilities - The Division is responsible for:
 - i. Notifying the appropriate Center, OSPO/DE, and OCC as soon as it becomes aware of a situation where administrative detention may be appropriate. The Division is to make a determination that it has a reason to believe an article of food is adulterated or misbranded and then respond accordingly to protect the public health. In situations where the food is adulterated within the meaning of section 402(a)(4) of the FD&C Act (e.g., failure to have and implement a seafood or juice HACCP plan when required, or other critical violations of risk-based preventive control standards), the Division should immediately initiate a PA call to consult with and obtain the concurrence of the appropriate Center compliance office, OCC, and OSPOP/DE prior to issuing an administrative detention order. Appropriate supporting documentation should be provided before the PA call.
 - ii. Ensuring scientific and policy support from the appropriate Center, policy support of OSPOP/DE, and legal support of OCC before issuing a detention order based on 402(a)(4) adulteration.
 - iii. Acquiring the approval of the Division Director in accordance with 21 CFR 1.391.
 - iv. Issuing the detention order.
 - v. Notifying the Director of DE, the senior compliance official or designee of the appropriate Center, and OCC by phone or e-mail that the order has been issued and supplying them with a copy of the detention order by the most expeditious means available (loading scanned copy into CMS, fax, express mail, e-mail, etc.) immediately after issuance. Notify the ACRA by Hot Item.
 - vi. Providing a copy of the supporting information, e.g., FDA Form 483, to DE compliance officer, the senior compliance official or designee of the appropriate Center, and OCC.

- vii. Notifying the Director of OSPOP/DE that the Division issued a detention order so that a presiding officer may be designated. At this time, the Division should provide a copy of the detention order and supporting information to the Director of OSPOP/DE so that he may provide a copy to the presiding officer, once one is designated.
 - viii. Once the food is detained, approving and monitoring the movement of detained food.
 - ix. Regularly monitoring the relevant phone, e-mail, and other incoming communications in the issuing Division's office, even over weekends, for receipt of an appeal with or without a hearing from the firm whose food is subject to the detention.
 - x. If the Division receives any communications from the firm whose food is subject to the detention, the Division must immediately notify the relevant parties in OCC and the presiding officer. If a presiding officer has not yet been named, this information should be provided to the Director of OSPOP/DE who will give this information to the presiding officer once one is designated.
 - xi. Pursuing, with appropriate speed, the follow-up legal or administrative enforcement action.
 - xii. When warranted, issuing a Detention Termination Notice ([Form FDA 2291](#)) in a timely manner (usually **within one (1) calendar day**).
- b. Center Responsibilities - The Center is responsible for:
- i. Providing a prompt review and a determination on whether there is reason to believe the article of food is adulterated or misbranded in conjunction with the PA call. The response should be provided concurrently to the Division, OSPOP/DE, and OCC by phone, fax, or e-mail and to EOC and CORE, if involved.
 - ii. Providing written documentation from a senior compliance official of the appropriate Center (i.e., Director, Division of Enforcement, Office of Compliance, CFSAN; or Director, Division of Compliance, Office of Surveillance and Compliance, CVM) of the confirmation on whether there is reason to believe that the article of food is adulterated or misbranded, including documentation necessary to support the subsequent legal or administrative action.
 - iii. Working with the Division Compliance Office to identify evidence needed to support the legal case.
 - iv. Promptly notifying the Division, OSPOP/DE, and OCC of any issues or Center concerns that need to be resolved, prior to providing support for the legal and/or administrative action.

- v. Expeditiously reviewing the subsequent legal or administrative action recommendation and providing expert witnesses and other support, as appropriate, for the legal and/or administrative action.
 - vi. Coordinating the legal and/or administrative action with DE and OCC.
 - vii. Selecting a center expert to serve on the PO's team should a hearing be granted. The center expert should avoid participating in the investigation and action that is the subject of the hearing to remain free of bias or prejudice.
 - viii. If more than one program/center is involved. The centers will decide a lead center. Depending on which center takes the lead, the corresponding ORA program office will take the lead.
- c. OSPOP/DE responsibilities – OSPOP, DE is responsible for:
- i. Providing a prompt review in conjunction with the PA call. The response should be provided concurrently to the Division, appropriate Center and OCC by phone, fax, or e-mail and to EOC and CORE, if involved.
 - ii. Coordinating the legal and/or administrative action with the Division, the appropriate Center and OCC.
 - iii. Arranging the designation of the presiding officer. This should be accomplished as soon as possible in the process once FDA makes a final determination to order a detention of food in consideration for the presiding officer's responsibilities in the potential appeal and informal hearing process and to provide the presiding officer notice of his/her role as soon as possible.
 - iv. Providing a copy of the detention order and supporting information to the designated presiding officer and confirming that copies of any communications between the firm whose food is detained, and the Division are provided to the presiding officer.
 - v. Confirm that copies of all materials provided to the presiding officer are provided to the team of OCC attorneys assigned to provide legal support to the presiding officer.
- d. OCC responsibilities – OCC is responsible for:
- i. Providing legal support and assessment during the PA call.
 - ii. Providing legal support to the personnel in the Division, appropriate Center, and OSPOP/DE involved in the administrative detention order and subsequent legal or administrative action.
 - iii. Assigning OCC attorney(s) to review information on the detention order.

- iv. Appointing a separate team of attorneys to provide legal support to the presiding officer for his/her role in making determinations on the informing hearing process and procedures.

5-3-4 Appeal of a Detention Order

1. *Appeal, With or Without an Informal Hearing*

Any person, who would be entitled to be a claimant for the article of food, if seized under section 304(a) of the Act, may appeal a detention order. The appeal must be submitted in writing, to the Division Director in whose Division the detained article of food is located, at the mailing address, e-mail address, or fax number identified in the detention order. The appeal must include a verified statement identifying the appellant's ownership or proprietary interest in the detained article of food, in accordance with Supplemental Admiralty Rule G of the Federal Rules of Civil Procedure. The appeal must include materials on which the appellant bases its request for an appeal.

If the detention order is appealed, the Agency must provide the appellant with an opportunity to request an informal hearing. The request for a hearing must be in writing, must be included in the request for an appeal, and must conform to the time frames specified below. The presiding officer has the authority to deny a hearing when the appeal raises no genuine and substantial issue of fact and FDA is entitled to judgment as a matter of law. If the presiding officer, in consultation with OCC, determines that a hearing is not justified, the presiding officer will issue written notice of that determination and provide it to all parties explaining the reason for denial. See [Exhibit 5-12](#) for Model letter denying hearing.

If the presiding officer grants the appellant's request for a hearing, then an informal hearing will be held within two (2) calendar days after the date the appeal is filed. The informal hearing will be conducted in accordance with 21 CFR Part 16 except where modified by 21 CFR 1.403.

2. *Time Frames*

The following time frames apply to filing an appeal of a detention order:

- a. Perishable food - The appeal must be filed within two (2) calendar days of receipt of the detention order.
- b. Non-perishable food - The appeal must be filed within ten (10) calendar days of receipt of the detention order. However, if the appeal includes a request for a hearing, the notice of intent to request a hearing must be filed within four (4) calendar days of receipt of the detention order, or the hearing

will not be granted. The notice of intent only relates to a hearing, which is part of an appeal.

The date of filing the appeal will be the date the submission is received by the Division office.

If a hearing is requested, and FDA grants the request as outlined in this chapter, the hearing must be held within two (2) calendar days after the date the appeal is filed. The decision to affirm or revoke the detention must be made within five (5) calendar days after the appeal is filed.

For additional operational guidance regarding administrative detention of food offered for import into the U.S., Divisions should refer to the Administrative Detention of Imported Foods sub-chapter of Chapter 9 of the [RPM](#).

A summary of these timeframes is presented in [Exhibits 5-8](#) and [5-9](#) "Deadlines for Administrative Detention of Food."

3. *Presiding Officer*

The Director, OSPOP/DE, ORA will designate the presiding officer upon the Division Director issuing a detention order. The presiding officer for an appeal must be a Division Director or another FDA official senior to the Division Director (21 CFR 1.404). Generally, a Director outside the Division where the detained article of food is located will serve as the presiding officer. The Director, OSPOP/DE, ORA should contact the potential presiding officer upon the Division Director issuing a detention order. If that individual is not able to serve as the presiding officer, the OSPOP/DE Director is responsible for arranging to have another Director or Agency official designated to serve as the presiding officer. All presiding officers must be designated consistent with current Agency regulations and delegations. OSPOP/DE will create a memorandum reflecting such designation and share it with the relevant parties.

Presiding Officer Responsibilities – The presiding officer is responsible for:

- a. Making a determination on whether to grant or deny an appeal with or without an informal hearing request from the owner of the detained article. Any person who would be entitled to be a claimant for the article of food, if seized under section 304(a) of the FD&C Act, may appeal a detention order and request an informal hearing as specified in 1.402. Procedures for establishing entitlement to be a claimant for purposes of section 304(a) of the FD&C Act are governed by Supplemental Rule C to the "Federal Rules of Civil Procedure."
- b. If an appeal with a hearing is requested, making a determination on whether the owner has raised a genuine and substantial issue of fact justifying a hearing (21 CFR 16.26(a)), and if not, the presiding officer will

issue correspondence to deny the request for an informal hearing on the administrative detention order. If the hearing is denied, the presiding officer must still decide a timely appeal (i.e. whether the administrative detention was proper under FDA's laws and regulations), as discussed below. All correspondence between the firm and the PO must be uploaded to CMS.

- c. If there is an appeal, but no hearing is requested, making a determination, as discussed below, on whether the administrative detention was proper under FDA's laws and regulations.
- d. Making determinations on whether to waive, modify, or suspend any provision under 21 CFR part 16 as authorized by 21 CFR 10.19 and 21 CFR 16.60(h).
- e. Presiding over the informal hearing. A Division Director or an individual senior to the Division Director will be designated for this role. Although the designated official should be informed about an impending administrative detention, the individual should refrain from becoming involved in decisions relating to issuing or monitoring the detention order. After the detention order has been issued, the designee, if serving as presiding officer, must insulate himself/herself from all aspects of the detention except those relating to his/her responsibilities as a presiding officer for the hearing, if requested as part of an appeal.
- f. Issuing appeal decisions in accordance with 21 CFR 1.405 as follows:
 - i. If there is an appeal with or without a request for a hearing, the presiding officer must issue a written report that includes a proposed decision confirming or revoking the detention by noon on the fifth (5th) calendar day after the appeal is filed; after providing four (4) hours in which the hearing participants could submit comments on the presiding officer's report under 21 CFR 1.403(h), the presiding officer must issue a final decision. The final decision must be issued by the end of the fifth (5th) calendar day after the appeal was filed. If FDA either fails to provide the appellant with an opportunity to request an informal hearing or fails to confirm or terminate the detention order within the five (5)-calendar day period, the detention order is deemed terminated.
 - ii. Even if the presiding officer denies the hearing request, the presiding officer must issue a decision on the appeal confirming or revoking the detention within five (5) calendar days after the date the appeal is filed. If the presiding officer fails to confirm or terminate the detention order during such five (5)-calendar day period, the detention order is deemed terminated. The PO's hearing report must be uploaded to CMS.
 - iii. If the owner of the detained article appeals the detention order and provides notice that he intends to request an informal hearing but does not file a timely request for an informal hearing, the presiding officer must issue a decision on the appeal confirming or revoking the

detention within five (5) calendar days after the date the appeal is filed. If the presiding officer fails to confirm or terminate the detention order during such five (5)-calendar day period, the detention order is deemed terminated.

In addition, 21 CFR 1.405 provides the following:

- a. If the presiding officer confirms a detention order, the article of food remains detained until we terminate the detention under 21 CFR 1.384 or the detention period expires under 21 CFR 1.379, whichever occurs first.
- b. If the presiding officer terminates a detention order, or the detention period expires, FDA must terminate the detention order as specified under 21 CFR 1.384.
- c. Confirmation of a detention order by the presiding officer is considered a final Agency action for purposes of 5 U.S.C. 702.
- d. See subsection 5-3-4 item #5(b) below for further responsibilities of the presiding officer.

4. *Communications between Parties to the Hearing and the Presiding Officer*

Parties to the hearing should avoid any off-the-record communication with the presiding officer. If any communication of this type occurs, it must be reduced to writing and made part of the administrative record of the hearing. The other party must be provided with a copy of the letter or memorandum of the communication and must be provided an opportunity to respond. See 21 CFR 16.44(b). Presiding Officers should consider placing delivery and read receipts on the email communications between the PO and the plaintiff.

The person who writes a letter or memorandum of the meeting between a participant in the hearing and the presiding officer must send a copy to all of the participants. See 21 CFR 16.44(c).

5. *Appeal Processing Responsibilities*

Division Responsibilities

- a. Preparation for an appeal should begin when the Division decides to detain an article of food. When the Division receives an appeal, the Division Director:
 - i. Dates and time stamp the appeal and notifies the appellant of receipt of the appeal in writing.
 - ii. Notifies, orally or by email, the Center, DE, OCC, and the Presiding Officer of the appeal immediately and forwards a copy of the appeal to them as soon as possible by fax or electronically.

Requests assistance of the Center, OSPOP/DE and OCC as needed. OCC will designate attorneys to advise the Division/Center and attorneys to advise the Presiding Officer.

- b. When the appeal includes a request for a hearing, the Division Director:
 - i. Prepares a general summary of the information that will be presented by FDA at the hearing in support of the detention order (“general summary”) and a comprehensive statement of the basis for the detention order (“comprehensive statement”), in accordance with 21 CFR 16.24(f).
 - ii. EXCEPTION: When a detention order is based on classified information, 21 CFR 16.24(f) does not apply, and the Division should consult with OCC to determine whether the presiding officer can give the appellant notice of the general nature of the information consistently with safeguarding the information and its source (21 CFR 1.403(e) and 1.406).
 - iii. The detention order ([Form FDA 2289](#)) may serve as the comprehensive statement only if the reason for detention is described in sufficient detail. See [Exhibit 5-10](#) for an example of a model letter for reasonable notice of matters to be considered at hearing. The model letter includes a general summary and a comprehensive statement.
- c. If the presiding officer grants the appellant’s request for a hearing, the Division Director forwards the general summary and the comprehensive statement to the appellant (excluding classified information), the presiding officer, and to the Center, OSPOP/DE and OCC representatives to the hearing. The Division office sends the documents immediately to all parties so that they arrive as soon as possible, but at least one (1) day prior to the hearing. However, if the detention order is based on classified information, the Division Director must not provide such information to the appellant. The Division Director must consult with OCC before issuing a detention order based on classified information.
- d. At least one (1) day before the hearing, provides the appellant, presiding officer, Center, OSPOP/DE, and OCC representatives to the hearing, written notice of, or copies of, if they could not reasonably be expected to obtain copies, any published articles or written information to be presented at or relied on at the hearing. See 21 CFR 16.24(g).
- e. When the appeal does not include a request for a hearing, the Division Director:
 - i. Forwards all the information that supports the detention to the presiding officer and the OCC attorneys representing the presiding officer. This includes FDA’s referenced general summary and

comprehensive statement and the information provided by the appellant on which the appellant bases its request for an appeal.

- ii. The information should arrive no later than the third (3rd) calendar day after the appeal is filed, so that the information can be reviewed, and a decision rendered within five (5) calendar days after the date the appeal is filed.

Presiding Officer Responsibilities

- a. When notified of an appeal, with or without a request for a hearing, the presiding officer:
 - i. Determines whether the appeal is not valid because the appeal has not been submitted within the established time frame or if the appeal does not demonstrate ownership or proprietary interest as required in 21 CFR 1.402(b). The presiding officer will notify the appellant if he/she determines that the appeal is not valid.
 - ii. At the discretion of the presiding officer, if sufficient time is available, the presiding officer may notify the appellant of the requirement to provide written demonstration of ownership or proprietary interest and allow the appellant to re-submit the appeal with the required information. The submission of the appeal must be accomplished within the applicable timeframe. The OCC attorneys representing the presiding officer should be consulted on this issue.
- b. When notified of an appeal, and a hearing is requested, the presiding officer:
 - i. Determines whether a hearing should be granted. A hearing will only be granted if the material submitted by the appellant raises a genuine and substantial issue of fact. See [21 CFR 16.26\(a\)](#). A hearing will not be granted on matters of law or policy.
 - ii. If the appeal does not clearly specify that a hearing is requested, a hearing will not be granted.
 - iii. If the presiding officer denies a hearing, the presiding officer notifies the appellant of the denial of a hearing in writing. See [Exhibit 12](#) for an example of a model letter denying the appellant's request for a hearing.
 - iv. If the presiding officer grants a hearing, the presiding officer orally contacts the parties as soon as possible and sets a date for a hearing to be held within two (2) calendar days after the date the appeal is filed. The hearing normally takes place at the Division office where the goods are located. If practical, a hearing may be conducted via teleconference or video conference.

- v. Provides all parties with written notification of the time, date, and location of the hearing, and secures technology (e.g., phone conference lines) for the hearing.
- vi. Provides the appellant with oral and written notification. See form letter as [Exhibit 5-11](#):
 - 1. of those portions of 21 CFR part 16 that are excluded or modified under 21 CFR 1.403 and waived or modified for hearings on appeal of administrative detentions (see "Informal Hearing on Appeal of a Detention Order." See subsection [5-3-5](#) item # 2);
 - 2. that the informal hearing is not a public hearing per 21 CFR 16.60(a), in order to protect investigatory records compiled for law enforcement purposes that are not available for public disclosure under 21 CFR 20.64, or trade secrets and confidential commercial information that is not available for public disclosure under 21 CFR 20.61;
 - 3. that the appellant should provide, at the hearing, a brief summary of any lengthy documents for presentation at the hearing (e.g., volumes of computer printouts);
 - 4. that the appellant should provide the Division Director written notice of, or a copy of (if the Division Director could not reasonably be expected to obtain a copy), any published articles or written information for presentation at or relied on at the hearing, at least one (1) day before the hearing, if feasible, as required by 21 CFR 16.24(g); and
 - 5. Of the requirements under 21 CFR 16.44(c). See Section [5-3-4](#), item # 4 "Communications between Parties to the Hearing and the Presiding Officer."
- vii. When notified of an appeal, and *no hearing is requested*, the presiding officer orally notifies the:
 - 1. parties that they should submit information supporting their positions as soon as possible, and no later than the third (3rd) calendar day after the appeal is filed, so that the information can be reviewed, and a decision issued within five (5) calendar days after the date the appeal is filed.
 - 2. Appellant of the requirement under 21 CFR 16.44(c). See Section [5-3-4](#), item # 4 "Communications between Parties to the Hearing and the Presiding Officer," above.

OCC Responsibilities; OCC is responsible for:

- a. Assigning OCC attorneys to represent the Division and Center during any appeal and hearing;

- b. Assigning different OCC attorneys to represent the Presiding Officer during any appeal and hearing;
- c. Expediting review of information provided by the Division; and,
- d. Working with the division to prepare for any hearing and appeal.

Center Responsibilities; The Center is responsible for providing:

- a. scientific, technical, and policy support to the Division; and,
- b. representatives to the hearing, if necessary.

DE Responsibilities; DE is responsible for confirming that all:

- a. Agency and OCC components are notified of and prepared for a hearing; and,
- b. documentation from the Division relating to the detention and hearing is provided to the Center compliance office and OCC.

6. *Termination of an Appeal*

The appeal process terminates if FDA institutes a seizure or injunction action regarding the article of food involved in the detention order. 21 CFR 1.402(c). A seizure or injunction action is instituted when such action is filed in court.

If a seizure or injunction action is filed in court, the Division Director will notify the presiding officer. The presiding officer will issue a letter to the appellant that the appeal has been terminated because a seizure or injunction action has been filed in court. See [Exhibit 5-24](#) for an example of a model letter notifying the appellant that the appeal has been terminated.

5-3-5 Informal Hearing on Appeal of a Detention Order

1. *Background*

Section 304(h)(4) of the FD&C Act requires FDA to provide the appellant with an opportunity for an appeal including an "informal hearing." Section 201(x) of the FD&C Act defines this term. 21 CFR 1.403 requires that FDA conduct the hearing in accordance with 21 CFR part 16, Regulatory Hearing before the Food and Drug Administration, with the waivers and modifications noted below in 5-3-5 item #2. 21 CFR 16.5(b) advises that Part 16 procedures apply to the extent that they are supplementary to, and not in conflict with, the other procedures specified in a regulation that provides a person with an opportunity for a hearing. 21 CFR 10.19 and 21 CFR 16.60(h) give the presiding officer the authority to suspend, modify, or waive provisions under part 16. A request for a hearing may be denied, in whole or in part, if the presiding officer determines that no genuine and

substantial issue of fact has been raised by the material submitted. The regulations at 21 CFR 16.26(a)). 21 CFR 10.19 and 21 CFR 16.60(h) give the presiding officer the authority to suspend, modify, or waive provisions under Part 16.

2. *Waivers and Modifications to 21 CFR Part 16*

If FDA grants a request for an informal hearing on an appeal of a detention order, FDA must conduct the hearing in accordance with 21 CFR Part 16, except that:

- a. The detention order under 21 CFR 1.393, rather than the notice under 21 CFR 16.22(a), provides notice of opportunity for the hearing and is part of the administrative record of the regulatory hearing under 21 CFR 16.80(a);
- b. A request for a hearing must be addressed to the FDA Division Director in whose Division the article of food involved is located;
- c. The provision in 21 CFR 16.22(b), providing that a person not be given less than three (3) working days after receipt of notice to request a hearing, does not apply;
- d. The provision in 21 CFR 16.24(e), stating that a hearing may not be required to be held at a time less than two (2) working days after receipt of the request for a hearing, does not apply;
- e. 21 CFR 1.406, rather than 21 CFR 16.24(f), describes the statement that will be provided to an appellant where a detention order is based on classified information;
- f. 21 CFR 1.404, rather than 21 CFR 16.42(a), describes the FDA employees, e.g., Division Directors or other official's senior to a Division Director, who preside at hearings;
- g. The presiding officer may require that the hearing be completed within one (1) calendar day, as appropriate;
- h. 21 CFR 16.60(e) and (f) do not apply to the hearing. The presiding officer must prepare a written report of the hearing. All written material presented at the hearing will be attached to the report. The presiding officer must include as part of the report of the hearing a finding on the credibility of witnesses (other than expert witnesses) whenever credibility is a material issue, and must include a proposed decision, with a statement of reasons. The hearing participant may review and comment on the presiding officer's report within 4 hours of issuance of the report. The presiding officer will then issue the final Agency decision;

- i. 21 CFR 16.80(a)(4) does not apply to the hearing. The presiding officer's report of the hearing and any comments on the report by the hearing participant under 21 CFR 1.403(h) are part of the administrative record;
- j. No party shall have the right under 21 CFR 16.119 to petition the Commissioner of Food and Drugs for reconsideration or a stay of the presiding officer's final Agency decision; and,
- k. If FDA grants a request for an informal hearing on an appeal of a detention order, the hearing must be conducted as a regulatory hearing pursuant to regulation in accordance with 21 CFR Part 16, except that 21 CFR 16.95(b) does not apply to the hearing. With respect to the regulatory hearing on an appeal of a detention order, the administrative record of the hearing specified in 21 CFR 16.80(a)(1), (a)(2), (a)(3), and (a)(5), and 1.403(i) constitutes the exclusive record for the presiding officer's final decision on an administrative detention. For purposes of judicial review under 21 CFR 10.45, the record of the administrative proceeding consists of the record of the hearing and the presiding officer's final decision.

In addition, 21 CFR 16.60(b), which provides that all parties may confront and conduct reasonable cross-examination of any person (except for the presiding officer and counsel for the parties) who makes any statement on the matter at the hearing, is modified. Reasonable questions will be allowed instead. Reference Congressional intent: House of Representatives Report no. 94-853. Also, see 21 CFR 16.5 and 16.60(h).

3. *Conducting the Hearing*

The presiding officer should inform the parties of the applicable modifications to 21 CFR Part 16 "Regulatory Hearing Before the Food and Drug Administration," as provided for in the administrative detention regulation (21 CFR 1.403). The presiding officer will explain that the purpose of the hearing is to determine whether FDA, at the time of the detention and as charged in the detention order, had reason to believe that the article of food is adulterated or misbranded. The FDA representative(s) must explain the basis for the detention and answer reasonable questions from the appellant.

The appellant may present relevant information to support his/her position that the article should not be subject to detention. Both parties may conduct reasonable questioning of the other (section 201(x) (4) of the FD&C Act; 21 CFR 16.60(b), as modified in Section 5-3-5, item #2).

The presiding officer will ensure that the material presented, and the questions asked are relevant to the issue of the hearing.

The presiding officer may, once the hearing commences, issue a summary decision on any issue in the hearing if the presiding officer determines from the material submitted in connection with the hearing, or from matters officially noticed, that there is no genuine and substantial issue of fact respecting that issue. 21 CFR 16.26(b).

The appellant may request that a transcript of the hearing be taken. However, the appellant must pay the cost of the transcript and furnish the presiding officer a copy for the record. FDA also may request a transcript of the hearing, in which case the costs are borne by the government.

The appellant may obtain a copy of the government transcript by submitting a request under the Freedom of Information Act (FOIA) (5 U.S.C. 552 et seq.). 21 CFR Part 20 applies to the release of the transcript.

The presiding officer should notify the parties that his/her decision will not await transcription or correction of the transcripts so ordered.

4. *Responsibilities For The Hearing:*

a. Center Responsibilities -

The Center will provide documents, witnesses, or office representatives for the hearing if requested by the Division or the OCC attorney counseling the Division.

b. OCC Responsibilities -

OCC will provide counsel for the Division, the Center and/or the presiding officer, as appropriate, for the hearing.

c. Division and Presiding Officer Responsibilities -

Section 5-3-5, item #3 "Conducting the Hearing" includes responsibilities of the Division and the presiding officer.

5-3-6 Issuing the Decision on an Appeal

1. *Decision on an Appeal after a Hearing*

The presiding officer must issue a written report of the hearing that includes a proposed decision confirming or revoking the detention by noon on the fifth (5th) calendar day after the appeal is filed. The hearing participants then have four (4) hours to review and comment on the report (21 CFR 1.405(a) and 1.403(h)). If classified information was used to support the detention, then any

confirmation of the detention must state whether it is based in whole or in part on that classified information but will not reveal the classified information.

The presiding officer must issue a final decision within five (5) calendar days after the appeal is filed. If the presiding officer fails to confirm or terminate the detention order within this five (5) calendar day period, the detention order is deemed terminated. 21 CFR 1.405(a). The appellant should be orally notified of the termination immediately. A copy of the termination notice should then promptly be mailed to the appellant via overnight delivery with delivery confirmation. See [Exhibit 13A](#) for Model Letter Final Decision on Appeal Detention Order Confirmation and [Exhibit 13B](#) for Model Letter Final Decision on Appeal Detention Order Revocation.

2. *Decision on an Appeal When Appellant Does Not Request a Hearing*

If there is an appeal of the detention order, but the appellant does not request a hearing, the presiding officer must issue a decision on the appeal confirming or revoking the detention within five (5) calendar days after the date the appeal was filed. If classified information was used to support the detention, then any confirmation of the detention must state whether it is based in whole or in part on that classified information but will not reveal the classified information.

If the presiding officer fails to confirm or terminate the detention order during this five (5) calendar day period, the detention order is deemed terminated. 21 CFR 1.405(b). The appellant should be orally notified of the termination immediately. A copy of the termination notice should then promptly be mailed to the appellant via overnight delivery with delivery confirmation. See [Exhibit 13A](#) for Model Letter Final Decision on Appeal Detention Order Confirmation and [Exhibit 13B](#) for Model Letter Final Decision on Appeal Detention Order Revocation.

3. *Decision on an Appeal When Appellant's Request for a Hearing is Denied*

If the presiding officer denies the appellant's request for a hearing, the presiding officer must issue a decision on the appeal confirming or revoking the detention within five (5) calendar days after the date the appeal was filed. If classified information was used to support the detention, then any confirmation of the detention must state whether it is based in whole or in part on that classified information but will not reveal the classified information.

If the presiding officer fails to confirm or terminate the detention order during the five (5) calendar day period, the detention order is deemed terminated. 21 CFR 1.405(c). The appellant should be orally notified of the termination immediately. A copy of the termination notice should then promptly be mailed to the appellant via overnight delivery with delivery confirmation. See [Exhibit 13A](#) for Model Letter Final Decision on Appeal Detention Order Confirmation and [Exhibit 13B](#) for Model Letter Final Decision on Appeal Detention Order Revocation.

5-3-7 Administrative Record and FOIA Requests

1. Administrative Record of Appeal with Hearing

The presiding officer should prepare the administrative record of the hearing, which consists of the following (21 CFR 1.403(k)):

- i. The notice of opportunity for hearing and the response (e.g., the detention order that indicates the opportunity for a hearing and the appeal with a request for hearing or appeal without a request for a hearing);
- ii. All written information and views submitted to the presiding officer in conjunction with the appeal with a hearing;
- iii. Any transcript of the hearing;
- iv. All letters and memoranda of meetings and communications between participants and the presiding officer referred to in 21 CFR 16.44(c);
- v. The presiding officer's written report of the hearing which includes the decision confirming or revoking the detention, with a statement of the reasons. The report must include a finding on credibility of witnesses (other than expert witnesses) whenever credibility is a material issue; and
- vi. The hearing participant's comments on the report, including comments on the proposed decision. 21 CFR 1.403(h) and (i).

The Division should file the original Administrative Record of the Hearing with the firm's official file at the Division office after completion of the report and send a copy to the appropriate Centers' compliance office, DE, OCC and to the presiding officer. The Division compliance branch should also upload a copy into CMS.

2. FOIA Requests

21 CFR Part 20 applies to all requests for the administrative record and other documents relating to administrative detentions.

5-4 DETENTION OF FOODS – OTHER STATUTORY AUTHORITY

5-4-1 Purpose

This section contains the procedures for exercising FDA's authority to detain meat, poultry and egg products as delegated to FDA under the provisions of the [Federal Meat Inspection Act](#) (FMIA), the [Poultry Products Inspection Act](#) (PPIA), or the [Egg Products Inspection Act](#) (EPIA).

For the purpose of this section only, the following definitions apply:

1. Meat And Meat Products

The carcasses of cattle, sheep, swine, goats, horses, other equines, parts of such carcasses, and products made wholly or in part from such carcasses.

2. Poultry And Poultry Products –

The carcasses of domesticated birds, parts of such carcasses, and products made wholly or in part from such carcasses.

EXCEPTION - In the case of both meat and poultry products, certain products are exempted from the above referenced Acts by USDA because they contain a relatively small portion of meat or poultry or historically have not been considered meat or poultry products.

3. Eggs

The shell eggs of the domesticated chicken, turkey, duck, goose or guinea.

4. Egg Products

Dried, frozen or liquid eggs, with or without added ingredients, except products exempted by USDA because they contain a relatively small proportion of eggs or historically have not been considered egg products.

5-4-2 Authority

The [Federal Meat Inspection Act](#), (MIA) as amended by Public Law (P.L.) 90-201; and Sections 19 and 20(b) of the [Poultry Products Inspection Act](#) (PPIA) as amended by P.L. 90-492; and Sections 19 and 23(d) of the [EPIA](#) provide certain detention powers.

The detention authority under the MIA and the PPIA provide that FDA representatives may detain articles subject to these acts if they are outside a USDA inspected plant and there is reason to believe that the products are adulterated or misbranded under the Act.

The detention authority under the EPIA provides that FDA representatives may detain products subject to that act if the products are found outside a USDA inspected plant and there is reason to believe that the products are in violation of the EPIA.

NOTE: Interstate Commerce is not a requirement for FDA jurisdiction over eggs and egg products because authority is based on violation of the Egg Products Inspection Act rather than the FFDCA.

The detention process is another regulatory tool to achieve compliance with the Act. It should be considered when such products are encountered during regular division operations, on assignment, or as a follow-up to complaints. This procedure becomes

most appropriate when no immediate arrangements can be made for local or state authority to take control of the product, and/or it appears that the product will not be held voluntarily.

5-4-3 Criteria For Effecting And Terminating Detentions

Use the following procedures in detention situations:

1. Exercise Of Detention Authority

a. Meat and Poultry Products

Detentions may be made when all of the following criteria are met:

- i. The article meets the jurisdictional requirement of interstate commerce in Section 304 of the Act and the article is in commercial channels;
- ii. The article is located in an establishment that does not have USDA meat or poultry inspection service;
- iii. The article is intended for human food or could readily be diverted into use for human food;
- iv. The article is adulterated or significantly misbranded under the Act.
NOTE: Detentions based solely on misbranding or on adulteration involving Section 402(b) of the Act must be cleared by the Center for Food Safety and Applied Nutrition (CFSAN) before detention; and,
- v. The respective USDA, Food Safety Inspection Service Division Office has been notified and the action is coordinated with that office.

b. Eggs and Egg Products

Detentions may be made when all of the following criteria are met:

- i. The article is in commercial channels.
NOTE: Interstate commerce is not a requirement for jurisdiction under the EPIA;
- ii. The article is located in an establishment that does not have USDA egg products inspection service;
- iii. The article is intended for human food or could readily be diverted into use for human food; and,
- iv. There is reason to believe the article is in violation of the EPIA.

2. Termination Of A Detention Action

Detention should be continued until one of the following criteria is met:

- a. State, county or municipal authorities have exercised jurisdiction and control of the article; or, in the case of meat or poultry, USDA has assumed control;
- b. It has been determined that there is no significant violation of the FFDCA, or the EPIA, and the USDA has been notified that we intend to terminate the detention action;
- c. The detained article has been denatured, destroyed or reconditioned under appropriate supervision;
- d. The detention period of twenty (20) consecutive days, counting the day the detention was executed as the first day, has expired; or,
- e. Seizure has been accomplished.

NOTE: Forward seizure recommendation as soon as possible after detention is accomplished, because the detention cannot be reinstated after the twenty (20) day detention period expires.

3. Procedures

The [IOM](#), Chapter 2, subchapter 2.7- Detention Activities contains specific inspectional instructions including initial reporting requirements, detention initiation, reconditioning, and termination.

5-5 ADMINISTRATIVE DETENTION OF DRUGS

5-5-1 Purpose

This section provides procedures and defines responsibilities for the Administrative Detention of drugs.

5-5-2 Background

The Food and Drug Administration Safety and Innovation Act (FDASIA) provided FDA with the authority to administratively detain drugs intended for human or animal use. It did so by amending section 304(g) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) to add drugs to the list of products subject to administrative detention. As a result, FDA has authority to detain drugs, devices, and tobacco products under section 304(g) of the FD&C Act as amended by FDASIA. Section 301(r) of the FD&C Act was also later amended to make it a prohibited act to move a detained drug in violation of a detention order under section 304(g). This authority is distinct from the authority to administratively detain

foods under section 304(h) of the FD&C Act (see Sec. 5-3 of the RPM for procedures related to the administrative detention of foods).

The intent of administrative detention is to protect the public health by preventing the movement, distribution, and use of products believed to be adulterated or misbranded until FDA has time to consider what regulatory action it should pursue concerning such products, including initiating enforcement action, if appropriate. FDA may conduct a seizure under section 304(a) of the FD&C Act, an injunction under section 302 of the FD&C Act or take other actions. Administrative detention is designed to permit swift and immediate action to ensure that adulterated or misbranded drugs do not enter commerce or, if they are already in commerce, to stop them from reaching consumers. FDA's administrative detention authority may only be exercised during an inspection of a facility or vehicle conducted under section 704 of the FD&C Act.

A detention order, before issuance, must be approved by the FDA Division Director in whose division the drugs are located. If prior written approval is not feasible, prior oral approval must be obtained and confirmed by written memorandum within FDA as soon as possible.

The detention period should be for 20 calendar days after the detention order is issued, unless the Division Director determines that a greater period is needed in order to seize the product, institute an injunction proceeding, or evaluate the need for legal action. In that case, he or she may extend the period by up to 10 calendar days.

Any person who would be entitled to claim the detained drug, may appeal the administrative detention and may also request an informal hearing on the appeal. The presiding officer's decision to affirm or revoke the detention order must occur within five (5) working days after receipt of the appeal if there is no request for an informal hearing or if appellant requests that the informal hearing be held within 5 working days from the appeal's filing date. If the appellant requests that a regulatory hearing be held at a date later than 5 working days after the appeal is filed, but not later than 20 calendar days after receipt of a detention order, the presiding officer must hold the hearing at a date agreed upon by FDA and the appellant. The presiding officer must decide whether to affirm or revoke the detention within 5 working days after the conclusion of the hearing.

1. *References*

The regulatory authority for administrative detention of drugs, relevant prohibited acts, and associated operations appears in sections 304(g), 301(r), and 201(x) of the FD&C Act, and in 21 CFR 1.980, 21 CFR part 16, 21 CFR 10.19, and 21 CFR 10.45. Investigations Operations Manual (IOM) Subchapter 2.7 Detention Activities also contains instructions for

implementing the administrative detention authority. See IOM 2.7.2.2 for high-level instructions for administrative detention of drugs.

5-5-3 Issuing and Terminating Detention Orders

Section 304(g) of the FD&C Act gives FDA the authority to administratively detain a drug when an investigator has reason to believe that the drug is adulterated or misbranded. An administrative detention order temporarily prevents the drug from being distributed in commerce while FDA determines whether to institute a seizure, injunction action, or other actions.

This enforcement tool should be considered when there is likelihood that the drug will be moved or distributed before a seizure can be accomplished. The Division Director should determine the applicability of their counterpart state's authorities when reasonable. The Division Director should contact the appropriate state officials to inquire if the state is willing to conduct a state embargo. Even if the state has embargo authority and is willing to use such authority, the Division Director should still consult with the Center Compliance Official, OSPOP/DE and OCC to determine whether the state embargo or FDA administrative detention is the appropriate enforcement action. The Division Director should contemplate leveraging public health resources including requesting state assistance in making the decision on whether an ADO should be placed on an adulterated or misbranded drug product.

If the Division Director concludes that the person in possession of the drug will voluntarily hold the drug and will provide assurances that integrity and security will be maintained over the drug on hand and/or provides adequate assurance they are willing and able to correct all violations prior to shipment, there is no need to detain the drug.

1. Basis for Detention

An investigator or other authorized FDA representative who is performing an inspection may order a drug detention (with appropriate Division Director approval) during an inspection of a facility or vehicle when he or she has reason to believe that the drug is adulterated or misbranded (section 304(g) of the FD&C Act and 21 CFR 1.980).

2. Approval of Detention Order by the Division Director

The Division Director in the geographic Division where the drug is located, must approve the detention order in writing. If prior written approval is not feasible, prior oral approval must be obtained and confirmed in writing as soon as possible (21 CFR 1.980(e)).

The Division Director should verify that there is reason to believe that the

drug is adulterated or misbranded. When there is reason to believe a drug is adulterated or misbranded, the Division Director may need to act quickly to protect the public health.

Prior to approving the detention order, the Division Director is expected to contact the Director of Compliance or their designee in the appropriate Center to ensure that the Center supports administrative detention. There should be sufficient reason to believe based on the observations made during the inspection that a product is adulterated or misbranded. Additionally, the Division Director should verify that the authorized FDA representative with reason to believe the drug is adulterated or misbranded has initiated a valid inspection under FDCA 704 (i.e. displayed credentials and issued a written notice of inspection to the most responsible person). (21 CFR 1.980(b)). Administrative detentions may not be ordered outside of an inspection (FDCA § 3014(g)(1)).

If the Division Director attempts, but is unable to make immediate contact with the senior compliance official and the Division Director has reason to believe a delay in issuance of an ADO covering finished product might result in serious injury or illness, the Division Director may immediately approve a detention order if one of the following exigent circumstances exist:

- i. There is evidence of product tampering or intentional adulteration;
- ii. A state or federal official has declared an emergency and the product appears to be adulterated or misbranded in response to that emergency after an FDA Notice of inspection has been issued and the FDA representative confirms the adulteration or misbranding appearance.
- iii. The firm is actively distributing finished product which is already subject to a center-approved Class I recall;
- iv. There is visible, gross microbiological contamination in a sterile product;
- v. The firm is distributing a finished sterile product with positive sterility test results or contains endotoxins that exceed specifications, and the firm does not claim the results are invalid;
- vi. The firm is distributing a finished non-sterile product with positive test results for a known pathogen, and the firm does not claim the results are invalid;

If the Division Director approves a Detention Order under these circumstances, the Director must immediately notify the Center and attempt to gain center concurrence.

If the Division Director is unable to obtain center concurrence within 24 hours of establishing contact with the Center, the Division Director must immediately terminate the order unless the center requests more time to evaluate

Detention Order and Detention Tags – Forms

Section 2.7.2.3 of the IOM provides instructions for completing the Detention Order (Form FDA 2289). Section 2.7.2.4 provides instructions for completing the Detention Tag (Form FDA 2290), which should be affixed to the drug that is subject to the detention order.

Because the detention order frames the issues for an appeal and informal hearing, if any, the violation must be identified as below. Although the agency may initiate judicial action based on any appropriate violation (whether or not listed as a basis for detention), FDA may not introduce additional basis for detention during an appeal or informal hearing if they were not included in the written order. The detention order must include the information required by 21 CFR 1.980(d)(3):

- (1) a statement that the drugs identified in the order are detained for the period shown
- (2) a brief, general statement of the reason(s) for the detention;
- (3) the location of the drugs;
- (4) a statement that these drugs are not to be used, moved, altered, or tampered with in any manner during that period, except as otherwise permitted in this document, without the written permission of the Division Director or designee;
- (5) identification of the detained drugs;
- (6) the detention order number;
- (7) the date and hour of the detention order;
- (8) the period of the detention;
- (9) the text of section 304(g) and information about the appeal process located in 21 CFR 1.980(g)(1) and (2);
- (10) a statement that any informal hearing on an appeal of a detention order must be conducted as a regulatory hearing under 21 CFR part 16, with certain exceptions as described in 21 CFR 1.980(g)(3).

(11) the location and telephone number of the FDA Division Office and Division Director. A continuation sheet may be used when all the information will not fit on the form.

3. Length of Detention

Initially, the drug should be detained for no more than 20 calendar days, unless the Division Director determines that additional time will be required to institute a seizure or to evaluate the need for other action. In such cases, the Division Director should authorize a detention period not to exceed 30 calendar days at the time the order is issued.

If the drug is detained for 20 calendar days and a seizure or other enforcement action cannot be instituted against the drug within that time frame, the detention can be extended to a total of 30 calendar days. If a detention is extended from 20 to 30 calendar days, amend the original detention order and place new tags or labels on the drug.

4. Movement of Detained Drug

No person may move a detained drug within or from the place where it has been detained until the Division Director terminates the detention order or the detention period expires, whichever comes first. This restriction prohibits any movement, use, alteration, or tampering with a detained drug (21 CFR 1.980(h)(1)), except to complete manufacturing or with written permission as explained below.

Movement to Complete Manufacturing (21 CFR 1.980(h)(2))

When a detained drug is not in final form for shipment (e.g. bulk tablets, unpackaged blister packs) and the manufacturer wants to complete work on the drug, then the manufacturer may move the drug within the establishment where it is detained in order to complete the work needed to put the drug in final form for shipment. In this instance, the manufacturer must orally notify the FDA official that issued the detention order or another responsible Division official of the movement as soon as it occurs. As soon as the drug is put into final form for shipment, it must be segregated from other drugs and the individual responsible for its movement must notify the FDA official that issued the detention order or another responsible Division official of its new location. Once in final form for shipment, the detained drug must not be moved further without prior written approval from the appropriate FDA official.

Other Movement with Written Permission (21 CFR 1.980(h)(3))

The Division Director that issued the detention order or another responsible Division official may authorize, in writing, the movement of the detained drug for any of the following purposes:

- i. To prevent interference with an establishment's operations or harm to the drug.
- ii. To destroy the drug.
- iii. To bring the drug into compliance with the FD&C Act and its implementing regulations.
- iv. For any other purposes that the FDA representative who issued the detention order, or other responsible FDA Division official, believes is appropriate in the case.

If the relevant FDA official grants permission to move the detained drug for any of the reasons listed above, the detained drug must remain segregated from other drugs and the person responsible for its movement must immediately notify the official orally or in writing who approved the movement, or another responsible FDA Division official, of the detained drug's new location. 21 CFR 1.980(h)(4). Unless otherwise permitted by the FDA representative who is notified of, or who approves, the movement of the drugs, the required tags must accompany the drugs during and after movement and must remain with the drugs until FDA terminates the detention or the detention period expires, whichever comes first. 21 CFR 1.980(h)(5). To effectuate this requirement, the authorizing official may specify in the written authorization how the tags should "accompany" the drugs in situations where it is unclear how the firm can comply with this requirement (e.g. firm needs to transfer drug from one large, tagged container into multiple containers for shipment/reprocessing.)

5. *Termination or Expiration of a Detention Order*

If FDA terminates a detention order, the FDA representative authorized to terminate the detention will issue a Detention Termination Notice releasing the drug to any person who received the detention order or that person's representative and will remove, or authorize in writing the removal of, the required tags or labels (21 CFR 1.980(j)). The Division Director has the authority to terminate a detention. Generally, the Program Division Director or program division employees will serve as the "FDA representative authorized to terminate" the detention and the Division Director, or other FDA representative authorized to terminate the detention, shall endeavor to issue the termination notice as soon as possible after one of the following occurs:

- i. FDA determines that the drug is not adulterated or misbranded.
- ii. FDA approves the voluntary destruction of the drug and the destruction is accomplished.
- iii. FDA approves voluntary compliance by reconditioning or other means (e.g., relabeling, voluntary recall, etc.).
- iv. A seizure action under section 304(a) of the FD&C Act has been instituted in court and the goods have been seized by the U.S. Marshals pursuant to a court-issued warrant. The filing of a complaint does not automatically terminate a detention order.
- v. The detention period expires.
- vi. The detention order is appealed, with or without an informal hearing, and the presiding officer revokes the detention order.

If any of the above conditions occurs, the Division Director must approve the termination of detention order and may do so by giving oral or written approval. The Division Director, or the investigator or compliance officer at the direction of the Division Director, issues a Detention Termination Notice (Form FDA 2291) to the person(s) who received the detention order. This termination notice should be provided to the person identified in the order or modified order who currently possesses the detained drug. Per 21 CFR 1.980(k), the termination notice must include or be accompanied by a statement advising the owner, operator, or agent in charge to keep records concerning the detention for the remainder of the two-year period from the date of detention, or such shorter period as FDA directs.

The Detention Termination Notice may be issued in person or by mail. If the Division issues the termination notice by mail, then the Division must also request that the Detention Tags (Form FDA 2290) be returned. The Division should, as matter of practice when a Detention Termination Notice is sent by mail, concurrently verbally notify the person who received the original detention order, or that person's representative, that the detention has been terminated. Any delivery receipt should be documented.

If the termination notice is issued in person, see Section 2.7.2.5 of the IOM for instructions. If the Division Director gives oral approval, then the Division Director should issue a written confirmation as well.

6. *Responsibilities for Issuing and Terminating Detention Orders*

The responsibilities of the relevant FDA components involved in issuing and terminating a detention order are set forth below.

a. Program Division Responsibilities - The Division is responsible for:

- i. Verifying that the investigator has reason to believe a drug is adulterated or misbranded and then responding accordingly to protect the public health.
- ii. Notifying the appropriate Center, OSPOP/DE, OCC, and other applicable program divisions as soon as it becomes aware of a situation where administrative detention may be appropriate.
- iii. Determining whether the person in possession of the drug will voluntarily hold the drug and provide assurance that integrity and security will be maintained over the drug on hand, in which case, there is no need to detain the goods.
- iv. Exploring the applicability of state regulatory oversight to include embargo authorities and license suspensions instead of administrative detention to conserve FDA resources (See 5-3-3 Issuing and Terminating Detention Orders).
- v. Ensuring support from the senior compliance official of the appropriate Center and OCC before issuing a detention order, unless exigent circumstances exist, and the Division attempts to make contact, but Center or OCC are not immediately available.
- vi. Obtaining the approval of the Division Director in accordance with 21 CFR 1.980(e).
- vii. Obtaining OCC approval of draft detention order (unless exigent circumstances exist, and the Division attempts to make contact, but OCC is not immediately available)
- viii. Issuing the detention order on Form FDA 2289, providing a brief, general statement of the reason(s) for the detention and stating the charge in the order in plain language. Ensuring all pages of the Form FDA 2289 are issued.
- ix. Informing the owner, operator, or agent in charge of the place where the drug is located that the drug is being administratively detained and that he or she has an opportunity to appeal and have a hearing on the detention.
- x. Informing the owner, operator, or agent in charge of the

establishment where the drug is detained of his or her responsibility to establish and maintain records as required by 21 CFR 1.980(k) at the time the FDA official issues the detention order, or as soon as possible thereafter.

xi. Notifying the senior compliance official, or designee, of the appropriate Center, Director of OSPOP/DE, and OCC by phone or e-mail that the order has been issued and supplying them with a copy of the detention order and a copy of any supporting information, e.g., FDA Form 483, by the most expeditious means available (loading scanned copies into CMS, fax, express mail, e-mail, etc.) immediately after issuance. Coordinate with OSPOP/DE to ensure that an appropriate presiding officer is identified.

xii. Notifying the ORA Office of Pharmaceutical Quality Operations Program Director that the Division Director issued a detention order. However, the Program Director should not become involved in decisions relating to issuing or monitoring the detention order. The Program Director may be the presiding officer who decides any appeal of the detention order, and consequently, this individual must avoid participating in the investigation or action that is the subject of the detention order and to remain free from bias or prejudice (21 CFR 16.42(b)).

xiii. If CMS is not used for initial notification, loading copies of all related documents into CMS within a reasonable time.

xiv. Expediting the preparation and processing of a seizure recommendation involving the detained drug. The Division should flag the recommendation to indicate that it involves a detained drug and show the date the detention expires and should forward the recommendation to the responsible Center and notify the OCC Regional Litigation Senior Enforcement Advisor. by the most expeditious means available (loading scanned copy into CMS, fax, express mail, e-mail, etc.) immediately after completion.

xv. Approving and monitoring any permitted movement of the drug once FDA issues the detention order.

xvi. Monitoring regularly the relevant phone, e-mail, and fax machine in the issuing Division's office, over weekends and holidays, for an appeal from any person that would be entitled to claim the drug had it been seized, unless the Program Division has no employees located in the Division office, in which case Division Office Personnel will monitor the fax machine.

xvii. If the Division Director or Program Division receives any communications regarding the ADO from any person that would be entitled to claim the detained drug had it been seized, the Division must immediately notify the relevant parties in ORA OPQO, the Division, OCC, OSPOP/DE, Center Compliance, and the presiding officer. All communications should be uploaded into CMS.

xviii. Monitoring the length of the detention and the progress of the seizure recommendation, as well as extending the detention order from 20 to 30 calendar days if the order will expire prior to the agency or State initiating any appropriate legal action.

xix. Coordinating with OCC, the U.S. Attorney's Office and the Marshal's Service if a complaint for seizure is to be filed.

xx. Issuing a Detention Termination Notice (Form FDA 2291) in a timely manner.

b. Center Responsibilities - The Center is responsible for:

i. Deciding whether to support the reasonable belief that the product is adulterated or misbranded at the time of the proposed detention. If the Center with jurisdiction over the product does not support the proposed detention, then the Division Director may not issue the order. Generally, a formal submission of documents supporting the detention is not necessary; rather, the Center the senior compliance official communicates his or her decision to the Division Director by phone, email, or other expedited communication.

ii. Coordinating Center case review with other Centers as necessary.

iii. Reviewing quickly any information provided by the Program Division, through OSPOP/DE, alerting the Program Division and OCC of any problems, and forwarding to the Program Division all requested documents.

iv. Providing expert testimony and other support, as appropriate.

v. Working with the Program Division Compliance Branch and OCC to identify evidence needed to support the legal case and appeal.

vi. Promptly notifying the Program Division, OSPOP/DE, and OCC of any issues or Center concerns that need to be resolved, prior to providing support for the administrative detention and subsequent

enforcement action.

vii. Coordinating the administrative detention and subsequent enforcement action with the Program Division, OSPOP/DE and OCC.

c. OSPOP/DE responsibilities –OSPOP, Division of Enforcement is responsible for:

i. Ensuring that the Center and OCC have received copies of the detention order, any appeal (with or without a request for hearing), and other supporting documents. OSPOP/DE will coordinate the detention to ensure that all appropriate FDA components have received notification and are preparing for a hearing in a timely manner.

ii. Designating the appropriate Presiding Officer should a hearing be necessary and ensure the Presiding Officer is in contact with designated attorneys from OCC to assist with the hearing process.

iii. Coordinating location for the conduct of a hearing as necessary.

iv. Obtaining transcription services to document the hearing as necessary.

v. Coordinate the administrative detention and subsequent enforcement action with the Program Division, the appropriate Center, and OCC. For example, OSPOP/DE enlists the support of the presiding officer, alerts ACRA, and assures that legal representation is available to the Division/Center and the presiding officer.

d. OCC Responsibilities – The Office of Chief Counsel is responsible for:

i. Reviewing quickly any information provided by the Program Division, including the proposed detention order, and, through OSPOP/DE, alerting the Program Division, Division Director, and the Center's senior compliance officials and OSPOP of any problems prior to the detention being put in place.

ii. Beginning preliminary preparations for any appeal. The appropriate Deputy Chief Counsel for Litigation shall make staff assignments in OCC and notify the Program Division of the attorneys assigned to the case. The Principal Deputy Chief Counsel shall make staff assignments in OCC for the presiding officer.

iii. Providing litigation support for any subsequent Agency enforcement action.

e. ORA Office of Pharmaceutical Quality Operations Program Director Responsibilities –

- i. Acting as a presiding officer, unless he or she removes himself or herself or is unavailable (21 CFR 1.980(g)(4), 21 CFR 16.40 and 16.42).
- ii. Insulating himself or herself from all aspects of a detention except those relating to his/her responsibilities as a presiding officer.

5-5-4 Appeal of a Detention Order

1. Appeal, With or Without an Informal Hearing

Under section 304(g) of the FD&C Act, any person who would be entitled to claim the drug if it had been seized under section 304(a) of the FD&C Act, may appeal a detention order. The appeal must be submitted in writing, to the Division Director in whose Division the detained drug is located, at the mailing address, e-mail address, or fax number identified in the detention order. The appeal must include a statement by the appellant asserting an ownership or proprietary interest in the detained drug. If the detained drug is located at a place other than an establishment owned and operated by the appellant, the appellant must include documents showing that the appellant would have legitimate authority to claim the drug if it had been seized.

If the detention order is appealed, the appellant has the right to request an informal hearing. The request for a hearing must be in writing and must conform to time frames. The presiding officer has the authority to deny a hearing, in whole or in part, when the appeal raises no genuine and substantial issue of fact and FDA is entitled to judgment as a matter of law. If the presiding officer, in consultation with OCC, determines that a hearing is not justified, the presiding officer will issue written notice of that determination and provide it to all parties explaining the reason for denial. 21 CFR 16.26(a). See Exhibit 5-25 for Model letter denying a hearing.

If granted, the informal hearing will be conducted in accordance with 21 CFR Part 16, except where modified by 21 CFR 1.980(g)(3) or as waived by the presiding officer under 21 CFR 16.60(h), as appropriate. See Exhibit 5-24 for Model letter granting a hearing.

2. Time Frames

The regulation allows an appellant 5 working days from receipt of the detention order (which also serves as notice of opportunity for a hearing) to appeal the detention, with or without a request for an informal hearing. The appeal must be in writing, must be addressed to the Division Director in whose Division the detained goods are located, and must contain a statement asserting an ownership or proprietary interest in the detained drug that would qualify the appellant to claim the drug if it had been seized. FDA will file the appeal on the day the appeal is received.

If the appellant does not request an informal hearing, the decision to affirm or revoke the detention must be rendered within 5 working days after the Division receives the appeal.

If the appellant does request a hearing, then the appellant must indicate whether the hearing is requested to be held within 5 working days after the appeal is received (an immediate hearing) or at a later date, but not later than 20 calendar days after the detention order was received (a delayed hearing).

When the appellant requests an immediate hearing, then the presiding officer holds the hearing and renders his/her decision within 5 working days after the date the appeal was filed. When the appellant requests a delayed hearing, the presiding officer schedules the hearing for no later than 20 calendar days after the detention order was received and issues his/her decision within 5 working days after the hearing concludes. If the appellant requests a delayed hearing, the presiding officer still must endeavor to conduct the hearing and issue his or her decision within 30 calendar days of the detention order being issued.

Presiding Officer Responsibilities – The presiding officer is responsible for:

- 1) Determining whether to grant or deny an appeal with or without an informal hearing request from the appellant in accordance with 21 CFR 1.980 and, as applicable, 21 CFR part 16. Any person who would be entitled to claim the drug if seized under section 304(a) of the FD&C Act, may appeal a detention order and may request an informal hearing as specified in 21 CFR 1.980.
- 2) If an appeal with a hearing is requested, determining whether the appellant has raised a genuine and substantial issue of fact justifying a hearing on the administrative detention order (21 CFR 16.26(a)), and if not, denying the request for an informal hearing, in whole or in part. If the hearing is denied, the presiding officer must still issue a decision to revoke or affirm the detention order (i.e., whether the investigator had reason to believe the drugs were adulterated or misbranded at the time of the detention).

- 3) If there is an appeal, but no hearing is requested, determining whether the investigator had reason to believe the drugs were adulterated or misbranded at the time of the detention, i.e. affirming or revoking the detention order. 21 CFR 1.980(g)(7).
- 4) Determining whether to waive, modify, or suspend any provision under 21 CFR part 16 as authorized by 21 CFR 10.19 and 21 CFR 16.60(h).
- 5) See section 5-3-4 item # 5(b) below for further responsibilities of the presiding officer.

4. *Communications Between Parties to the Hearing and the Presiding Officer*

Parties to the hearing should avoid any off-the-record communication with the presiding officer. If any communication of this type occurs, it must be documented in writing and made part of the administrative record of the hearing. The other party must be provided with a copy of the letter or memorandum of the communication and must be provided an opportunity to respond (21 CFR 16.44(b)).

The person who writes a letter or memorandum of the meeting between a participant in the hearing and the presiding officer must send a copy to all the participants (21 CFR 16.44(c)).

5. *Appeal Processing Responsibilities*

a. Program Division Responsibilities

The Program Division should begin preparing for an appeal at the time it decides to detain a drug, because a potential claimant to the detained drugs may request an immediate hearing.

- i. When the Division Director receives an appeal, the Division Director, or the Program Division acting at the direction of the Division Director:

Date and time stamp the appeal and notifies the appellant in writing that it has received the appeal. If the appeal does not demonstrate an ownership or proprietary interest as required in 21 CFR 1.980(g)(1) and (2), contact the appellant and clarify this information. The appellant must submit any missing information to the Division Director in writing.

Immediately notifies, orally or by email, the Center, OSPOP/DE, OCC, and the presiding officer of the appeal, and forwards a copy of the appeal to them as soon as possible by fax or electronically.

Requests assistance of the Center, OSPOP/DE, and OCC as needed. OCC will designate attorneys to advise the Program Division, Center, and presiding officer.

ii. When the appeal includes a request for a hearing, the Division Director, or the Program Division acting at the direction of the Division Director:

Prepares a general summary of the information that will be presented by FDA at the hearing in support of the detention order ("general summary") and a comprehensive statement of the basis for the detention order ("comprehensive statement"), in accordance with 21 CFR 16.24(f). The detention order may serve as the comprehensive statement only if the reason for detention is described in sufficient detail.

Forwards the general summary and the comprehensive statement to the appellant (21 CFR 16.24(f)), the presiding officer, and the Center, OSPOP/DE, and OCC representatives. The Program Division sends the documents immediately to all parties so that they arrive as soon as possible, but at least one day prior to the hearing.

At least one day before the hearing, provides the appellant, presiding officer, and the Center, OSPOP/DE, and OCC representatives to the hearing, written notice of any published articles or written information to be presented at or relied upon at the hearing. A copy will also be provided in advance if the other participants could not reasonably be expected to have or be able to obtain a copy. If written notice or a copy is not provided, the presiding officer may, if time permits, allow the party who did not receive the notice or copy additional time after the close of the hearing to make a submission concerning the article or information. (21 CFR 16.24(g)).

iii. When the appeal does not include a request for a hearing, the Division Director, or the Program Division acting at the direction of the Division Director:

Forwards all the information that supports the detention to the presiding officer and all OCC attorneys participating in the appeal. This includes the general summary and comprehensive statement and any additional information provided by the appellant. The information is expected to arrive within sufficient time for the presiding officer to render a decision on the appeal, affirming or revoking the detention, within 5 working days after the filing of the

appeal.

b. Presiding Officer Responsibilities

i. When notified of an appeal, with or without a request for hearing, the presiding officer:

Determines whether the appeal is valid because the appeal has been submitted within the established time frame or if the appeal demonstrates ownership or proprietary interest as required in 21 CFR 1.980(g)(1), (2).

ii. When notified of an appeal, and a hearing is requested, the presiding officer:

Determines whether a hearing should be granted in whole or in part. A hearing will only be granted if the material submitted by the appellant raises a genuine and substantial issue of fact (21 CFR 16.26(a)). A hearing will not be granted on matters of law or policy. See Exhibit 5-24 Model Letter Granting a Hearing.

If the presiding officer denies a hearing, the presiding officer notifies the appellant of the hearing denial in writing. See Exhibit 5-25 for an example of a model letter denying an appellant's request for a hearing.

If the presiding officer grants a hearing, the presiding officer orally contacts the parties as soon as possible to set a hearing date. Depending on whether the appellant selected an immediate or delayed hearing, the presiding officer will set a hearing date and time to allow for a decision with the time frames. If practicable, a hearing may be conducted via teleconference or video conference.

Provides all parties with written notification of the time, date, and location of the hearing. The hearing normally takes place at the Division Office in the geographic Division where the detained drugs are located.

Provides the appellant with oral and written notification of the following:

Notification of those portions of 21 CFR Part 16 that are excluded or modified under 21 CFR 1.980(g)(3) and waived or modified for hearings on appeal of administrative detentions (see "5-X-5").

Notification whether the informal hearing is to be public or not per 21 CFR 16.60(a). The Commissioner, or other official with delegated authority, determines whether all or part of a hearing should be closed to prevent a clearly unwarranted invasion of personal privacy; to prevent the disclosure of a trade secret or confidential commercial or financial information that is not available for public disclosure under 20.61; or to protect investigatory records compiled for law enforcement purposes that are not available for public disclosure under 20.64.

Notification that the appellant should briefly summarize at the hearing any lengthy documents that they are presenting (e.g., voluminous computer printouts).

Notification that, if feasible, the appellant should provide the Division Director, at least 1 day before the hearing, written notice of, or a copy of (if the Division Director could not reasonably be expected to have or be able to obtain a copy), any published articles or written information that appellant intends to present or rely upon at the hearing, as required by 21 CFR 16.24(g).

Notification of the requirements under 21 CFR 16.44(c) (see "Communications Between Parties to the Hearing and the Presiding Officer").

iii. When there is an appeal, and no hearing is requested, the presiding officer is responsible for:

Immediately notifying the parties orally to submit information supporting their positions as soon as possible so that the information can be reviewed, and a decision reached within 5 working days after the appeal was received.

Orally notifying the appellant orally or in writing of the requirement under 21 CFR 16.44(c) (see "Communication Between Parties to the Hearing and the Presiding Officer").

c. OCC Responsibilities – The Office of Chief Counsel is responsible for all of the following:

i. Assigning OCC attorney(s) to represent advise the Division during any appeal and hearing.

ii. Assigning different OCC attorney(s) to represent the

presiding officer during any appeal and hearing.

iii. Expediting review of information provided by the Division (or presiding officer, depending on whom OCC is supporting).

iv. Working with the Division (or presiding officer, depending on whom OCC is supporting) to prepare for any hearing and appeal.

d. Center Responsibilities - The Center is responsible for providing:

i. Scientific, technical, and policy support to the Division.

ii. Subject Matter Expert Witnesses at the hearing, if necessary.

e. Division of Enforcement (DE) Responsibilities - Division of Enforcement is responsible for ensuring that all:

i. All relevant FDA components are notified of and prepared for a hearing; and

ii. Documentation from the Division Director and/or the Program Division relating to the detention and hearing is provided to the Center's senior compliance official and OCC.

5-5-5 Informal Hearing on Appeal of a Detention Order

1. Background

Section 304(g) of the FD&C Act requires FDA to provide the appellant with an opportunity for an appeal including an "informal hearing," as defined in 201(x) of the FD&C Act. 21 CFR 1.980(g)(3) requires that FDA conduct the hearing in accordance with 21 CFR part 16, Regulatory Hearing before the Food and Drug Administration, with certain limited exceptions noted below. 21 CFR 16.5(b) advises that part 16 procedures apply to the extent that they are supplementary to, and not in conflict with, the other procedures specified in a regulation, in this case 21 CFR 1.980, that provides a person with an opportunity for a hearing and specifies some procedures for the hearing, but not a comprehensive set of procedures. Further, 21 CFR 10.19 and 21 CFR 16.60(h) give the presiding officer the general authority to suspend, modify, or waive provisions under part 16.

According to 21 CFR 1.980(g), the presiding officer must be the ORA Program Director or another senior official above Division Director. DE is responsible to ensuring a presiding officer is assigned.

Modifications to procedural requirements in 21 CFR Part 16

The presiding officer must conduct the hearing in accordance with 21 CFR part 16, except the following sections of 21 CFR 16, as detailed in 21 CFR 1.980(g)(3):

- a. §16.22(a). Under 21 CFR 1.980(d), the detention order provides notice of the opportunity for the hearing, rather than the notice under 21 CFR 16.22(a), and the detention order is part of the administrative record of the regulatory hearing under 21 CFR 16.80(a).
- b. §16.22(b). Under 21 CFR 1.980(g)(3)(ii), a request for a hearing must be addressed to the FDA Division Director in whose Division the detained drug is located.
- c. §16.24(e). The hearing may be held within 2 working days after the request for hearing is received. The last sentence in 21 CFR 16.24(e), stating that a hearing may not be required to be held at a time less than 2 working days after the request for hearing is received does not apply to a hearing under this section. §16.42(a).
- d. §16.42(a). 21 CFR 1.980(g)(4), rather than §16.42(a), notes that that ORA Program Directors or other FDA officials senior to an FDA Division Director may preside at hearings under this section.

After making the requisite findings under 21 CFR 10.19, the presiding officer has the authority to waive, suspend, or modify any of the other provisions in 21 CFR part 16. 21 CFR 16.60(h). In conducting a hearing under this section, the presiding officer should also waive the following other provisions, if appropriate:

- a. §16.60(f), which requires the presiding officer to include as part of the report of the hearing: a finding on the credibility of witnesses (other than expert witnesses) whenever credibility is a material issue; and a proposed decision, with a statement of reasons.
- b. §16.95(b)(1) & (2) states that the Administrative Record of a Regulatory Hearing (21 CFR 16.80(a)(1)-(5)) is the exclusive record and basis for the decision. These provisions may be modified as follows: the presiding officer bases the decision, in most cases, on all information presented to him or her prior to or during the hearing. The decision is not to be based on the following information or documents, if they are not received or completed by the presiding officer prior to the end of the hearing as required by the FD&C Act and its implementing regulations:
 - i. Information and views submitted to the presiding officer after the hearing are not part of the official record unless the presiding officer permits post-hearing submissions and the information is submitted within the period specified by the presiding officer (21 CFR 16.80(a)(2)).
 - ii. Any transcript of the hearing (21 CFR 16.80(a)(3)).
 - iii. The presiding officer's report of the hearing and comments on the

report under 21 CFR 16.60(e) and 16.80(a)(4).

In addition, the presiding officer may, if appropriate, waive the part of 21 CFR 16.60(b) providing that all parties may confront and conduct reasonable cross-examination of any person (except for the presiding officer and counsel for the parties) who makes any statement on the matter at the hearing. See 21 CFR 16.5 and 16.60(h).

2. *Conducting the Hearing*

At the start, the presiding officer reminds the parties of the applicable modifications under 1.980(g)(3), to 21 CFR part 16 “Regulatory Hearing Before the Food and Drug Administration.” The presiding officer explains that the purpose of the hearing is to determine whether the FDA investigator, at the time of the detention and as set forth in the detention order, had reason to believe that the drug was adulterated or misbranded. The issue is not whether the drugs are actually adulterated or misbranded. That question is properly left to the Division Court in any subsequent enforcement action.

The FDA representative(s) is/are present to explain the basis for the detention and answer reasonable questions from the appellant.

The appellant then presents relevant information to support his/her position that the drug should not be subject to detention.

The presiding officer will ensure that the material presented, and the questions asked are relevant to the issue of the hearing and reasonable.

The presiding officer may, once the hearing commences, issue a summary decision on any issue in the hearing, if the presiding officer determines from the material submitted in connection with the hearing, or from matters officially noticed, that there is no genuine and substantial issue of fact respecting that issue (21 CFR 16.26(b)).

The appellant may request that the hearing be transcribed. However, the appellant must pay the cost of having the hearing transcribed and furnish FDA a copy for the record. FDA also may request a transcript of the hearing, in which case the costs are borne by the agency.

The presiding officer should notify the parties that his/her decision will not await transcription or any correction of the transcripts that is ordered.

3. *Responsibilities For The Hearing:*

a. Center Responsibilities -

The Center will provide documents, Subject Matter Expert witnesses, and office representatives for the hearing if requested by the Program Division and/or the OCC attorney representing the Program Division.

b. **OCC Responsibilities -**

OCC will provide counsel for the Program Division and the presiding officer, as appropriate, for the hearing.

c. **Program Division and Presiding Officer Responsibilities -**

Section 5-5-5, item # 2 “Conducting the Hearing” includes responsibilities of the Program Division and the presiding officer. The Program Division is responsible for assigning a Compliance Officer who has not previously been involved in the case to provide regulatory background and administrative assistance to the Presiding Officer.

5-5-6 Issuing the Decision on an Appeal

1. *Decision on an Appeal When Appellant Does Not Request a Hearing*

If there is an appeal of the detention order, but the appellant does not request a hearing, the presiding officer must render a decision on the appeal, affirming or revoking the detention, within 5 working days after the appeal has been filed. The rationale behind the decision made should be documented in the record under 21 CFR 1.980(g)(7).

2. *Decision on an Appeal after a Hearing*

The appellant has the option of selecting an immediate or delayed hearing. If the appellant requests an immediate hearing (within 5 working days after the appeal is received), then the presiding officer must hold the hearing and render a decision affirming or revoking the detention within 5 working days after the appeal was received (21 CFR 1.980(g)(5)). In contrast, if the appellant requests a hearing be held later than 5 working days after the appeal was filed, but not more than 20 calendar days after the detention order issued, then the presiding officer must hold the hearing on an agreed-upon date and decide whether to affirm or revoke the detention order within 5 working days after the hearing closes (21 CFR 1.980(g)(6)). The detention may not be extended past the otherwise applicable 30-day period.

3. *Basis for Rendering a Decision*

If the presiding officer determines that the investigator had reason to believe that the drug was adulterated or misbranded at the time of the detention under one or more of the bases set forth in the detention order, the presiding officer will affirm

the detention order. If there was no reason to believe the drugs were adulterated or misbranded, the presiding officer will revoke the detention order.

4. Issuance of the Order

The presiding officer issues the decision in the form of an order. (See Exhibit 5-26 for model order confirming detention and Exhibit 5-27 for a model order revoking the detention.) The parties to the appeal should be orally notified of the order immediately. Copies of the order should then be mailed to the parties via overnight delivery with documented return receipt.

The presiding officer must render his/her decision on the detention within the time frames listed previously. The presiding officer cannot delay his/her order pending completion of a written decision and any report of the hearing (discussed subsequently). When possible, the presiding officer's order should be issued at the same time as the written decision and any report of the hearing. However, in cases where the presiding officer needs additional time to complete the written decision and any report of the hearing, the written order may issue first, and the written decision may issue separately from and shortly thereafter the order. All parties involved should receive a copy of both the written order and the written decision.

5. Written Decision and Report of Hearing

The presiding officer must prepare a written decision report that includes the reasons and bases for his or her order (§ 16.95(b)(2)). The written decision must include any report of the hearing required under 21 CFR 16.60(e), if applicable. All written material submitted during the hearing and any report of the hearing must be attached to the written decision (21 CFR 16.60(e)). Any transcripts of the hearing should be included, if available.

Whenever time permits, the participants will be given the opportunity to review and comment on the written decision and report of the hearing. However, the presiding officer should set a time limit for the participants to comment. (As previously noted, whenever possible, the written decision and report of the hearing should be issued with the order as a single document).

5-5-7 Administrative Record and FOIA Requests

1. Administrative Record of Appeal without a Hearing

The presiding officer must prepare the administrative record of the appeal, which consists of the following:

- a. The detention order and the appeal.
- b. All written information submitted to the presiding officer in conjunction with the

- appeal.
- c. All letters and memoranda of meetings and communications between participants and the presiding officer referred to in 21 CFR 16.44(c).
- d. The presiding officer's order and written decision.

2. Administrative Record of Appeal with Hearing

The presiding officer must prepare the administrative record of the hearing, which consists of the following:

- a. The detention order and the appeal.
- b. All written information submitted to the presiding officer in conjunction with the appeal and hearing.
- c. Any transcript of the hearing, if available.
- d. All letters and memoranda of meetings and communications between participants and the presiding officer referred to in 21 CFR 16.44(c).
- e. The presiding officer's written decision, report of the hearing, order, and any comments or written decision or report of the hearing permitted under Section 201(x) of the FD&C Act and 21 CFR 16.60(e).

The presiding officer will forward the completed original administrative record to the Program Division Director. The Program Division will ensure storage of the original Administrative Record, with the firm's official file at the Division office after completion of the report. The Program Division will ensure that an electronic copy is uploaded into the CMS Case and is distributed to the Division Director, OCC, OSPOP/DE, the Center, and the ORA Office of Pharmaceutical Quality Operations

3. FOIA Requests

21 CFR part 20 applies to all requests for the administrative record and other documents relating to administrative detentions.

5-6 ADMINISTRATIVE DETENTION OF DEVICES

5-6-1 Purpose

This section provides the procedures and defines responsibilities for the Administrative Detention of Devices.

5-6-2 Detention of Devices

1. Background

Section 304(g) of the Act authorizes the FDA to detain devices intended for human use for a period of up to thirty (30) calendar days if, during an inspection, the FDA has reason to believe the devices are adulterated or misbranded. The intent of administrative detention is to protect the public by preventing

distribution or use of violative devices until FDA has had time to consider the appropriate action to take and, where appropriate, to initiate a regulatory action. The action of choice, in most cases, is a seizure. Detention of devices requires prior approval from the division director in which the devices are located and the concurrence of the appropriate center's director for compliance.

Any person entitled to claim the devices, if seizure occurred, may appeal the detention and may request a hearing on the appeal. The decision to affirm or revoke the detention must occur within five (5) working days of receipt of the appeal if there is no request for a hearing or if the request for a hearing is within five (5) working days after filing the appeal. If requesting the hearing for a date more than 5 working days after receiving the appeal, the decision must occur within five (5) working days after the conclusion of the hearing.

The Center for Biologics Evaluation and Research (CBER), the Center for Drug Evaluation and Research (CDER), and the Center for Devices and Radiological Health (CDRH) are responsible for administering the medical device amendments. See 21 CFR Part 3.

2. References

The regulatory authority for administrative detention and associated operations appears in Sections 304(g) and 201(x) of the Act, and in 21 CFR 800.55, 21 CFR Part 16, 21 CFR 5.47, and 21 CFR 10.19. The [IOM](#) Chapter 2, Subchapter 2.7, Detention Activities contains the instructions for implementing the detention authority.

3. Detention Procedure

This enforcement tool should be considered when there is likelihood that the device(s) will be moved or distributed before seizure can be accomplished. Whenever possible, state embargoes should be used instead of administrative detention because the latter can be resource intensive.

If the division director concludes that the person in possession of the device(s) will voluntarily hold the product, will provide assurance that integrity and security will be maintained over the devices on hand, and agrees to correct the violation(s) prior to shipment, there is no need to detain the goods.

At a minimum, prior to approving the detention order, the division director contacts the senior compliance official in the appropriate center to ensure that the Agency supports an administrative detention based on the violations observed. This ensures that the Agency considers recent developments or changes not yet communicated to the division. In addition, the division director notifies headquarters of the impending seizure recommendation. Contacts are:

For a conventional medical device:

Director, Office of Compliance (HFZ-300), CDRH
(301) 796-5500

or, for a biological device:

Director, Office of Compliance and Biologics Quality (HFM-600), CBER
240-402-9153.

Concurrence is by telephone. The division or headquarters does not require written concurrence except for cause, for example, for issues of science, policy, or law involving precedent or questionable facts.

a. Approval of Detention Order By The Division Director

The division director approves a detention order, before issuance, either orally or in writing. If the approval is oral, it should be placed in writing as soon as possible.

b. Detention Order Issuance

An investigator or other authorized agent signs the order. Issue the order in writing to the owner, operator, agent, or other responsible person in charge of the place where the device is located.

When issuing the order, the FDA investigator informs the owner, agent or other responsible person that they have the opportunity to appeal and have a hearing on the detention as noted on the order. If the order is not issued to the owner or agent of the owner of the device, then the division sends, as soon as possible, copies of the detention order and 21 CFR 800.55(g)(1) & (2) to the owner, via certified mail return receipt requested.

c. Form of Order

Issue the detention order on [Form FDA 2289](#) Detention Notice.

Section 2.7.2.3 of the [IOM](#) contains instructions for completion of the form.

The detention order frames the issues for appeal or informal hearing, which may result from the detention. Therefore, the information on the order concerning the reason for detention is very important.

There is no requirement that the order include all of the reasons for believing that the product is adulterated or misbranded. Only list the more significant violations. However, if a violation is not identified in the order, it may not be relied on to support the detention. State the charge in the order in factual, non-statutory language. For example, if the investigator finds a sterile, individually packaged syringe with holes along the seams of the

packaging, black greasy spots on the needle, and the label lacks the Zip Code of the manufacturer, describe the apparent violation in the reason for detention as "there is reason to believe the device is:

Adulterated per Section 501(a)(2)(A) of the Act because there are holes in the package and black spots on the needles. The firm prepared, packed, or held the product under insanitary conditions whereby it may have been rendered injurious to health.

Misbranded per Section 502(a) because the label states that it is sterile and the integrity of the package is compromised by holes. The labeling is false or misleading."

Note: Use a "continuation sheet" if all of the charges will not fit on the form.

Note: Charges used in the detention order do not necessarily limit the charges that may be identified in a subsequent complaint filed in court.

d. Length of Detention

According to statute, a detention is for twenty (20) calendar days unless the division believes that additional time is required to accomplish a legal action. In such cases, the detention is for thirty (30) calendar days at the time of issuing the order. When extending a detention from twenty (20) to thirty (30) days, issue another detention order and place new tags on the devices.

By statute, the detention cannot last for longer than thirty (30) calendar days.

e. Movement, Use, etc. of Detained Devices

Except as noted below, without the written permission of the Agency, detained devices cannot be moved, used, altered, or tampered with in any manner. Therefore, if possible, the investigator should segregate the detained devices from other devices or products at the time of the detention, so they remain undisturbed.

With the approval of the division director, the investigator who detained the devices or any other responsible division official may authorize, in writing, the movement of detained material. Whoever moves the devices must immediately notify (orally) the authorizing official of the new location.

The only exception to the prohibition on movement without written permission is when the goods are not in final form for shipment and the manufacturer wants to complete work on them. The manufacturer may move them within the facility where detained to complete manufacture but

must orally notify FDA of the movement as it occurs. When completing manufacturing, the manufacturer must immediately segregate the detained devices from other products and orally notify FDA of their new location.

However, the manufacturer may not move the devices from the establishment without prior written approval of the division director as referenced above.

Note: 21 CFR 800.55(h)(2) prohibits further movement even within the establishment without FDA approval.

f. Legal Actions Against Detained Devices

The division should expedite the preparation and processing of a seizure recommendation involving the detained devices. The recommendation should be flagged to indicate that it involves detained devices and show the date the detention expires and should be forwarded to the responsible center by overnight delivery service.

The center compliance office, ORA, and OCC should likewise expedite their reviews to accomplish the legal action prior to expiration of the detention. If the move the goods and the violative product may find its way into commercial distribution.

The division is responsible for monitoring the length of the detention and the progress of the recommendation. If a twenty (20)-day detention expires prior to accomplishing the legal action, the division should extend the detention for an additional ten (10) days.

The division is responsible for coordination with the U.S. Attorney's office and the Marshal's Service, ensuring prompt filing of the complaint, and seizure of the goods.

The division is also responsible for immediately providing oral notice to the appropriate center compliance office, OCC, and the presiding officer of the accomplishment of the seizure or of any appeal of a detention order.

g. Recordkeeping Requirements

At the time of issuance of a detention order, or as soon as possible thereafter, the division informs the owner, operator, or agent in charge of the establishment where the devices are detained of their responsibility to establish and maintain records as required by 21 CFR 800.55(k).

h. Termination of Detention Orders

i. The reasons for termination of Detention orders:

- FDA determines that the device(s) is (are) not violative.
- FDA approves voluntary destruction or compliance by reconditioning or other means (e.g., relabeling).
- FDA revokes the detention on appeal.
- FDA accomplishes a regulatory action against the product. Actual seizure or entry of TRO or an order by consent or otherwise of preliminary injunction is necessary. The filing of a complaint does not necessarily terminate a detention order.
- The detention period expires.

The division director, within whose division the devices are detained, must approve termination of detention orders. Approval is oral or written, and if oral, confirmation is in writing. The division issues the Detention Termination Notice ([Form FDA 2291](#)) to the person(s) who received the Detention Notice, or his representative and, if movement of the devices occurred prior to the termination, to the person possessing the devices. Issuance of the notice is in person or by mail. If the termination notice is issued by mail, request that the Detention Tags ([Form FDA 2290](#)) be returned. If the termination notice is issued in person, see [IOM 2.7.2.5](#) for advising the owners, operators, or agents in charge to keep the records concerning the detention for the remainder of the two year period from the date of detention or such shorter period as FDA directs.

4. Responsibilities for Issuing and Terminating Detention Orders

a. Division Responsibilities As referenced above, the division is responsible for:

- i. Ensuring support from the senior compliance official of the appropriate center before issuing a detention order.
- ii. Issuing the detention order.
- iii. Notifying the Director of the Division of Enforcement (DE) by phone of the detention and supplying that person with a copy of the detention order by the most expeditious means available (fax, express mail, etc.) immediately after issuance.
- iv. Approving and monitoring the movement of detained devices.
- v. Notifying OSPOP/DE and the program director that the division issued a detention order.

NOTE: Keep the Division Director insulated from detention proceedings after the detention is in place in order to avoid even the appearance of bias or prejudice.

- vi. Pursuing the follow-up legal action as discussed under the heading, "Legal Actions Against Detained Devices."
- b. Center Compliance Office Responsibilities

Division contact with the center, for concurrence, is a routine procedure. If the director of compliance for the center will not support a proposed detention, do not issue the order. Communication of the director's decision to the division is by phone, e-mail, or other expedited communication. Generally, a formal submission of documents supporting detention is not necessary.

The compliance office will quickly review any information provided by the division, through DE, alert the division, and OCC of any problems, and forward to the division all requested documents. The compliance office will provide expert witnesses and other support, as appropriate.
- c. Office of Chief Counsel Responsibilities

OCC will quickly review any information provided by the division, and through DE, alert the division, the center office, of any problems, prior to the detention being put in place.

The Deputy CC for Litigation or the Deputy CC for Regulations and Hearings shall make staff assignments in OCC and notify the center and DE of the attorney assigned to the case. OCC will begin preliminary preparations for any appeal. OCC will determine whether the division and the program(s) require legal counsel.
- d. DE Responsibilities

Upon notification that a detention has been affected or a subsequent appeal received by the division:

DE will immediately notify the center compliance office and OCC, and deliver to them copies of the detention order, request for hearing, and other supporting documents. DE will coordinate the detention to ensure that all Agency and OCC components receive notification and prepare for a hearing in a timely manner.
- e. Division Responsibilities

The Division must insulate himself/herself, after the detention is in place, from all aspects of a detention except those relating to his/her responsibilities as a presiding officer. Responsibilities at that time are in the next section, "Appeal of a Detention Order."

5-6-3 Appeal Of A Detention Order

1. General Information

a. Background

Section 304(g) of the Act permits anyone who is entitled to claim the goods, if seized, to appeal a detention order.

If appealing the detention, Section 304(g) requires that the Agency afford the appellant with an opportunity for an informal hearing. If the appellant does not request an informal hearing, the decision to affirm or revoke the detention must be rendered within five (5) working days after the filing of the appeal. The appellant may request the holding of an informal hearing either within five (5) working days after filing the appeal or at a later date, but not later than twenty (20) calendar days after receipt of the detention order. 21 CFR 800.55(g)(1). If the appellant requests a hearing within five (5) working days after filing the appeal, the presiding officer holds the hearing and renders a decision within five (5) working days of the filing of the appeal. In the event of a request for a delayed hearing, the scheduling of the hearing must occur after the fifth working day following the appeal, and a decision must be issued within five (5) working days of the hearing's conclusion.

Regardless of the scheduling of the hearing, there is no extension past the thirty (30)-calendar day detention period without the consent of the appellant. (The provision for extension of the detention found in 21 CFR 800.55(g)(6) is incorrect and should not be followed.)

b. Time to Appeal

The regulations allow an appellant five (5) working days from the receipt of the detention order (which also serves as a notice of opportunity for a hearing) to appeal the detention, with or without a request for an informal hearing. The appeal must be in writing, must be addressed to the division director of the division office within whose area the goods are detained, and must contain a statement asserting that interest (e.g., ownership) in the detained goods would qualify the appellant to claim the goods if they were to be seized. The postmark on the appeal letter will determine the date of the appeal.

The division director will allow one (1) day of additional time for the receipt of an appeal request. Allow additional time if the appellant shows that it was impossible to appeal earlier.

c. Presiding and Deciding Official

The director for the division where the division is located and in which the goods were detained must be the presiding and deciding official unless he/she disqualifies him/herself (21 CFR 800.55(g)(4), 21 CFR 16.40 and 16.42, and 21 CFR 5.47). In the event of disqualification, the Division will immediately arrange for another Division to preside and provide immediate notification of any such change to the division director and the appellant.

Communications Between Parties to the Hearing And the Presiding Officer
Avoid any off-the-record communication between parties to the hearing and the presiding officer. If any such communication occurs, reduce it to writing and make it a part of the record. The presiding officer must supply a copy of any memoranda of such communication, which would affect his or her decision, to the other party, giving them an opportunity to respond. 21 CFR 16.44(b).

The person who originates any written communication between a participant in the hearing and the presiding officer must send a copy of any such communication to all of the participants. 21 CFR 16.44(c).

2. *Appeal Processing Responsibilities*

a. Division Responsibilities

Preparation for an appeal should begin when the division decides to detain a device(s), in case a hearing is requested within five (5) working days of the filing of the appeal.

i. When the division receives an appeal, the director:

- Dates and time-stamps the appeal, and notifies the appellant of receipt of the appeal. If the appeal does not specify that a hearing is or is not requested, does not demonstrate ownership or proprietary interest as required in 21 CFR 800.55(g)(1) and (2), or does not specify the time period within which to hold a hearing (see "Appeal of a Detention Order- Background"), contact the appellant and clarify this information. Make any declaration of ownership or proprietary interest in writing.
- Orally notifies the Division and the Director, DE of the appeal immediately and forwards a copy of the appeal to them as soon as possible. Requests assistance of OCC and the appropriate center for completing the next item.

ii. When the appeal includes a request for a hearing:

- Prepare (1) a general summary of the information that the detention and (2) a comprehensive statement of the basis for the action. The Detention Order (notice) may serve as the comprehensive statement only if the reason for detention is described in sufficient detail. See Exhibits 5-14 and 5-15 for an example of a general summary and a comprehensive statement respectively. See Exhibit 5-16 for examples of reasons detailed enough for the FDA 2289 to serve as a comprehensive statement.
- Forward the general summary and comprehensive statement to appellant (21 CFR 16.24 (f) and Section 201 (x)(3) of the Act, the Division, and any office and OCC representatives to the hearing. Send the documents immediately so that they arrive as soon as possible, but at least one (1) day prior to the hearing.
- At least one (1) day before the hearing, provide the appellant, the Division, and any office and OCC representatives to the hearing, written notice of, or copies of, if they could not reasonably be expected to obtain copies, and published articles or written information to be presented at or relied on at the hearing (21 CFR 16.24 (g)).

iii. When the appeal does not include a request for a hearing, the division forwards all the information that supports the detention to the Division acting as the deciding official. The division includes the referenced general summary and comprehensive statement and any additional information provided by the appellant. It must arrive within sufficient time to be reviewed and for a decision to be rendered within five (5) working days after receipt of the appeal.

b. Presiding Division Responsibility

When notified of an appeal, the Division

i. If a hearing is requested,

- Orally contact the parties as soon as possible. Depending on the time period within which the appellant requests a hearing, either set a hearing date and time to allow for a decision within five (5) working days after the date of receipt of the appeal by the division, or set a hearing date and time later than five (5) working days after receipt of the appeal by the division, but not later than twenty (20) calendar days after issuance of the detention order. The hearing normally takes place at the division office where the goods are located.

- Provide all parties with written notification of the time, date, and location of the hearing.
- Provide the appellant with oral and written notification (see form letter as Exhibit 5-17) of the following:
 - ii. Notification of those portions of 21 CFR Part 16 that are excluded or modified under 21 CFR 800.55(g)(3) and waived or modified for hearings on appeal of administrative detentions. See [subsection 5-5-4 "Informal Hearing on Appeal of a Detention Order."](#)
 - iii. Notification that the informal hearing is not a public hearing per 21 CFR 16.60(a), in order to protect investigatory records compiled for law enforcement purposes that are not available for public disclosure under 21 CFR 20.64, or trade secret material under 21 CFR 20.61.
 - iv. Notification that the appellant should provide, at the hearing, a brief summary of any lengthy documents for presentation at the hearing (e.g., volumes of computer printouts).
 - v. Notification that if feasible, at least one (1) day before the hearing, the appellant should provide the division director written notice of, or a copy of (if the division director could not reasonably be expected to obtain a copy), any published articles or written information for presentation at or relied on at the hearing as required by 21 CFR 16.24(g).
 - vi. Notification of the requirements under 21 CFR 16.44(c) (see "Communications Between Parties to the Hearing and the Presiding Officer.")
 - vii. If an appeal is made but no hearing is requested, the presiding officer must immediately orally notify the parties to submit information supporting their positions as soon as possible so that the information can be reviewed, and a decision reached within five (5) working days of the receipt of the appeal. We will accept additional information submitted prior to the decision. The presiding officer orally notifies the appellant of the requirement under 21 CFR 16.44(c) (see "Communications Between Parties to the Hearing and the Presiding Officer.")

When advice of the CC is needed, contact the Deputy CC for Litigation.

5-6-4 Informal Hearing On Appeal Of A Detention Order

Section 304(g) of the Act states that upon appeal of a detention order, the Agency will afford the appellant with an opportunity for an "informal hearing." Section 201(x) of the Act defines an informal hearing and lists specific provisions. 21 CFR 800.55(g)(3) provides that 21 CFR Part 16, Regulatory Hearing, establishes the procedures for conducting the informal hearing. 21 CFR 16.5 of the regulations advises that Part 16

procedures apply to the extent that they are supplementary to, and not in conflict with, other procedures specified for the hearing. 21 CFR 16.60(h) gives the presiding officer the power to suspend, modify, or waive provisions under Part 16.

1. *Waivers, Modifications, Etc. To 21 CFR Part 16*

21 CFR 800.55(g)(3) waives the following sections of 21 CFR Part 16:

- a. §16.22(a) concerning the issuance of a separate notice of opportunity for hearing because the detention notice FDA 2289 serves that function under 21 CFR 800.55(g)(3)(i).
- b. §16.22(b) concerning the forwarding of the appeal to the presiding officer because 21 CFR 800.55 (g)(1) requires sending the appeal to the division director.
- c. §16.24(e) concerning not permitting the hearing to be held within two (2) days of the receipt of the appeal because time constraints cannot allow for such a restriction.
- d. §16.42(a) regarding those persons who may act as the presiding officer because 21 CFR 800.55(g)(4) only allows Divisions to be presiding officers.

The presiding officer has the authority to waive, suspend, or modify any of the provisions under Part 16 (21 CFR 10.19 and 21 CFR 16.60(h)). The presiding officer must waive the following other provisions:

- a. §16.60(f) which requires the hearing officer to make a recommended decision with statement of reasons to the deciding official because the Division performs both functions.
- b. §16.95(b)(1) & (2) which state that the Administrative Record of a Regulatory Hearing (21 CFR 16.80(a)(1)-(5)) is the exclusive record and basis for the decision, are modified as follows: FDA bases the decision, in most cases, on all information presented to the presiding officer prior to or during the hearing. The decision is not to be based on the following information or documents, if they are not received or completed by the presiding officer within the time necessary for the presiding officer to review or complete them prior to making the decision as required by the Act or regulation:
 - i. Information and views submitted to the presiding officer after the hearing are not part of the official record unless the presiding officer permits post- hearing submissions and submittal of information occurs within the period specified by the presiding officer (21 CFR 16.80(a)(2)).
 - ii. Any transcript of the hearing (21 CFR 16.80(a)(3)).

- iii. The presiding officer's report of the hearing and comments on the report under 21 CFR 16.60(e) and 16.80(a)(4).

FDA waives that part of 21 CFR 16.60(b) which provides that all parties may confront and conduct reasonable cross-examination of any person (except for the presiding officer and counsel for the parties) who makes any statement on the matter at the hearing. There is an allowance for reasonable questions instead. Reference Congressional intent: House of Representatives Report no. 94-853. Also, see 21 CFR 16.5 and 16.60(h).

2. *Responsibilities for the Hearing*

a. Center Responsibilities

The center will provide documents, witnesses, or office representatives for the hearing if requested by the division or the OCC attorney counseling the division.

b. Office Of Chief Counsel Responsibilities

OCC will provide for the division and/or the presiding officer, as appropriate, for the hearing.

c. Division And Presiding Division Responsibilities

The section "Conducting the Hearing" includes individual responsibilities of the division and the presiding Division.

3. *Conducting The Hearing – General Procedures/Responsibilities*

At the onset, the presiding officer reminds the parties of the modifications to Part 16 that apply and explain the purpose or issue of the hearing. The issue at the hearing is whether FDA had reason to believe the devices were adulterated or misbranded at the time of the detention and as charged in the detention order. The issue is not whether the law has been violated. That question is properly left to the court trial, if one is held.

The FDA representative(s) is present to explain the bases for the detention and answer reasonable questions from the appellant.

The appellant then presents relevant information and reasons why he believes the Agency did not have reason to detain the product.

The FDA representatives may then ask reasonable questions (see Section 201(x)(4) of the Act).

The presiding officer ensures that the material presented, and the questions asked are relevant to the issue of the hearing.

The appellant may request a transcript of the hearing. However, the appellant must pay the cost of it and furnish the presiding officer a copy for the record. The Agency can also request a transcript of the hearing and the costs are borne by the government.

If the appellant wishes a copy of the government transcript, he/she may obtain it via a Freedom of Information (FOI) Act request. 21 CFR Part 20 applies to the release of the transcript.

The presiding officer notifies the parties that his decision will not await transcription or correction of the transcripts so ordered.

5-6-5 Requirements After A Hearing On Appeal Of A Detention Order

1. *Presiding Division Responsibility*

a. Confirming or Revoking the Detention Order

i. Time Period for Rendering Decision

As referenced in [subsection 5-5-3 "Appeal of a Detention Order - Background,"](#) the presiding officer must by order, confirm or revoke the detention order within five (5) working days of the receipt of the appeal by the division director, if there is no hearing requested or if the appellant requests a hearing within five (5) working days. However, if the appellant requests a hearing later than the referenced five (5) working day time frame, but not later than twenty (20) calendar days after issuance of the detention order, then the presiding officer must, by order, confirm or revoke the detention order within five (5) working days after the close of the hearing. 21 CFR 800.55(g)(5) and (6). The detention may not be extended past the otherwise applicable thirty (30)-day period (see "Appeal of a Detention Order - Background") without the consent of the appellant.

ii. Basis for Rendering Decision

If the Agency can show that it had a reason to believe that the devices were adulterated or misbranded at the time of the detention under one or more of the charges in the detention order, the presiding officer will affirm the detention order. If not, the presiding officer will revoke the detention order.

iii. Issuance of the Order

The decision is issued in the form of an order. (See [Exhibit 5-18](#) for model order.) The parties to the appeal should be orally notified of the order immediately. Copies of the order should then be mailed to them via certified mail return receipt requested.

FDA must order the decision rendered on the detention within the above time frames; however, the completion of the written decision and report of the hearing (discussed below) cannot delay the order. Normally, the order is consolidated with the written decision and report of the hearing. However, there are cases when the Agency needs additional time to complete the written decision and report of the hearing. In that case, it is separate from and will shortly follow the order.

b. Written Decision and Report of Hearing

The presiding officer must prepare a written decision to include the reasons and basis for his decision. 21 CFR § 16.95(b)(2). The written decision must include the report of the hearing required by Section 201(x)(5) of the Act and 21 CFR 16.60(e). All written material submitted during the hearing must be attached to the written decision and report of the hearing (Section 201(x)(5) of the Act and 21 CFR 16.60(e)). Any transcripts of the hearing must be included.

Whenever time permits, the participants will be given the opportunity to review and comment on the written decision and report of the hearing. However, the presiding officer should set a time limit for the participants to comment. (As previously noted, whenever possible, the written decision and report of the hearing should be issued with the order as a single document).

c. Administrative Record of the Hearing

The presiding officer must prepare the Administrative Record of the Hearing, which consists of the following items:

- i. The detention order and the appeal.
- ii. All written information and views submitted to the presiding officer in conjunction with the hearing.
- iii. Any transcript of the hearing.
- iv. The presiding officer's written decision, report of the hearing, order, and any comments on the written decision or report of the

hearing permitted under Section 201(y) of the Act and 21 CFR 16.60(e).

- v. All letters and memoranda of meetings and communications between participants and the presiding officer referred to in 21 CFR 16.44(c).

File the original Administrative Record of the Hearing with the firm's official file at the division office after completion of the report. A copy should be forwarded to the center involved for its information. A copy should be maintained in the office of the Division that held the hearing.

2. *FOI Requests*

21 CFR Part 20 applies to all requests for documents involved in administrative detentions.

5-7 LICENSE REVOCATION OR SUSPENSION

5-7-1 Purpose

This section contains procedures for revoking and suspending biologic licenses issued under the Public Health Service Act (PHS Act) [42 U.S.C. 264]. These procedures are applicable to actions recommended by the division or by CBER.

"Revocation" is the cancellation of a license and the withdrawal of the authorization to introduce or deliver for introduction into interstate commerce, biological products, at either the request of the manufacturer or when grounds exist for the Agency to initiate such an action.

"Suspension" is a summary action taken by the Agency and may be an initial or intermediate step in the revocation process. Suspension provides for the immediate withdrawal of the authorization to introduce or deliver for introduction, biological products into interstate commerce when the Commissioner has reasonable grounds to believe that any of the grounds for revocation exist and that by reason thereof there is a danger to health.

5-7-2 General

Licenses issued for the manufacture of specific biologic products under the provisions of Section 351(a) of the PHS Act, may be: 1) revoked upon request of the licensee or by initiative of the Commissioner when sufficient grounds exist; or 2) suspended if one or more of the grounds for revocation exists and presents a danger to health (see 21 CFR 601.5 and 601.6).

CBER's Office of Compliance and Biologics Quality (OCBQ), Division of Case Management (DCM) reviews recommendations for license revocation and suspension proposed by the division offices or the appropriate unit within CBER. If DCM concurs with the recommendation, it is forwarded to OCC for review. If OCC concurs, the recommendation and action letter are sent to the Director, CBER for concurrence and signature. Pursuant to [SMG 1410.203](#), the Commissioner has delegated the authority to issue notices of revocation and suspension to the Director and Deputy Director, CBER.

OCBQ ensures that recommendations for license revocation or suspension are supported with evidence of violations of the applicable statutes and regulations. License suspensions and revocations are significant enforcement actions with possible far-reaching consequences. As such, it is important to consider the impact that the action may have on product supply as part of the Agency's review of a proposed license suspension or revocation action.

When the license relates to multiple locations, revocation may be limited to one or more of the locations, if inspectional findings support that approach.

In the absence of willful noncompliance or a history of violations of a significant nature, the division or CBER inspection review unit considers issuing a Warning Letter or conducting a meeting with the firm, rather than recommending revocation as a first-choice remedy.

Part V of the Compliance Program Guides for inspections of CBER-regulated products contains information on deviations that may warrant regulatory or administrative action. These inspection programs are located [on CBER's Compliance Programs page](#).

5-7-3 General Considerations for Revocation

The Agency may consider revocation of a biologic license when any of the conditions specified in 21 CFR 601.5 exist. In establishing that the grounds for revocation in 21 CFR 601.5 are met, the recommending unit considers the two courses of action provided in the regulations: 1) notice of intent to revoke with the possibility of demonstrating or achieving compliance, or 2) in cases involving willfulness, notice of FDA's intention to move directly to revocation without providing an opportunity to demonstrate or achieve compliance.

1. Notice of Intent to Revoke

Inspectional findings must demonstrate a current history of repeated or continuous significant deviations that represent a breakdown of process controls, rather than isolated incidents. Ordinarily, a demonstration of prior warning to the firm is via Warning Letter and/or a meeting or other contact with the firm before consideration of license revocation. If a past Warning Letter issued and one or more non-violative inspection(s) follows it, a recommendation for license revocation based on current significant deficiencies must document whether the

deficiencies are of a continuing nature and how the current inspection relates to any previous inspection which resulted in the Warning Letter or other communication with the firm that provided the firm notice of such deficiencies. Issuance of a Warning letter in the past may not preclude issuance of an additional Warning Letter, especially if the nature and cause of the violation have changed. For example, a firm issued a Warning Letter three years ago for viral marker testing violations may warrant issuance of another Warning Letter or other action, rather than proceeding to license revocation, if the current inspection shows violations in different areas of the operation or manufacturing practices, e.g., computer validation.

In addition, FDA may proceed to revocation upon suspension of a license, as provided by 21 CFR 601.6(b).

Upon issuance of a "Notice of Intent to Revoke" letter (except in cases involving willfulness), we provide the licensee an opportunity to demonstrate or achieve compliance before instituting proceedings for revocation of the license.

2. *Direct Revocation*

FDA may proceed directly to revocation in cases involving willful conduct. Willful conduct is established by showing that an individual: 1) knowingly committed a prohibited act, such as records falsification or concealment; or 2) acted with careless disregard of the regulatory requirements, as exemplified by repeatedly failing to correct violations. In cases involving willfulness, FDA ordinarily does not provide the licensee with the opportunity to demonstrate or achieve compliance, in accordance with 21 CFR 601.5(b). In all cases, FDA notifies the licensee of the opportunity to request a hearing pursuant to 21 CFR 12.21(b).

5-7-4 Issues Not Supporting License Revocation

CBER ordinarily will not support license revocation when the following issues are the basis for the recommendation to revoke:

1. *Biological Product Deviation Reports*

Biological product deviation reports, in and of themselves, ordinarily may not form the basis for a license revocation unless the firm failed to recognize the error, failed to investigate and properly document the investigation, failed to implement corrective action to prevent its recurrence, or failed to notify FDA if so required under 21 CFR 600.14. In addition, in order to meet the grounds for license revocation, the deviation must be of such a nature or extent as to represent a firm's failure to establish or maintain control over one or more of the systems employed for the manufacture of biological products.

2. *Isolated Incidents*

Isolated occurrences do not ordinarily establish grounds for license revocation, unless there is documentation to demonstrate that the occurrences represent a pattern of violative activity.

3. *Past Violations*

Violations that occurred prior to the current FDA inspection, and for which implementation of appropriate corrective action prevents reoccurrence, ordinarily do not form the basis for license revocation. However, FDA must document previous violations even with correction, or no repeats, because they may demonstrate a pattern or history of non-compliance. If violations persist, such a pattern is pertinent to a future decision to proceed to revocation.

5-7-5 Revocation Procedures

If the inspection review unit is considering revocation as an enforcement option, contact CBER, DCM, during the inspection or soon after issuance of the FDA 483. Discussions with CBER prior to submission of a recommendation will facilitate the processing of the recommendation.

If the inspection review unit believes license revocation is appropriate, that office submits a recommendation to DCM for revocation with supporting documentation. Include the division director's concurrence on recommendations for revocation. In addition to forwarding documentation of the violations, the recommending unit submits a detailed summary of the firm's inspectional and compliance history over the past five years. The recommending unit also assesses the impact of license revocation on the supply of the biological products involved. The initial CBER contact is DCM, HFM-610, 240-402-9155.

CBER assigns a consumer safety officer from HFM-610 to each revocation recommendation. If using express delivery, send to:

Food and Drug Administration
Center for Biologics Evaluation & Research
Attn: Division of Case Management (HFM-610)
WO Building 75 Room 5004
10903 New Hampshire Ave.
Silver Spring, MD 20993

CBER personnel review the information received and determine whether the inspectional findings support revocation of the firm's license.

If CBER does not concur with the revocation recommendation, it communicates its decision to the recommending unit. CBER sends a memorandum confirming the reasons for the disapproval and provides other enforcement options, if appropriate.

If CBER concurs with the division's recommendation, it prepares an Action Memorandum with supporting documentation to the Director, CBER, and a letter notifying the licensee of the Agency's intention to initiate proceedings to revoke the license. This package is forwarded to OCC for review (see [RPM](#) Chapter 4, Exhibit 4-1). If OCC concurs, the recommendation and action letter are sent to the Director, CBER for concurrence and signature. Recommendations that CBER has initiated are also routed to the Director of CBER for clearance. Prior to doing so, however, the CBER initiating office contacts the appropriate division office to advise the division of the action proposed by CBER.

After the Director signs the letter, the Director, DCM verbally advises the most responsible person at the firm of the Agency's intention to revoke the license. DCM then transmits a copy of the letter to the firm electronically (by e-mail or fax) and sends the original with proof of delivery.

CBER's OCBQ advises the division office and/or recommending unit within CBER of the action concurrently. In addition, OCBQ transmits copies of the Action Memorandum and the revocation letter to the recommending unit via e-mail.

Both CBER and the recommending unit review the establishment's response to the letter of revocation expeditiously. The recommending unit provides CBER with its conclusions and comments regarding the adequacy of the firm's response.

The Agency usually gives an establishment the opportunity to demonstrate or achieve compliance. If the establishment has not waived its opportunity for a hearing by voluntarily requesting revocation, CBER's OCBQ and the firm continue to correspond until all corrective actions appear satisfactory. CBER will distribute copies of all correspondence between CBER and the firm to the recommending unit for review. When the recommending unit and CBER's OCBQ agree that all corrective actions appear satisfactory, CBER will ask the division office to conduct a follow up inspection expeditiously.

The division will advise CBER of the approximate date of reinspection and notify CBER by telephone or electronically of its findings and recommendation. Afterwards, the division sends a written recommendation either to move toward revocation or to discontinue proceedings for license revocation.

In some instances, the firm may have made significant progress in demonstrating or achieving compliance, but after review of the FDA 483 and the firm's response(s), the division and/or CBER may view a limited follow-up inspection as necessary prior to making a final determination on the matter of revocation.

Following reinspection, if CBER and the division determine that the firm demonstrated or achieved compliance, CBER will notify the firm of this determination.

In cases involving willfulness, ordinarily the establishment has ten (10) days from the date of the revocation letter to waive the opportunity for hearing by requesting voluntary revocation in writing. If the establishment does not waive the opportunity for a hearing by surrendering the license within the ten (10)-day time frame, DCM forwards a request to CBER's Regulations and Policy Staff, to prepare the *Federal Register* Notice of Opportunity for Hearing.

FDA publishes the Notice of Opportunity for Hearing on a proposal to revoke a license in the Federal Register together with an explanation of the grounds for the proposed action. A person subject to the notice has thirty (30) days after its issuance to request a hearing. There is no extension of the thirty (30)-day period. A request for hearing must set forth specific facts showing that there is a genuine and substantial issue of fact that justifies a hearing, and may not rely upon mere allegations or denials.

5-7-6 General Considerations For Suspension

Pursuant to 21 CFR 601.6, the Commissioner may suspend a license if the Commissioner has reasonable grounds to believe that any of the grounds for revocation exist and that by reason thereof there is a danger to health. Investigators obtain documentary evidence to support revocation and danger to health, and CBER conducts an evaluation of the danger to health.

Once CBER determines that a danger to health exists, the recommending unit immediately contacts the appropriate state health authorities. In addition, the division considers legal actions such as injunction or seizure, particularly if a given state health department lacks regulatory authority over intrastate operations or if the license suspension does not result in immediate corrective action. The recommending unit provides CBER with any information obtained regarding the state health department authority and the likelihood it may take regulatory action based on FDA's findings.

If a blood establishment is involved, the recommending unit determines the approximate number of annual collections and the percentage of blood products distributed in interstate commerce. The recommending unit, together with CBER, examines supply issues and considers contacting the large national blood organizations to ensure that a license suspension will not adversely affect the public health.

As in the case of revocation, when there are multiple locations encompassed by one license, suspension may be limited to one or more of the locations, if inspectional findings warrant that approach.

5-7-7 Suspension Procedures

If the inspecting unit believes a danger to health exists, it should contact CBER's DCM, HFM-610, 240-402-9155 immediately, during the inspection, and provide specific, substantive information relating to the grounds for suspension. It must not wait until the conclusion of the inspection to make contact. At that time, DCM assigns a consumer safety officer from HFM-610 to the suspension recommendation who will work with the investigators in case development.

The inspecting unit should transmit a copy of the FDA 483 (draft or final copy) as quickly as possible to DCM by facsimile, e-mail, or express delivery, along with any additional requested preliminary information and/or documentation. To avoid delay, do not send supporting documentation through the regular mail system if other means of transmission are available. If using overnight express delivery, send to:

Food and Drug Administration
Center for Biologics Evaluation & Research
Attn: Division of Case Management (HFM-610)
Building 75, Room 5004
19093 New Hampshire Avenue
Silver Spring, MD 20993

DCM will consult, as necessary, with the appropriate scientific/medical staff to determine if a danger to health exists. If a danger to health exists, the inspecting office will be advised and should submit a recommendation in a brief memorandum that includes the basis of the recommendation. Transmit the recommendation by e-mail. Recommendations for suspension are given a high priority and supervisors are to act promptly. Recommendations for suspension should have the concurrence of the division director. The division will make every effort to expedite the submission of a recommendation to CBER to suspend operations under license at an establishment whose practices present an imminent danger to health.

Frequently DCM may concur with a suspension recommendation after receiving the FDA 483 but before receiving the EIR. In cases involving complex issues, DCM may need to review the completed EIR before reaching a decision. In either event, write the EIR promptly and forward by express mail service to DCM.

Depending upon the products involved, CBER may ask the recommending unit to obtain a complete inventory of the products on the firm's premises.

If DCM concurs with the suspension recommendation, it will prepare an Action Memorandum and a letter of suspension within three (3) working days of receipt of the recommendation. Documents will be sent to OCC for review as soon as available. See [RPM](#) Chapter 4, Exhibit 4-1. Upon OCC concurrence, the Director, CBER, who notes the date and time of signature, signs the Action Memorandum and letter of suspension. The Director, OCBQ or DCM will immediately telephone the firm and advise it of the

suspension of its biologics license. DCM will then send the letter to the firm electronically and by certified mail.

CBER may concurrently advise the recommending unit of FDA's action. In some situations, CBER may arrange to transmit a copy of the suspension letter to the division for hand delivery to the firm.

If CBER does not concur with a suspension recommendation, it communicates its decision to the recommending unit. DCM will prepare a memorandum explaining the reasons for the disapproval. If CBER disagrees with the suspension recommendation based on the absence of a danger to health, and any of the conditions specified in 21 CFR 601.5(b) exist, DCM considers whether it is appropriate to revoke the license or send a Warning Letter and will discuss these options with the recommending unit.

DCM and the recommending unit concurrently review the reply to a letter of suspension and continue to correspond with the firm until both agree that all corrective actions appear satisfactory. At this point, DCM notifies the firm, ordinarily by telephone (later confirmed by letter), that limited operations may resume for the purpose of a reinspection to determine that the corrective actions implemented are effective. CBER requests that the division office conduct a follow up inspection expeditiously, generally within thirty (30) days of resumption of limited operations.

The division office advises CBER of the approximate date of reinspection. As soon as possible upon its conclusion, the division notifies CBER by telephone of its findings and recommendation (CBER contact is DCM, HFM-610, 240-402-9155). The division follows-up by sending a written recommendation on the last day of the inspection or shortly thereafter. If issuing a FDA 483, the division forwards a copy of the firm's response, if any, to CBER. In addition, the division sends a written copy of the establishment inspection report to CBER as quickly as possible to support continued suspension, revocation or reinstatement.

In some instances, the firm may have made significant progress in achieving compliance, but after review of the FDA 483 and the firm's response(s), the division and/or CBER may view a limited follow-up inspection as necessary prior to making a final determination as to whether to recommend reinstatement of the license.

If the follow-up inspection indicates inadequate corrective actions and continued deviations, the division obtains additional documentation and notifies CBER as soon as possible. CBER decides whether to allow the firm to continue in limited operations or to cease all operations. In addition, CBER considers the possibility of proceeding toward license revocation.

If the firm is achieving compliance, CBER prepares an Action Memorandum and letter of reinstatement for the signature of the Director, CBER. After the letter is signed, the Director OCBQ or DCM telephones the firm and advises it that the Agency has lifted the

suspension of the firm's activities and they may now ship products collected or manufactured since the date they resumed limited operations. Also, DCM advises the division by telephone and sends a copy of the reinstatement letter, which, if appropriate, may contain instructions to the firm for filing a request to use products in inventory at the time of suspension.

On a case-by-case basis, CBER evaluates written requests for release of products in inventory at the time of suspension. Communicate in writing all decisions regarding the disposition of products to the firm (copy to the division). CBER may request that the division monitor the disposition of the inventory.

Send copies of all correspondence, verbal and written communications, and EIRs relating to suspensions of operations under license, to the attention of:

Food and Drug Administration
Center for Biologics Evaluation & Research
Bldg 75, Room 5004
10903 New Hampshire Avenue
Silver Spring, MD 20903
ATTN: Division of Case Management, HFM-610

5-8 ORDERS OF RETENTION, RECALL, DESTRUCTION AND CESSATION OF MANUFACTURING RELATED TO HUMAN CELL, TISSUE AND CELLULAR AND TISSUE-BASED PRODUCTS (HCT/Ps)

5-8-1 Purpose

This section contains procedures for issuing an Order of Retention, Recall, Destruction and Cessation of Manufacturing (Order) related to human cell, tissue, and cellular and tissue-based products (HCT/Ps) pursuant to 21 CFR 1271.440 - promulgated under section 361 of the PHS Act.

5-8-2 Background

In February 1997, FDA proposed a new, comprehensive approach to the regulation of human cells, tissues, and cellular and tissue-based products (HCT/Ps). FDA proposed a tiered, risk based approach under which some HCT/Ps would be regulated only under Section 361 of the PHS Act and the newly proposed regulations in order to prevent the introduction, transmission, and spread of communicable diseases. Other HCT/Ps would also be regulated as drugs, devices, and/or biological products.

Since that time, the agency has published multiple regulations to fully implement this approach. In January 2001, we issued regulations to create a new, unified system for

registering HCT/P establishments and for listing their HCT/Ps (66 FR 5447). In May 2004, FDA issued regulations requiring most cell and tissue donors to be tested and screened for risk factors for, and clinical evidence of, relevant communicable disease agents and diseases (69 FR 29786). In November 2004, FDA issued regulations requiring HCT/P establishments to follow current good tissue practice (CGTP), which governs the methods used in, and the facilities and controls used for, the manufacture of HCT/Ps; recordkeeping; and the establishment of a quality program. The CGTP regulations also contain certain labeling and reporting requirements, as well as inspection and enforcement provisions (69 FR 68612). These regulations apply to HCT/Ps recovered on or after May 25, 2005. HCT/Ps that were recovered before this effective date are subject to 21 CFR Part 1270, and subparts A and B of Part 1271, as appropriate.

HCT/Ps that meet all of the criteria set forth in 21 CFR 1271.10(a) are subject to regulation solely under 21 CFR Part 1271 and section 361 of the PHS Act, so no premarket approval is required. HCT/Ps that do not meet all of the criteria in 21 CFR 1271.10(a) are regulated also as drugs, devices, and/or biological products.

Part 1271 contains six subparts:

- Subpart A of Part 1271 – scope, purpose, and definitions
- Subpart B of Part 1271 - registration
- Subpart C of Part 1271 - screening and testing of donors to determine eligibility
- Subpart D of Part 1271 - provisions on CGTP
- Subpart E of Part 1271 - certain labeling and reporting requirements
- Subpart F of Part 1271 - inspection and enforcement provisions.

The subparts apply as follows:

- Subparts A through D apply to all HCT/Ps, i.e., to HCT/Ps regulated solely under section 361 of the PHS Act and Part 1271, as well as to those regulated as drugs, devices, and/or biological products.
- Subparts E and F, which pertain to labeling, reporting, inspection, and enforcement, apply only to those HCT/Ps regulated solely under section 361 of the PHS Act and Part 1271. However, with the exception of two provisions (Sec. 1271.150(c) and 1271.155), subparts D and E are not being implemented for reproductive HCT/Ps.

21 CFR 1271.440 authorizes FDA to issue Orders of Retention, Recall, Destruction, and Cessation of Manufacturing in certain circumstances. Such an order is intended for use in situations when needed to prevent the introduction, transmission, or spread of communicable diseases, and applies only to those HCT/Ps regulated solely under section 361 of the PHS Act and Part 1271.

5-8-3 General Considerations

The agency may consider an Order of Retention, Recall, Destruction, or Cessation of Manufacturing when any of the conditions specified in 21 CFR 1271.440(a) exist. Under this provision, an Order may be justified when the agency finds that there are reasonable grounds to believe that an HCT/P is a violative HCT/P because:

1. The HCT/P was manufactured in violation of the regulations in Part 1271 and, therefore, the conditions of manufacture of the HCT/P do not provide adequate protections against the risk of communicable disease transmission; or
2. The HCT/P is infected or contaminated so as to be a source of dangerous infection to humans; or
3. An establishment is in violation of the regulations in Part 1271 and, therefore does not provide adequate protections against the risks of communicable disease transmission.

Based upon one or more of the above findings, the agency may order the retention, recall, and/or destruction of the violative HCT/P; take possession of and/or destroy the violative HCT/PS; or order the establishment to cease manufacture until compliance with Part 1271 has been achieved.

NOTE: FDA will not issue an order for the destruction of reproductive HCT/PS, nor will FDA carry out such destruction itself. 21 CFR 1271.440(f).

5-8-4 Procedures for Orders of Retention, Recall, or Destruction of HCT/PS

An Order of Retention, Recall, or Destruction of HCT/PS may be appropriate in situations where there are significant concerns regarding the source or violative nature of the HCT/P, the adequacy of the screening and/or testing, or a failure of the establishment to fulfill stated commitments to gain control over violative HCT/PS.

As soon as practicable after the possibility of issuing an Order of Retention, Recall, or Destruction is first identified, the division should contact the Chief, Blood and Tissue Compliance Branch (BTCB)/DCM, in CBER's OCBQ. It is important to make this initial contact during the inspection if possible; do not wait until the conclusion of the inspection to contact CBER. Discussions with CBER prior to submission of a recommendation will facilitate the processing of the recommendation.

The division should upload a copy of the FDA 483 (draft or final) into CMS along with any additional, preliminary information and/or documentation as quickly as possible and should notify BTCB/DCM, for example by e-mail. BTCB/DCM, will notify CBER's Office of Cellular, Tissue, and Gene Therapies (OCTGT) and OCC of the potential for an Order as appropriate.

If the division believes an Order of Retention, Recall, or Destruction is appropriate, complete documentation of the violative conditions should be collected, including an inventory of products on the premises as well as those products distributed (including names and addresses of consignees and HCT/Ps shipped to consignees) as of the last day of the inspection.

The division prepares and submits a written recommendation for an Order of Retention, Recall, or Destruction to CBER. Include the division director's concurrence with recommendations for Orders. Transmit the Order recommendation, FDA 483, and all supporting documentation via MARCS-CMS or, where needed, by e-mail.

All divisions should identify Order recommendations as high priorities and make every effort to expedite submissions of the documents described above. BTCB/DCM reviews the information received, also as a high priority, and determines whether the inspectional findings support the issuance of an Order of Retention, Recall, or Destruction.

CBER may concur with issuance of an Order after reviewing the FDA 483 and supporting documentation, but before receiving the EIR, if the violations are serious and if there are not adequate protections against risks of communicable disease transmission. It is essential that the division completes the EIR expeditiously and forwards it, along with the exhibits and additional supporting documentation, by uploading it into MARCS-CMS. In cases involving complex issues, CBER may need to review the completed EIR before deciding whether to concur with the recommendation to issue an Order.

BTCB/DCM transmits the FDA 483 and other available supporting documentation as needed to the Division of Human Tissues (DHT), OCTGT. If one or more of the conditions in 21 CFR 1271.440(a) (as described above in [subsection 5-7-2](#)) are present, DHT will confirm this in writing, signed by the Director, DHT or designee.

If CBER concurs with the Order recommendation, and OCTGT has confirmed that one or more of the conditions in 21 CFR 1271.440(a) are present, BTCB/DCM drafts the Order of Retention, Recall, or Destruction.

The draft Order, FDA 483, and supporting documentation are uploaded into MARCS-CMS for OCC review. If OCC concurs with the issuance of the Order, BTCB/DCM prepares the Order for signature by the CBER Center Director and delivers it to the Office of the Center Director for signature.

On the date that the Order is signed, the Director, OCBQ attempts to contact the HCT/P establishment by phone to notify the establishment that the Order is in effect. A copy of the order will be sent to the establishment by fax if possible, as soon as possible, after this call has taken place.

Also on the date the Order is signed, BTCB/DCM forwards the Order via overnight delivery to the division office for delivery to the HCT/P establishment. It is preferable to have the original, signed Order hand-delivered to the HCT/P establishment by an FDA investigator. If this is not practicable, the original signed order can be sent to the HCT/P establishment via overnight delivery.

If CBER does not concur with the Order recommendation, BTCB/DCM will notify the division regarding this decision by telephone or electronic mail, and forward a memorandum to the responsible division official explaining the reasons for non-concurrence and describing other potential regulatory actions, if appropriate.

If OCC does not concur with the Order recommendation, OCC will provide a written statement of its rationale to CBER, with a copy to the division office.

5-8-5 Follow-Up to Orders of Retention, Recall, or Destruction

The Order of Retention, Recall, or Destruction will ordinarily provide that the HCT/P be recalled and/or destroyed within five (5) working days from the date of receipt of the Order. The division should promptly verify that the recall and/or destruction is carried out expeditiously, and the HCT/P establishment's action should be monitored or witnessed, as appropriate, by an FDA investigator. The division should manage recalls as provided for in Chapter 7. The Order will require the HCT/P establishment to notify its consignees to return or retain affected HCT/PS in their inventories.

As an alternative to proceeding with recall and/or destruction, other arrangements for ensuring the proper disposition of the HCT/P may be agreed upon by the person receiving the written Order and FDA. Such arrangements may include, among other things, providing FDA with records or other written information that adequately ensures that the HCT/P has been recovered, processed, stored and distributed in compliance with the regulations and that, except as provided under 21 CFR 1271.60, 1271.65, and 1271.90, the donor of the cells or tissue for the HCT/P has been determined to be eligible. If the violative HCT/PS can be reconditioned to become suitable for implantation, transplantation, infusion, or transfer into a human recipient as a result of these corrective actions, the establishment may be authorized to release the HCT/P for distribution.

If alternative arrangements are proposed by the HCT/P establishment, the division and CBER should review the proposal concurrently. The HCT/P establishment must retain the violative HCT/PS in quarantine status until FDA agrees that the appropriate corrective actions have been implemented and adequate documentation has been provided to FDA to address the issues identified in the Order of Retention, Recall, or Destruction.

If FDA orders the destruction of HCT/PS, it is the firm's responsibility to destroy all violative HCT/PS and provide to FDA records documenting destruction. The division monitors the destruction of violative HCT/PS and obtains destruction records.

The regulations provide the agency with the authority to take possession of and/or destroy the violative HCT/Ps. The division must notify BTCB/DCM if it believes that taking possession of HCT/Ps may be appropriate. If CBER agrees that taking possession of HCT/Ps is appropriate in a particular situation, CBER will provide guidance on procedures for handling and destroying the HCT/Ps safely.

The division will schedule a follow-up inspection as appropriate. If the division observes continued deviations, it should contact BTCB/DCM during the inspection. The division and CBER will jointly consider what action to take.

5-8-6 Procedures for Orders of Cessation of Manufacturing

An Order of Cessation of Manufacturing may be appropriate in situations where there are significant concerns regarding one or more steps in the manufacture of HCT/Ps, or a failure of the establishment to fulfill stated commitments to gain control over or to bring the areas of manufacturing into compliance with the applicable regulations.

As soon as practicable after the possibility of issuing an Order of Cessation of Manufacturing is first identified, the division should contact the Chief, BTCB/ DCM, in CBER's OCBQ. It is important to make this initial contact during the inspection if possible; do not wait until the conclusion of the inspection to contact CBER. Discussions with CBER prior to submission of a recommendation will facilitate the processing of the recommendation.

The division should transmit a copy of the FDA 483 (draft or final) as quickly as possible to BTCB/DCM by e-mail, along with any additional, preliminary information and/or documentation. BTCB/DCM will notify CBER's OCTGT and OCC of the potential for an Order as appropriate.

If the division believes an Order of Cessation of Manufacturing is appropriate, complete documentation of the violative conditions should be collected, including an inventory of products on the premises as of the last day of the inspection.

An Order of Cessation of Manufacturing will be effective immediately if FDA determines there are reasonable grounds to believe there is a danger to health. BTCB/DCM will consult, as necessary, with the appropriate scientific/medical staff to determine whether there are reasonable grounds to believe that there is a danger to health. This evaluation will be documented by BTCB/DCM, working with appropriate scientific/medical staff. If a determination is made that a danger to health exists, the division will be advised immediately.

The division prepares and submits a written recommendation for issuance of an Order of Cessation of Manufacturing to CBER. Include the division director's concurrence with

recommendations for Orders. Transmit the Order recommendation, FDA 483, and all supporting documentation via MARCS-CMS or, where needed, by electronic mail.

All divisions should identify Order recommendations as high priorities and make every effort to expedite submissions of the documents described above. BTCB/DCM reviews the information received, also as a high priority, and determines whether the inspectional findings support the issuance of an Order of Cessation of Manufacturing.

CBER may concur with issuance of an Order after reviewing the FDA 483 and supporting documentation, but before receiving the EIR if the violations are serious and if there are not adequate protections against the risks of communicable disease transmission. It is essential that the division completes the EIR expeditiously and forwards it to BTCB/DCM, along with the exhibits and additional supporting documentation, by uploading it into MARCS-CMS. In cases involving complex issues, CBER may need to review the completed EIR before deciding whether to concur with the recommendation to issue an Order.

BTCB/DCM transmits the FDA 483 and other available supporting documentation as needed to the Division of Human Tissues (DHT), OCTGT. If one or more of the conditions in 21 CFR 1271.440(a) (as described above in [subsection 5-7-2](#)) are present, DHT will confirm this in writing, signed by the Director, DHT (or designee). If there are reasonable grounds to believe there is a danger to health, this must also be documented and signed by the Director, DHT (or designee).

If CBER concurs with the Order recommendation, and OCTGT has confirmed that one or more of the conditions in 21 CFR 1271.440(a) are present, BTCB/DCM drafts the Order of Cessation of Manufacturing.

The draft Order, FDA 483, and supporting documentation are uploaded into MARCS-CMS for OCC review. If OCC concurs with the issuance of the Order, BTCB/DCM prepares the Order for signature by the CBER Center Director and delivers it to the Office of the Center Director for signature.

On the date that the Order is signed, the Director, OCBQ attempts to contact the HCT/P establishment by phone to notify the establishment that the Order is in effect. A copy of the Order will be sent to the establishment expeditiously, by fax or e-mail if possible, as soon as possible after this call has taken place.

Also on the date the Order is signed, BTCB/DCM forwards the Order via overnight delivery to the division office for delivery to the HCT/P establishment. It is preferable to have the original, signed Order hand-delivered to the HCT/P establishment by an FDA investigator. If this is not practicable, the original signed order can be sent to the HCT/P establishment via overnight delivery.

If CBER does not concur with the Order recommendation, BTCB/DCM will notify the division regarding this decision by telephone or electronic mail, and forward a memorandum to the responsible division official explaining the reasons for non-concurrence and describing other potential regulatory actions, if appropriate.

If OCC does not concur with the Order recommendation, OCC will provide a written statement of its rationale to CBER, with a copy to the division office.

5-8-7 Follow Up to Orders of Cessation of Manufacturing

When FDA determines there are reasonable grounds to believe there is a danger to health, an Order of Cessation of Manufacturing is effective immediately. In other situations, the Order of Cessation of Manufacturing is effective after one of the following events, whichever is later: 1) passage of five (5) working days from the establishment's receipt of the Order; or, 2) if the establishment requests a Part 16 hearing, a decision in the proceedings. The Order will specify the regulations with which the HCT/P establishment must achieve compliance and will ordinarily specify the particular operations covered by the Order. The establishment is permitted to implement corrective actions in order to resume operations. However, the firm may not resume any operations subject to the Order without written authorization from FDA.

The division and CBER should concurrently review all correspondence received subsequent to issuance of an Order of Cessation concurrently. All meetings between the FDA and the Order recipient should include the appropriate division and CBER personnel.

5-8-8 Part 16 Hearing

The recipient of an Order may request a hearing by submitting a written request in accordance with 21 CFR Part 16 as described in the Order and in 21 CFR 1271.440(e). The recipient must make the request within five (5) working days of receipt of a written Order of Retention, Recall, Destruction, and/or Cessation of Manufacturing, or within five (5) working days of the agency's possession of an HCT/P. The HCT/P establishment may request additional time (beyond five (5) working days) to consider whether to request a hearing. Reasonable requests for additional time will usually be granted. IOCC, the ORA Ombuds, and FDA Office of the Ombudsman, and the division office should be notified promptly upon receipt of a Part 16 hearing request, and for a request for additional time to request a hearing.

For an Order requiring destruction of HCT/Ps, a request for a Part 16 hearing places the portion of the Order requiring destruction of the violative tissue in abeyance, pending the outcome of the hearing. The portion of the Order requiring recall and retention of violative HCT/Ps, however, is not placed in abeyance or affected by the hearing request.

As described above, if an Order of Cessation of Manufacturing is not immediately in effect, it is effective after one of the following events, whichever is later: 1) passage of five (5) working days from the establishment's receipt of the Order; or, 2) if the establishment requests a Part 16 hearing, a decision in the proceeding. If a Part 16 hearing is requested but denied, or if the Presiding Officer concludes after a Part 16 hearing that the Order was properly issued, the procedures in section 5-7-6 will be followed to notify the HCT/P establishment of the requirement to cease manufacturing.

5-9 CIVIL MONEY PENALTIES AND NO-TOBACCO-SALE ORDERS

5-9-1 Civil Money Penalty Authorities

The Civil Money Penalties (CMPs) included in this section are monetary penalties that are assessed by FDA for violations of the FFDCa (the Act) or the PHS Act. Information on electronic products civil penalties under section 539(b) of the Act can be found in [RPM Chapter 6](#), section 6-6.

CMPs are authorized under the following sections of the Act and the Public Health Service Act. See 21 CFR 17.2 for the current maximum CMP amounts allowed.

1. Food

- a. Section 303(f)(2)(A) of the Act, 21 U.S.C. 333(f)(2)(A) – Authorizes CMPs against any person who introduces, or delivers for introduction, into interstate commerce an article of food that bears or contains a pesticide chemical residue that is unsafe within the meaning of section 408(a).

Section 303(f)(2)(B) of the Act, 21 U.S.C. 333(f)(2)(B), states that a CMP cannot be assessed against any person who grew the article of food. That section also prohibits use of the seizure, injunction, or criminal authorities if a CMP is assessed.

2. Drugs

- a. Section 303(b)(2) of the Act, 21 U.S.C. 333(b)(2) – Authorizes CMPs against a manufacturer or distributor:
 - i. if one of their representatives, during the course of their employment or association with the manufacturer or distributor, is convicted of selling, purchasing, or trading or offering to sell, purchase, or trade a prescription drug sample in violation of section 503(c)(1) and 301(t); or is convicted of violating any State law that prohibits the sale, purchase, or trade of a prescription drug sample subject to section 503(b), or the offer to sell, purchase, or trade such a prescription drug sample.

- b. Section 303(b)(3) of the Act, 21 U.S.C. 333(b)(3) – Authorizes CMPs against a manufacturer or distributor:
 - i. if they fail to report to the Secretary any convictions of their representatives for violations of section 503(c)(1) or a State law because of the sale, purchase, or trade of a prescription drug sample, or the offer to sell, purchase, or trade a prescription drug sample.
- c. Section 303(f)(3)(A) of the Act, 21 U.S.C. 333(f)(3)(A) – Authorizes CMPs against any person who violates section 301(jj), 21 U.S.C. 331(jj), by:
 - i. failing to submit the certification required by section 402(j)(5)(B) of the Public Health Service Act, 42 U.S.C. 282(j)(5)(B), when submitting certain human drug applications and submissions to FDA, or knowingly submitting a false certification;
 - ii. failing to submit clinical trial information required by section 402(j) of the Public Health Service Act, 42 U.S.C. 282(j); or
 - iii. submitting clinical trial information under section 402(j), 42 U.S.C. 282(j), that is false or misleading in any particular under section 402(j)(5)(D), 42 U.S.C. 282(j)(5)(D).
- d. Section 303(f)(3)(B) of the Act, 21 U.S.C. 333(f)(3)(B) – Authorizes CMPs (in addition to those under section 303(f)(3)(A) above) if a violation of section 301(jj), 21 U.S.C. 331(jj), is not corrected within the thirty (30)-day period following notification under section 402(j)(5)(C)(ii), 42 U.S.C. 282(j)(5)(C)(ii), for each day of the violation after such period until the violation is corrected.
- e. Section 303(f)(4)(A) of the Act, 21 U.S.C. 333(f)(4)(A) – Authorizes CMPs against any responsible person (defined in section 505-1, 21 U.S.C. 355-1) that violates a requirement of:
 - i. Section 505(o), 21 U.S.C. 355(o) – Postmarket studies and clinical trials; labeling;
 - ii. Section 505(p), 21 U.S.C. 355(p) – Risk evaluation and mitigation strategy; or
 - iii. Section 505-1, 21 U.S.C. 355-1 – Risk evaluation and mitigation strategies.
- f. Section 303(g)(1) of the Act, 21 U.S.C. 333(g)(1) – Authorizes CMPs against a person who is a holder of an approved new drug application for a prescription drug, or the holder of an approved biologics license application, if such person disseminates or causes another party to

disseminate a direct-to-consumer advertisement that is false or misleading.

- g. Section 307(a) of the Act, 21 U.S.C. 335b (a) – Authorizes CMPs against any person that:
 - i. Knowingly made or caused to be made, to any officer, employee, or agent of the Department of Health and Human Services (“DHHS personnel”), a false statement or misrepresentation of a material fact in connection with an abbreviated new drug application (ANDA);
 - ii. bribed or attempted to bribe or paid or attempted to pay an illegal gratuity to “DHHS personnel” in connection with an ANDA;
 - iii. destroyed, altered, removed, or secreted, or procured the destruction, alteration, removal, or secretion of any material document or other material evidence which was the property of or in the possession of DHHS for the purpose of interfering with DHHS’s discharge of its responsibilities in connection with an ANDA;
 - iv. knowingly failed to disclose to an officer or employee of DHHS, a material fact relating to any drug subject to an ANDA, which such person had an obligation to disclose;
 - v. knowingly obstructed a DHHS investigation into any drug subject to an ANDA;
 - vi. has an approved or pending drug product application and has knowingly used in any capacity the services of a person who was debarred under section 306; or
 - vii. is debarred and, during the period of debarment, provided services in any capacity to a person that had an approved or pending drug product application.

3. Biologics

- a. Section 303(f)(3)(A) of the Act, 21 U.S.C. 333(f)(3)(A) – Authorizes CMPs against any person who violates section 301 (jj), 21 U.S.C. 331 (jj), by:
 - i. failing to submit the certification required by section 402(j)(5)(B) of the Public Health Service Act, 42 U.S.C. 282(j)(5)(B), when submitting certain biological product applications and submissions to FDA, or knowingly submitting a false certification;
 - ii. failing to submit clinical trial information required by section 402(j) of the Public Health Service Act, 42 U.S.C. 282(j); or
 - iii. submitting clinical trial information under section 402(j), 42 U.S.C. 282(j), that is false or misleading in any particular under section 402(j)(5)(D), 42 U.S.C. 282(j)(5)(D).
- b. Section 303(f)(3)(B) of the Act, 21 U.S.C. 333(f)(3)(B) – Authorizes CMPs (in addition to those under section 303(f)(3)(A) above) if a violation of section

301(jj), 21 U.S.C. 331(jj), is not corrected within the thirty (30)-day period following notification under section 402(j)(5)(C)(ii), 42 U.S.C. 282(j)(5)(C)(ii), for each day of the violation after such period until the violation is corrected.

- c. Section 303(f)(4)(A) of the Act, 21 U.S.C. 333(f)(4)(A) – Authorizes CMPs against any responsible person (defined in section 505-1, 21 U.S.C. 355-1) that violates a requirement of:
 - i. section 505(o), 21 U.S.C. 355(o) – Postmarket studies and clinical trials; labeling;
 - ii. section 505(p), 21 U.S.C. 355(p) – Risk evaluation and mitigation strategy; or
 - iii. section 505-1, 21 U.S.C. 355-1 – Risk evaluation and mitigation strategies.
- d. Section 303(g)(1) of the Act, 21 U.S.C. 333(g)(1) – Authorizes CMPs against a person who is a holder of an approved new drug application for a prescription drug, or the holder of an approved biologics license application, if such person disseminates or causes another party to disseminate a direct-to-consumer advertisement that is false or misleading.
- e. Section 351(d)(2) of the Public Health Service Act, 42 U.S.C. 262(d)(2) – Authorizes CMPs for any violation of an order issued by the Secretary to immediately recall a batch, lot, or other quantity of a licensed biological product that presents an imminent or substantial hazard to the public health.
- f. Section 2128(b)(1) of the PHS Act, 42 U.S.C. 300aa-28(b)(1) – Authorizes CMPs against any vaccine manufacturer who intentionally destroys, alters, falsifies, or conceals any record or report required by 42 U.S.C. 300aa-28(a)(1) or (2).

The penalty applies to the person who intentionally destroyed, altered, falsified, or concealed such record or report; to the person who directed that such record or report be destroyed, altered, falsified, or concealed; and to the vaccine manufacturer for which such person is an agent, employee, or representative. Each act of destruction, alteration, falsification, or concealment is treated as a separate occurrence.

4. Devices

- a. Section 303(f)(3)(A) of the Act, 21 U.S.C. 333(f)(3)(A) – Authorizes CMPs against any person who violates section 301(jj), 21 U.S.C. 331 (jj), by:
 - i. failing to submit the certification required by section 402(j)(5)(B) of the PHS Act, 42 U.S.C. 282(j)(5)(B), when submitting certain device applications and submissions to FDA, or knowingly submitting a false certification;

- ii. failing to submit clinical trial information required by section 402(j) of the PHS Act, 42 U.S.C. 282(j); or
 - iii. submitting clinical trial information under section 402(j), 42 U.S.C. 282(j), that is false or misleading in any particular under section 402(j)(5)(D), 42 U.S.C. 282(j)(5)(D).
- b. Section 303(f)(3)(B) of the Act, 21 U.S.C. 333(f)(3)(B) – Authorizes CMPs (in addition to those under section 303(f)(3)(A) above) if a violation of section 301(jj), 21 U.S.C. 331(jj), is not corrected within the thirty (30)-day period following notification under section 402(j)(5)(C)(ii), 42 U.S.C. 282(j)(5)(C)(ii), for each day of the violation after such period until the violation is corrected.
- c. Section 303(f)(1)(A) of the Act, 21 U.S.C. 333(f)(1)(A)² – Authorizes CMPs against any person who violates a requirement which relates to devices. Except that, in accordance with Section 303(f)(1)(B), CMPs do not apply to:
 - i. any person who violates the requirements of section 519(a) (e.g., Medical Device Reporting), or section 520(f) (Quality System Regulation), unless the violations constitute a significant or knowing departure from the requirements, or a risk to public health;
 - ii. any person who commits minor violations of section 519(e) (Device Tracking), or section 519(g) (only with respect to correction reports), if the person demonstrates substantial compliance with such section; or
 - iii. violations of section 501(a)(2)(A) which involve one or more devices which are not defective.

Note that a person accredited under section 704(g)(2) who is substantially not in compliance with the standards of accreditation under that section, or who poses a threat to public health or fails to act in a manner that is consistent with the purposes of that section, is considered to have violated a requirement of the Act that relates to devices.

5. Mammography Facilities

- a. Section 354(h)(3) of the PHS Act, 42 U.S.C. 263b(h)(3) – Authorizes CMPs for:
 - i. Failure to obtain a certificate as required by 42 U.S.C. 263b(b);

² This section has been variously referred to as section 303(f) and 303(g) because of confusion at the time of legislative enactment in 1990. The explanatory notes to FDAAA of 2007 clarified that this section is now subsection (f).

- ii. Each failure by a facility to substantially comply with, or each day on which a facility fails to substantially comply with, the quality standards established under 42 U.S.C. 263b(f), codified at 21 CFR Part 900, or the requirements of 42 U.S.C. 263b(d)(1)(B)(ii);
- iii. Each failure to notify a patient of risk as required pursuant to 42 U.S.C. 263b(h)(2); and
- iv. Each violation, or for each aiding and abetting in a violation of, any provision of, or regulation promulgated under, this section by an owner, operator, or any employee of a facility required to have a certificate.

6. Tobacco Products

- a. Section 303(f)(9) of the Act, 21 U.S.C. 333(f)(9)– Authorizes CMPs for violations of tobacco product requirements.
- b. Section 303(f)(9)(A) of the Act, 21 U.S.C. 333(f)(9)(A)– Authorizes CMPs against any person who violates a requirement of the Act which relates to tobacco products. Such person shall be liable to United States for a civil penalty in an amount not to exceed \$15,000 for each such violation, and not to exceed \$1,000,000 for all such violations adjudicated in a single proceeding.
- c. Section 303(f)(9)(B) of the Act, 21 U.S.C. 333(f)(9)(B) – Authorizes enhanced CMPs in an amount not to exceed \$250,000 per violation, and not to exceed \$1,000,000 for all such violations adjudicated in a single proceeding.
 - i. if a person intentionally violates a requirement of:
 - Section 902(5) of the Act, 21 U.S.C. 387b(5), which deems a tobacco product to be adulterated if it is, or purports to be or is represented as, a tobacco product which is subject to a tobacco products standard established under section 907 unless such tobacco product is in all respects in conformity with such standard.
 - Section 902(6) of the Act, 21 U.S.C. 387b(6), which deems a tobacco product to be adulterated if (A) it is required by section 910(a) to have premarket review and does not have an order in effect under section 910(c)(1)(A)(i). or (B) it is in violation of an order under section 910(c)(1)(A).
 - Section 904 of the Act, 21 U.S.C. 387d, which requires each tobacco product manufacturer or importer, or agents thereof, to submit health information to the Secretary, as set forth in that section.
 - Section 908(c) of the Act, 21 U.S.C. 387h(c), which requires the appropriate person (including the manufacturers,

importers, distributors, or retailers of the tobacco product) to immediately cease distribution of such tobacco product if the Secretary finds that there is a reasonable probability that the product contains a manufacturing or other defect not ordinarily contained in tobacco products on the market that would cause serious, adverse health consequences or death.

- Section 911(a) of the Act, 21 U.S.C. 387k(a), which prohibits any person from introducing or delivering for introduction into interstate commerce any modified risk tobacco product unless an order issued pursuant to subsection 911(g) is effective with respect to such product.
- ii. if a person violates a requirement of:
- Section 911(g)(2)(C)(ii) of the Act, 21 U.S.C. 387k(g)(2)(C)(ii), which requires that an order under section 911(g) be conditioned on the applicant's agreement to conduct postmarket surveillance and studies and to submit to the Secretary the results of such surveillance and studies to determine the impact of the order on consumer perception, behavior, and health and to enable the Secretary to review the accuracy of the determinations upon which the order was based in accordance with a protocol approved by the Secretary.
 - Section 911(i)(1) of the Act, 21 U.S.C. 387k(i)(1), which requires with respect to a tobacco product for which an applicant obtained an order under section 911(g)(1) that the applicant conduct postmarket surveillance and studies for such a tobacco product to determine the impact of the order issuance on consumer perception, behavior, and health, to enable the Secretary to review the accuracy of the determinations upon which the order was based, and to provide information that the Secretary determines is otherwise necessary regarding the use or health risks involving the tobacco product. The results of postmarket surveillance and studies must be submitted to the Secretary on an annual basis.

Tobacco Retailers

- a. Section 103(q)(2)(A) of the Family Smoking Prevention and Tobacco Control Act, Public Law 111-31 ("Tobacco Control Act") 21 U.S.C. 333 – Authorizes CMPs against tobacco retailers for violating restrictions promulgated under section 906(d) of the Act, including the regulations at 21 CFR Part 1140. This section provides reduced penalties for retailers with an approved training program. At this time, and until FDA issues

regulations setting the standards for an approved training program, all applicable CMPs will proceed under the reduced penalty schedule.

- b. Section 303(f)(8) of the Act, 21 U.S.C. 333(f)(8) – Authorizes imposition of a no-tobacco-sale order prohibiting the sale of tobacco products against a particular tobacco retail outlet that has committed “repeated violations” of restrictions promulgated under section 906(d) of the Act, including the regulations at 21 CFR Part 1140. (Section 103(q)(1)(A) of the Tobacco Control Act defines “repeated violation” as including at least 5 violations of particular requirements over a 36-month period at a particular retail outlet that constitute a repeated violation). A no-tobacco-sale order may be imposed with a CMP.

5-9-2 Reduction Of Civil Money Penalties For Small Entities

The Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA) (Public Law 10-121) was enacted on March 29, 1996, and seeks to improve the regulatory climate for small entities by, among other things, requiring agencies to establish small entity penalty reduction policies.

The FDA may reduce CMPs for small entities as mandated by the SBREFA and the Presidential Memorandum of April 21, 1995 (60 FR 20621, April 26, 1995).

5-9-3 Civil Money Penalty Recommendations

When it is determined that CMP is the appropriate course of action, the Division’s Compliance Officer should submit the recommendation package to the appropriate Center, except for tobacco retailers.

1. DIVISION RESPONSIBILITIES

The Division recommends a CMP by transmitting to the Center, at a minimum, a cover memorandum recommending the action, a draft cover letter to respondents and a Complaint accompanied by the supporting evidence.

2. CENTER RESPONSIBILITIES

The Center is responsible for the technical, regulatory, policy and scientific review of the Division’s CMP recommendation. Changes to proposed recommendations should be made only after discussion with the Division’s compliance staff.

Note: The Center for Tobacco Products (CTP) will initiate CMP actions against tobacco retailers.

NOTE: The Center with jurisdiction over the product under study in an applicable clinical trial for which there has been a violation of section 301(jj) of the Act will initiate CMP actions under sections 303(f)(3)(A) and 303(f)(3)(B) of the Act.

Approved referrals transmitted to DE should include intact original case files organized as submitted from the Division, the Center's proposed changes to respondent letters/Complaint and the Center's approval memorandum providing Center contact information, justification for imposition of civil money penalties and other information necessary to review and process the action.

3. DE RESPONSIBILITIES

OSPOP, DE will review the appropriateness of the action and the adequacy of the draft cover letter to respondents and Complaint to ensure compliance with existing procedures, policies, regulations or statutes. Changes to proposed recommendations should be made only after discussion with the Center and the Division's compliance staff.

Approved recommendations to OCC should include DE's transmittal memorandum, DE's proposed changes to the respondent letters/Complaint and original materials submitted by the Division and Center.

4. OFFICE OF CHIEF COUNSEL RESPONSIBILITIES

OCC Approved recommendations will be processed in accordance with procedures outlined in 21 CFR Part 17; or, in the case of civil penalties authorized under section 307(a) of the Act, in accordance with the procedures in section 307(b) of the Act.

5-10 DISQUALIFICATION OF CLINICAL INVESTIGATORS

5-10-1 Purpose

This procedure describes the process, including timeframes, for initiating disqualification proceedings – from completion of the inspection to issuance of the Notice of Initiation of Disqualification Proceedings and Opportunity to Explain (NIDPOE) to the clinical investigator. In addition, it includes the processes and timeframes for follow-up to a response to a NIDPOE, through issuance of a Notice of Opportunity for Hearing (NOOH).³ This procedure is intended for use by center Bioresearch Monitoring (BIMO) Program Units, staff in the Office of the Commissioner (OC), the Office of Regulatory Affairs (ORA), and OCC. Adherence to the procedures described in this chapter will assist the agency in achieving a uniform approach to the disqualification process.

³ Criteria for initiation of disqualification proceedings are included in the [Compliance Program Guidance Manual](#) (CPGM) [7348.811 for Bioresearch Monitoring: Clinical Investigators](#), Part V. B.

5-10-2 Criteria for Initiating Disqualification Proceedings

Criteria for initiating disqualification proceedings are found at 21 CFR 312.70, 511.1(c), and 812.119 and are discussed in the clinical investigator CPGM [7348.811](#). See footnote 2. As discussed in t [Part V](#). B.), a decision to initiate disqualification proceedings often starts with a decision to classify the EIR as Official Action Indicated (OAI).

5-10-3 Initiating the Disqualification Process

When a clinical investigator inspection reveals serious noncompliance, communication with the center is essential, as noted in the CPGM [7348.811 Part II](#), B.3., since collection of appropriate supporting evidence is vital. In addition, this will allow the center to provide advance notice to OCC and other appropriate offices if it appears a recommendation for disqualification may be considered. It is also recommended that the division investigator contact the Bioresearch Monitoring Specialist in DE, OSPOP/DE, ORA who can provide assistance with the process and serve as an additional resource. The resulting EIR, with violations indexed to the supporting evidence and exhibits appropriately tabbed for easy reference, should be forwarded to the center BIMO Program Unit **within thirty (30) days** of completion of the inspection.

Because center BIMO Program Units need to expeditiously review inspectional findings that warrant initiation of disqualification proceedings, center BIMO Program Units should review and prioritize **within fourteen (14) days of receipt** all EIRs with a division office recommendation of OAI, with or without a recommendation for clinical investigator disqualification. Center BIMO Program Units should review and prioritize EIRs with Referred to Center (RTC) designations within a similar timeframe to determine if any warrant an OAI designation and therefore possible initiation of disqualification proceedings. EIRs with division office recommendations other than OAI or RTC may also support initiation of disqualification proceedings. When a BIMO reviewer identifies such an EIR, the timeframes discussed below would apply.

Once the potential for initiating disqualification proceedings is identified, the assigned BIMO reviewer analyzes the inspectional findings and determines if the findings are supported by sufficient evidence of regulatory significance. The BIMO reviewer also determines if the division office has received any response to the Form FDA 483 and requests a copy of all responses. After reviewing all materials associated with the most recent inspection, as well as any information available in the center's inspectional files/databases, the BIMO reviewer drafts his/her rationale for or against initiation of disqualification proceedings. Consultation with office/center regulatory personnel and/or OCC attorneys during this review may be warranted.

If initiation of disqualification proceedings is not deemed warranted, the BIMO reviewer prepares a document explaining that conclusion, for review by his/her supervisor, and initiates other appropriate actions. If initiation of disqualification proceedings is deemed warranted, the BIMO reviewer prepares appropriate documentation for the

administrative record which will support all subsequent steps in the process. The portion of the administrative record supporting issuance of a Notice of Initiation of Disqualification Proceedings and Opportunity to Explain (NIDPOE) will include such documents as:

1. A chart and/or memo summarizing the significant inspectional findings and regulatory violations supporting the disqualification action;
2. A chronology/inspectional history of the clinical investigator;
3. A draft NIDPOE (see [Exhibit 5-21](#) for sample); and
3. A draft Consent Agreement (see [Exhibit 5-22](#) for sample)

The NIDPOE file should be appropriately indexed to facilitate review by center management, OCC, and ORA. For example, violations cited in the NIDPOE should be indexed to the supporting evidence supplied with the EIR. During preparation of the NIDPOE file, the BIMO Program Unit should alert all relevant center and Agency offices that this file is in preparation to ensure timely review. Review of the NIDPOE file should proceed according to center-specific procedures. The NIDPOE file should be ready for OCC review **within four (4) months from receipt of the EIR**. OCC should concur, with comments/suggested edits as necessary, or arrange for a discussion with appropriate center BIMO personnel if non-concurrence is considered, **within four (4) months** of receipt of the draft NIDPOE.

Upon receipt of OCC concurrence, the BIMO Program Unit incorporates any changes and/or additions to the NIDPOE letter and routes the entire NIDPOE file to the appropriate center official for signature of the NIDPOE. This signature should be affixed **within fourteen (14) days** of receipt of OCC concurrence. The NIDPOE file and signed NIDPOE are returned to the BIMO Program Unit. The BIMO Program Unit should issue the signed NIDPOE, with the consent agreement, to the clinical investigator within one **(1) working day of receipt** and distribute copies to the appropriate Agency units, as described below.

The NIDPOE directs the clinical investigator to write or call the center, **within fifteen (15) working days**, to arrange for an informal conference or to indicate the intent to respond to the allegations in writing. If the clinical investigator chooses to submit a written response, the NIDPOE directs him/her to respond **within thirty (30) working days of receipt of the NIDPOE**.

5-10-4 Notice of Initiation of Disqualification Proceedings and Opportunity to Explain (NIDPOE)

Delivery

A NIDPOE should be sent by certified mail (return receipt requested), or other method that documents transmission and receipt of delivery. If such delivery is unsuccessful, the center should contact the Director, Investigations Branch (DIB) in the appropriate

division office and request that the NIDPOE be hand delivered by Agency personnel. The Center will provide the division with addresses and alternative locations for delivery.

Distribution

The issuance of a NIDPOE is a significant regulatory action and appropriate Agency units should be promptly advised of its issuance. These include:

[To blind copy electronically, send to the relevant party at firstname.lastname@fda.hhs.gov; for hardcopy distribution at the White Oak (WO) campus, include the building and room numbers]

OCC; WO31/WO32

DFOI; ELEM-1029

OGCP; WO32-5129

ORA, Division of Enforcement; WO32 *[Originating Center - Center files and distribution]*

[Relevant Division Office - Division Personnel, including the Division Director; the Director, Investigations Branch; and the Division investigator(s)]

CDER, OSI; WO51

CBER, BIMO Group; HFM-664

CVM, BIMO Group; HFV-234

CDRH, BIMO Group; WO66, BIMO@cdrh.fda.gov

CFSAN, BIMO Group; HFS-205

The Center will forward the NIDPOE to the Center's FOI program for redaction and posting on FDA's webpage [Clinical Investigators - Disqualification Proceedings](#).

5-10-5 Consent Agreements

After issuance of the NIDPOE, the clinical investigator may choose to enter into a consent agreement with FDA. A finalized consent agreement between FDA and the clinical investigator terminates the administrative proceedings in this matter. The option of entering into a consent agreement with the Agency is available at any time throughout the disqualification proceedings, up to the issuance of the Commissioner's Decision under 21 CFR 16.95 or issuance of a notification of disqualification under 21 CFR 312.70, 511.1(c), or 812.119. The consent agreement may be signed by an FDA official as listed in Staff Manual Guide 1410.21- General Redelegations of Authority, Paragraph 1.P. As noted above, a sample consent agreement is included in Exhibit 5-22.

5-10-6 Informal Conference with the Clinical Investigator

In the NIDPOE, the center will offer the investigator the opportunity to submit an explanation in writing, or at the investigator's option, in an informal conference. If the clinical investigator submits a written response, the regulations do not require the center to hold an informal conference, but the center may choose to do so. If an informal

conference is requested, the center should schedule it as soon as possible, usually **within thirty (30) days** of the request.

At the informal conference, the clinical investigator may be accompanied by a representative of his/her choosing and may provide documents for the record. A clinical investigator may submit written materials to FDA within fifteen (15) days after the informal conference.

At a minimum, FDA personnel attending the conference will include staff from the center BIMO Program Unit and counsel from OCC who reviewed the NIDPOE. FDA may also include other personnel with appropriate expertise or relevant experience with the case (e.g., a Medical Officer from the review team for the study involved, the FDA division investigator who conducted the inspection at the clinical investigator's site). The center should make arrangements for the informal conference, notify all pertinent parties of the specifics, and arrange to have the discussion transcribed for the administrative record. These informal meetings should be scheduled for up to two (2) hours. Because the meeting is informal, there is no prescribed format, but the meeting should address all allegations listed in the NIDPOE.

Following the informal conference, the center will provide a copy of the written transcript to the clinical investigator. The center, in consultation with OCC, should promptly review any new explanation or evidence provided by the clinical investigator. If it no longer appears that disqualification is warranted, alternatives such as a detailed corrective action plan may be considered. The center BIMO Program Unit should notify the clinical investigator in writing **within thirty (30) days** of the informal conference of this decision not to proceed with the disqualification and include the specifics of any such alternative corrective action plan.

If the clinical investigator's explanation is not accepted by the Center, disqualification is still warranted and the center should issue a Notice of Opportunity for Hearing (NOOH) to the clinical investigator.

5-10-7 The Notice of Opportunity for Hearing (NOOH)

If a clinical investigator fails to respond to a NIDPOE or the center determines that the clinical investigator's written or oral explanation is inadequate, the regulations provide that the clinical investigator be given an opportunity for a regulatory hearing under 21 CFR part 16 on the question of whether the investigator is eligible to receive test articles and eligible to conduct any clinical investigation that supports an application for a research or marketing permit for products regulated by FDA. Center BIMO Program Units should prepare an NOOH using the sample document provided in Exhibit 5-23. The NOOH should be prepared **within thirty (30) days** of a center's decision that a clinical investigator's written or oral explanation is inadequate, or after it is clear the clinical investigator has chosen not to respond to the NIDPOE. The center should consult with OCC during the preparation of the NOOH and clear the NOOH in

accordance with center procedures. The center-approved NOOH and the administrative record (which includes the NIDPOE file and all follow-up information/documents) should be forwarded to OCC for review and clearance. **Within thirty (30) working days** of receipt, OCC should concur or provide comments to the BIMO Program Unit as to what is necessary to achieve concurrence with the NOOH.

Within five (5) working days of OCC concurrence, after incorporating any OCC additions/changes, the BIMO Program Unit forwards both the paper and electronic copies of the NOOH and the administrative record to the Division of Enforcement (DE). DE has **five (5) working days** to review and clear the NOOH for signature. If DE, during its review, proposes substantive changes to the NOOH, DE will clear their proposed changes with OCC, who will consult with the BIMO Program Unit when necessary. **Within five (5) working days**, after clearing any substantive DE additions/changes with OCC as necessary (OCC will consult with the Center as necessary and notify the center about any changes); DE forwards the NOOH and the administrative record to the Associate Commissioner for Regulatory Affairs (ACRA) in the ORA for review and signature; and, requests redaction of the NOOH by the Center's FOI office and posting of the redacted NOOH on FDA's website. The ACRA should sign the NOOH, or provide comments to DE as to what is necessary to achieve his/her signature, **within five (5) working days** of receipt. Upon receipt of the signed NOOH (**within one (1) working day**), DE date stamps and issues the NOOH to the clinical investigator and/or his/her counsel by certified mail (return receipt requested) or other documented method of transmission. If delivery of the NOOH cannot be confirmed, the Director, DE, will contact the local division office and request that the NOOH be delivered by FDA personnel. The Center will provide the division with addresses and alternative locations for delivery. Upon issuance of the NOOH, DE provides a copy of the signed NOOH to the center BIMO Program Unit, which is responsible for appropriately distributing copies of the NOOH within FDA (see NIDPOE distribution list above). The Center will forward the NOOH to the Center's FOI program for redaction and posting on FDA's webpage, Clinical Investigators - Disqualification Proceedings.

The NOOH provides that the investigator has ten (10) working days from receipt of the NOOH to request a hearing. If the clinical investigator does not respond within this time frame, the clinical investigator will be deemed to have waived the right to a regulatory hearing and the Agency will make a decision on the matter based on the facts available to the Agency.

DE will advise the center BIMO Program Unit of the response (or lack thereof) to the NOOH letter after ten (10) working days. Subsequent actions are discussed and determined by the center BIMO Program Unit, OCC, and DE as outlined in the Sample Notice of Opportunity for Hearing in Exhibit 5-23. The center BIMO Program Unit is responsible for preparing a memo for summary decision regarding the disqualification.

See SMG 7711 for details of the process to be followed after issuance of a NOOH.

The clinical investigator disqualification proceedings described above are summarized in the flowchart found in Exhibit 5-20.

5-11 EXHIBITS

Exhibit 5-1	Model Section 305 Notice
Exhibit 5-2	Model Charge Sheet
Exhibit 5-3	Model Charges
Exhibit 5-4	Legal Status Sheet
Exhibit 5-5	Information Sheet
Exhibit 5-6	Summary Format - Section 305 Meeting
Exhibit 5-7	Notification of Non-Prosecution
Exhibit 5-8	Timeframes for Administrative Detention of Food (AD of Food) – Appellant's Deadlines
Exhibit 5-9	Timeframes for AD of Food – FDA's Deadlines
Exhibit 5-10	Model General Summary of Information – AD of Food
Exhibit 5-11	Model Comprehensive Statement – AD of Food
Exhibit 5-12	Model Hearing Confirmation Letter – AD of Food
Exhibit 5-13	5-13 A MODEL LETTER – FINAL DECISION ON APPEAL OF ADMINISTRATIVE DETENTION ORDER – CONFIRMATION
	5-13B MODEL LETTER – FINAL DECISION ON APPEAL OF ADMINISTRATIVE DETENTION ORDER – REVOCATION
	5-13C MODEL LETTER TERMINATING APPEAL – Administrative Detention of Food
Exhibit 5-14	Model General Summary of Information (Administrative Detention of Devices (AD of Devices)
Exhibit 5-15	Model Comprehensive Statement – AD of Devices
Exhibit 5-16	Examples of Detailed Statements – AD of Devices
Exhibit 5-17	Model Hearing Confirmation Letter – AD of Devices
Exhibit 5-18	Model Order – AD of Devices
Exhibit 5-19	Model Order of Retention, Recall, And/Or Destruction
Exhibit 5-20	Disqualification Proceedings Flowchart
Exhibit 5-21	Sample NIDPOE
Exhibit 5-22	Sample Consent Agreement
Exhibit 5-23	Sample Notice of Opportunity for Hearing (NOOH)

Exhibit 5-1 MODEL SECTION 305 NOTICE

In reply refer to: Sample No. Product

Firm Name and Individual Date

Street Address

City, State, Zip

Investigation by this Administration indicates your responsibility for violations of the Federal Food, Drug, and Cosmetic Act, and other Federal Laws, as described in the attached Charge Sheet, with respect to the following:

Shipment of an article labeled in part "Cream Style White Sweet Corn Net Weight 5 lb 10 oz" by (Firm, Location), to (Firm, Location), on or about (date).

A meeting has been scheduled for (day, date, time) at (location), to give you an opportunity to present your views on this matter. The enclosed **INFORMATION SHEET** explains the purpose and nature of the meeting, and how you may reply. If no response is received on or before the date set, our decision on whether to refer the matter to the Department of Justice for prosecution will be based on the evidence in hand.

By direction of the Secretary of the Department of Health and Human Services:

/s/

Compliance Officer

(IMPORTANT: NOTE ALL ENCLOSURES CAREFULLY)

Enclosures:

Legal Status Sheet (3) Charge Sheet Information Sheet Regulations

Exhibit 5-2 MODEL CHARGE SHEET

CHARGE SHEET

(In Connection with Enclosed Section 305 Notice)

Sample Nos.	Sample Nos.
Sample #, Product	Sample #, Product
Sample #, Product	Sample #, Product
Sample #, Product	Sample #, Product
Sample #, Product	Sample #, Product
Sample #, Product	Sample #, Product
Sample #, Product	Sample #, Product

PROHIBITED ACT: Section 301(a) of the Federal Food, Drug, and Cosmetic Act. The introduction or delivery for introduction into interstate commerce of any food that is adulterated.

CHARGES: The articles are adulterated in the following respects: Sample #)
Sample #)
Sample #) They contain insect fragments and rodent hair fragments. Sample #)
Sample #) Sample #) Sample #) Sample #)
Sample #) It contains insects, insect fragments, and rodent hair fragments.
Sample #) It contains insect fragments.
Sample #) It contains insect larvae, insect fragments, and rodent hair fragments.

All Samples) The factory in which the articles were prepared was infested with insects and rodents which may have contaminated the articles

Exhibit 5-3 MODEL CHARGES**SPECIMEN CHARGE**

(Do not quote the section of the Act listed below on the Charge Sheet)

Adulterated Foods**402(a)(1)**

- The soybeans contain an added poisonous or deleterious substance, namely, crotalaria seeds, which may render them injurious to health.
- The frozen eggs contain added salmonella microorganisms, pathogenic bacteria, which may render them injurious to health.
- The article contains selenium, a poisonous or deleterious substance, in a quantity that would ordinarily render it injurious to health.

402(a)(2)(A)

- The articles contain an added deleterious substance, namely, metal fragments, which is unsafe since it is not required in the production of this food and can be avoided by good manufacturing practices.
- The cod fillets contain oxytetracycline that is unsafe, since oxytetracycline is not required in the production of this food and can be avoided by good manufacturing practices.

NOTE: Generally, the use of Section 402(a)(2)(A) as a basis for charges should be limited; other sections, such as 402(a)(1), are usually preferred.

402(a)(2)(B)

- The berries contain heptachlor, which is not generally recognized as safe, and for use of which a tolerance has not been prescribed by regulation.
- The cabbage contains excessive Toxaphene.

402(a)(2)(C)

- The article contains a food additive, namely lead, which is unsafe within the meaning of Section 409(a) since its use and intended use are not in conformity with a regulation or exemption in effect.

402(a)(2)(D)

- The meat intended for human food contains a new animal drug, namely MGA, which is unsafe in that there is no approved new animal drug application in effect for this use.

402(a)(3)

- The article contains insect parts and insect excreta.

- The article contains rodent excreta pellets.
- The nuts are rancid.
- Some of the cans contain decomposed salmon.
- The catsup contains decomposed tomatoes
- The peanut butter contains grit.

402(a)(4)

- The factory (warehouse) in which it was prepared and packed (held) was infested with rodents and insects, which may have contaminated it.

402(a)(5)

- Some of the boxes contain emaciated and diseased birds.
- Some of the boxes contained birds that were not slaughtered but that died from other causes.

402(a)(7)

- The article has been subjected to radiation, not provided for by the Food Additives Regulations.

402(b)(1)

- The article is deficient in Vitamin B.
- The butter contains less than 80% milkfat.

402(b)(2)

- Mineral oil has been used to replace part of the vegetable oil.
- Chicory has been used in part instead of coffee.

402(b)(3)

- Blemished, old potatoes have been colored and waxed to resemble new potatoes and to conceal the blemishes.

402(b)(4)

- The ground pepper contains ground olive seeds.
- The poppy seeds are brown and have been artificially colored to appear to be blue poppy seeds.

402(c)

- The article contains a color additive, namely, "butter yellow," not permitted by regulation for use in food.
- The article contains a color additive, namely, FD&C Purple Number 8, for which no tolerance has been established

402(d)

- Some pieces of the candy contain a metallic toy.
- The candy is filled with alcohol

402(e)

- The article contains vegetable oil that is rancid.
- The milk used to manufacture the butter contained flies and manure

Misbranded Foods

403(a)

- The label falsely represents it to contain a significant amount of honey but the amount present, if any, is inconsequential.
- The label bears statements that falsely represent, in the setting in which they are presented, that the article will supply an unusually large amount of protein in a quantity which is low in calories, and that the article is therefore of significant value for weight reducing.
- The labeling falsely represents that the product contains copper, folic acid, cobalt and calcium pantothenate.
- The label falsely represents the article to be canned peas, whereas the article is canned spinach

403(b)

- It was offered as lemon extract by the price list sent to the consignee on or about May 2, XXXX, but it is in fact an extract of lemon grass oil

403(c)

- The word "Imitation" on the label is in type of smaller size and less prominence than the type in which the words "Vanilla Extract" appear.
- The label fails to bear the name "Imitation Strawberry Preserves."

403(d)

- The can has a depressed top and bottom and contains a thick corrugated inner liner, which give the container the appearance of containing more nuts than it does.
- The container is slack-filled

403(e)(1)

- The label fails to bear the name of the manufacturer, packer, or distributor.

403(e)(2)

- The label statement "net weight 4 oz." is inaccurate.

- The article is short weight.

403(f)

- The statement of ingredients on the label is inconspicuous.
- The name and address of the manufacturer is printed on the cellophane bag in white ink and lacks contrast with the white candy mints contained therein

403(g)(1)

- The article is represented as raspberry preserves but contains less fruit than the standard of identity requires.
- The article purports to be French dressing but contains less fat than specified in that standard.
- The egg noodles are deficient in egg solids content

403(g)(2)

- The article is bleached flour but the label does not state that it is bleached.
- The article purports to be enriched macaroni, and its label fails to bear the name of that food.
- The article purports to be Fruit Butter, but its label fails to bear the name of the optional ingredient, lime juice, present in the food.

403(h)(1)

- The article contains excessive blemished fruit but its label does not bear the statement of substandard quality prescribed for canned peaches.
- Its quality falls below the standard for canned tomatoes, since it contains excessive peel.

403(h)(2)

- The cans are underfilled but the label does not bear the statement of substandard fill prescribed for canned peas.

403(i)(1)

- The article is ground cinnamon but its label does not bear the name "ground cinnamon."

403(i)(2)

- Flour is present but is not named in the label listing of ingredients.
- The label fails to bear a statement of ingredients of the article by their common or usual names.

403(j)

- Its label fails to bear a statement of the percentage of the USRDA for the vitamins B(1), B(2), niacinamide and the mineral iron, as required by the special dietary regulations.
- The label fails to state the percent by weight of methylcellulose present; and in juxtaposition with name of such constituent, the word "non-nutritive," as required by the special dietary regulations

403(k)

- The labeling fails to state the fact that a chemical preservative has been added.
- The article is artificially colored, but its labeling fails to state that fact

403(l)

- The oranges contain biphenyl (diphenyl applied post harvest), but its shipping container fails to bear labeling declaring the name and function of the pesticide chemical

403(m)

- The article is a color mixture but its label does not declare the name of the color components contained therein

Adulterated Drugs

501(a)(1)

- The aspirin tablets contain rodent hairs.

501(a)(2)(A)

- The plant in which the aspirin tablets were manufactured was infested with rodents which may have contaminated them.

501(a)(2)(B)

- The door of the sterile filling room was left open while filling bottles of an eye solution.
- The methods used in its packing do not conform to current good manufacturing practices in that Isopropyl alcohol is labeled as Citrate of Magnesia.

501(a)(3)

- Its container is composed in part of lead, which may render the contents injurious to health.

501(a)(4)(A)

- The color used is in excess of the limits prescribed in the regulations.

501(a)(4)(B)

- FD&C Red #4 intended for use in a drug for internal administration, and such use is for coloring purposes only.

501(a)(5)

- The article is a new animal drug and there is no approved new animal drug application in effect for this drug.

501(a)(6)

- The cattle feed contains a new animal drug, namely Carbadox, which is unsafe in that there is no approved new animal drug application in effect for this use.

501(b)

- The article purports to be an official NF drug but fails to comply with the compendium's standard for strength.
- It contains cresol, a substance not permitted by the U. S. Pharmacopeia Monograph for Water for Injection, which the drug purports to be.
- Magnesium carbonate, which the NF formula requires in Solution of Magnesium Citrate, has been replaced by sodium carbonate

501(c)

- The article contains Neomycin Sulfate which is below the potency declared on the label.
- The quality of the article namely, Rubber Prophylactics, falls below that which it is purported to possess

501(d)(1)

- The article has been mixed or packed so as to reduce its quality or strength.

501(d)(2)

- P-aminosalicylic acid has been substituted in part for conjugated para-amino salicylic ascorbate.

Misbranded Drugs

502(a)

- Its labeling represents it as a treatment for influenza and related diseases, but it is not an effective treatment for these diseases.
- The article falsely claims that it will remove ascarids from hogs

502(b)(1)

- Its label does not bear the name and place of business of the manufacturer.

502(b)(2)

- Its label does not bear an accurate statement of the quantity of contents.

502(c)

- The statement "24 tablets" appears on the back label and is on a pink label in red type

502(e)(1)(A)(i)

- The label does not show that the drug is aspirin.

502(e)(1)(A)(ii)

- The quantity of bromide per tablet is not stated on the label.
- Its label fails to list all of the active ingredients.

502(f)(1)

- The directions do not state the uses of the drug.
- Its (O-T-C drug) labeling does not contain directions adequate for the treatment of diabetes, for which use the drug is recommended in advertising (as distinguished from labeling).
- The prescription drug lacks adequate full disclosure information.

502(f)(2)

- The labeling does not warn against use of the drug in case of nausea, vomiting, abdominal pain, or other symptoms of appendicitis.
- The labeling gives no warning that use of the drug in excess of what the directions call for may result in nervousness and sleeplessness.

502(g)

- It is not packaged in tight containers as required by the United States Pharmacopoeia

502(i)(1)

- The container is slack-filled.

502(i)(2)

- It is an imitation of citrate of magnesia.

502(i)(3)

- The article, namely argel leaves, is offered for sale as senna.

502(j)

- It is dangerous to health when one tablet is taken every three hours as recommended in the labeling.
- It is dangerous to health when taken in the dosage suggested in its labeling

502(m)

- The label fails to provide directions for use to preclude adding excessive color additive to the drug.

502(n)(1)

- The advertisement for Miltown which appeared in the May 19, 20XX edition of the Pleasant Medical Journal did not show the established name.

502(n)(2)

- • The advertisement for "Triple Sulfa" tablets which appeared _____ etc. did not list the active ingredients by their established names.

502(n)(3)

- The advertisement for "Triple Sulfa" tablets which appeared in the May 19, 20XX edition of _____ contained or recommended indications for use or a dosage recommendation, but not the brief summary of side effects, contraindications, and effectiveness.

502(o)

- The potassium chloride tablets were manufactured in an unregistered plant

503(b)(4)(A)

- The label for the article, namely chloralhydrate, does not bear the symbol "Rx only".

503(b)(4)(B)

- • The aspirin tablet label bears the symbol "Rx only," but the drug is not entitled to such designation.

505(a)

- The article, namely, Meproamate, is a new drug and was shipped in interstate commerce without an approved new drug application

Cosmetics

601(a)

- The article contains paraphenylenediamine, a coal tar dye which is a deleterious substance, but its label does not carry adequate warnings or directions to make a preliminary patch test before use.
- It contains formaldehyde, a deleterious substance.

601(b)

- Some of its components contain rodent excreta pellets

601(c)

- The plant in which the article was prepared was infested with rodents

601(d)

- Its container is composed in part of lead

601(e)

- The color used is not authorized by the regulations (or is in excess of the limits prescribed in the regulations.)

602(a)

- The article is represented as containing a substantial amount of lanolin, but lanolin is a minor constituent of the cream

5-1-2

602(b)(1)

- The label for the eye shadow does not bear the name and location of the manufacturer, namely, New York Pencil Co., Inc., New York, N.Y.

602(b)(2)

- The article does not bear a statement of the quantity of contents.

602(c)

- The statement of the quantity of contents appears on the bottom of the container (oval jar)

602(d)

- The nontransparent container is composed of an outer and inner wall with a 1/8 inch space between the walls

602(e)

- The label fails to provide directions for use to preclude adding excessive color additive to the cosmetic

Title 42

351(a)

- The Source Plasma (Human) was drawn and shipped from an unlicensed establishment.
- The label fails to bear the expiration date and license number of the establishment

351(b)

- The label states the blood is Hgb negative, but the records show the unit is Hgb positive.
- The donor number on the unit label is false.
- The product is pooled serum, but the label falsely states it was drawn from one donor

351(c)

- Inspection of the establishment by a duly authorized investigator was refused

351(e)

- Officers of your firm interfered with the investigator in the performance of his duties by refusing to provide necessary records for his review

Title 18, Section 1001

- The firm was aware that test animals had died, but concealed that fact.
- You advised FDA Investigators that you had no connection with the study, knowing the statement to be false.
- The study that was submitted with NDA 80-125 contains fictitious entries.
- The documents submitted in support of your application contain false statements.

Exhibit 5-4 LEGAL STATUS SHEET

SAMPLE NO: _____

A. STATUS OF FIRM AT TIME OF ALLEGED VIOLATIONS

Date _____

Full name of firm _____

Please check and fill in appropriate section below:

1. Corporation ☐ Year Incorporated _____ Under laws of what state? _____

Names and Titles of principal officers

(include first name and middle initial)2. Partnership ☐

Name of each partner

(include first name and middle initial)3. Sole Ownership ☐

Name of Owner

(include first name and middle initial)**B. STATUS OF FIRM AT PRESENT TIME**

Date: _____

Same as above ☐ Different ☐

Full name of firm _____

1. Corporation ☐ Year Incorporated _____ Under laws of what state? _____

Names and titles of principal officers

(include first name and middle initial)

2. Partnership

Name of each partner

(include first name and middle initial)

3. Sole Ownership

Name of Owner

(include first name and middle initial)

Signature _____

Title _____

Exhibit 5-5 INFORMATION SHEET

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

INFORMATION SHEET IN CONNECTION WITH ENCLOSED SECTION 305 NOTICE

OBJECT OF THE MEETING

This meeting is scheduled to give the person or persons who appear to be responsible for the violations of the **Federal Food, Drug, and Cosmetic Act**, and other Federal Laws, as specified in the attached Charge Sheet an opportunity to explain voluntarily any circumstances connected with the preparation, handling, shipment, or sale of the articles involved which would indicate that criminal action should not be taken. You are not compelled, however, to answer. Any civil action which may have been taken against the goods involved, such as seizure, does not preclude prosecution of those responsible for the violation: the meeting concerns the possible criminal action only. A copy of the Federal Food, Drug, and Cosmetic Act and regulations for its enforcement may be had upon request.

NATURE OF THE MEETING

This meeting is informal and confined to questions of fact. For your convenience in submitting required information concerning the status of your firm both on the date of response to this notice and on the date of alleged violation, the attached Legal Status forms may be filled out and returned with your answer, whether written or by personal appearance. Your answer may consist of the disclosure of any pertinent facts, letters, files, guaranties, shipping documents, analyses, arguments, etc., which you feel may present valid reasons why you should not be prosecuted.

GUARANTIES

In the case of articles that are adulterated or misbranded when introduced in interstate commerce the Federal Food, Drug, and Cosmetic Act (the Act) places responsibility on the interstate shipper, even though he may be only the distributor and not the manufacturer. Distributors may relieve themselves of responsibility if they hold a legal guaranty under Section 303(c) of the Act. If the articles were sold to you by a person residing in the United States and guaranteed by such person to comply with the provisions of the Act, you should submit:

- Evidence of that fact, and
- A statement as to whether the product at the time of the apparent violation by you was in the identical condition and bore the same labels as when received by you from the guarantor, and

- The full name of the person who, if called upon, can identify the pertinent records and testify to the facts as you present them.

HOW TO ANSWER

You may appear in person or by attorney or other designated representative, or you may submit your response in the form of a letter in lieu of personal appearance. If written response is made, please submit your letter and all accompanying documents in **triplicate**. Documents submitted at personal appearance should be in **triplicate**. **All documents should be conspicuously identified by the reference number shown on the upper right corner of the Section 305 Notice.**

RESULT OF THE MEETING

After the meeting has been held and all the facts considered, if it is the conclusion of the Secretary of the Department of Health and Human Services that prosecution should be recommended, the facts in the matter will be transmitted to the Department of Justice for appropriate action.

FORM FDA 466a (7/80) PREVIOUS EDITION IS OBSOLETE.

Exhibit 5-6 SUMMARY FORMAT - SECTION 305 MEETING

SUMMARY

FIRM AND INDIVIDUAL CITED: SAMPLE NO. AND PRODUCT:

DATE OF MEETING:

WHERE HELD:

PRESENT:

(List attendees - name, title, etc.)

WRITTEN SUMMARY

Compliance Officer_____

_____Division

(distribution)

Exhibit 5-7 NOTIFICATION OF NON-PROSECUTION

Dear _____:

Pursuant to 21 CFR 7.85(h), this is to advise you of the decision not to proceed with criminal prosecution of (firm name and/or individual name or names) based on the charges set forth in the Section 305 Notice dated__.

This decision is based on the evidence we have at this time and does not preclude the initiation of criminal prosecution, based in whole or in part on any or all of the charges set forth in the Notice, should new evidence or subsequent violations of the law reveal the need for such action. In such case, a new Section 305 Notice will issue except as provided in 21 CFR 7.84(a)(2) and (3)

Division Director

EXHIBIT 5-8 DEADLINES FOR ADMINISTRATIVE DETENTION OF FOOD**Appellant's Deadlines**

Action	Perishable Food	Non-perishable Food
Requesting a Hearing	Two (2) calendar days Request for hearing must be included in request for appeal.	Four (4) calendar days Notice of intent to request a hearing must be filed within four (4) calendar days of receipt of detention order—or FDA will not grant the hearing. Request for hearing must be filed within ten (10) calendar days from receipt of detention order.
Filing an Appeal	Two (2) calendar days Appeal must be filed within two (2) calendar days of receipt of detention order (the appeal may or may not include a request for a hearing)	Ten (10) calendar days Appeal must be filed within ten (10) calendar days of receipt of detention order.

EXHIBIT 5-9 TIMEFRAMES FOR ADMINISTRATIVE DETENTION OF FOOD

	FDA's Deadlines
Holding a Hearing	Two 2 calendar days If the Appeal includes a request for a hearing, and FDA grants the request, the hearing must be held within two (2) calendar days after the date the appeal is filed.
Written Report of the Hearing	Noon of the fifth (5 th) calendar day The presiding officer must issue a written report that includes a proposed decision confirming or revoking the detention by noon on the fifth (5 th) calendar day after the appeal is filed. The hearing participants have four (4) hours to submit comments. The presiding officer must issue a decision on the appeal within five (5) calendar days after the appeal is filed. [See "Decision on an Appeal (with or without a hearing)" below]
Decision on an Appeal (with or without a hearing)	Five (5) calendar days If a detention order is appealed, the presiding officer must issue a decision on the appeal confirming or revoking the detention within (five) 5 calendar days after the appeal is filed. If the presiding officer fails to confirm or terminate the detention order within this time frame, the detention is deemed terminated.
Seizure of Perishable Foods	Four (4) calendar days to send recommendation to DOJ If FDA initiates a seizure action against Perishable Food, FDA will send the seizure recommendation to the Department of Justice within four (4) calendar days after the detention order is issued, unless extenuating circumstances exist. If the fourth (4 th) calendar day is not a working day, OCC must advise DOJ on the last working day before the deadline of its plans to recommend a seizure and will send the seizure as soon as practicable on the first working day after the non-work day.

Exhibit 5-10 MODEL GENERAL SUMMARY OF INFORMATION – Administrative Detention of Food***[Division Letterhead]**

Date
Mr. John E. Smith
XYZ, Inc.
123 Smith Lane
Anywhere, MS

RE: Administrative Detention Order DO **[insert #]**

Dear Mr. Smith:

Pursuant to section 16.24(f) of Title 21 of the Code of Federal Regulations (21 CFR 16.24(f)), this letter provides notice of matters to be considered at the hearing requested as part of your appeal of administrative detention order DO **[insert #]**. As authorized under section 304(h) of the Federal Food, Drug, and Cosmetic Act (Act), the U.S. Food and Drug Administration (FDA) administratively detained **[insert description of food]** located at **[insert location]** on **[insert date]** because the Agency has reason to believe that the food is **[adulterated or misbranded]**. You may find the Act and its implementing regulations through links on FDA's home page at www.fda.gov.

[If the administrative detention is based, in whole or in part on CLASSIFIED information, consult with OCC on the classified information and insert the following:

FDA's decision to administratively detain the food is based [in whole or in part] on classified information. In accordance with 21 CFR 1.406, FDA will not provide you with this information. [Insert a statement about the general nature of our basis for the detention, if the classified information and its source can be safeguarded.]

[If the administrative detention is not based on CLASSIFIED information, insert the following:

FDA's decision to administratively detain your food is based on the following information:

[Insert a comprehensive statement of the basis for the administrative detention, including applicable misbranding or adulteration charges. Also provide a general summary of the information that FDA will present at the hearing in support of the administrative detention.

Examples of sources of supporting information for the summary include, but are not limited to:

1. Form FDA 483 Inspectional Observations that documents objectionable conditions or practices
2. Establishment Inspection Report (EIR) including Exhibits, which describe, in detail, objectionable conditions or practices observed, including product manufacturing information, responsible individuals, and documents collected
3. Sample information including Collection Reports and analytical results or data analysis
4. The food label and labeling
5. Affidavits relating to the adulteration or misbranding
6. Records (e.g., supplier, manufacturer, and distribution records)
7. Epidemiological data from Centers for Disease Control and Prevention or other public health officials that establishes an association between the detained food with foodborne illness
8. Reportable food reports]

If you have any questions regarding information in this letter, you may contact me at **[Division Director's phone number]** prior to the hearing.

Sincerely yours,

Division Director

Exhibit 5-11 MODEL LETTER GRANTING HEARING – Administrative Detention of Food**[Division/OE Letterhead]**

Date
Mr. John E. Smith
XYZ, Inc.
123 Smith Lane
Anywhere, MS

RE: Administrative Detention Order DO **[insert #]**

Dear Mr. Smith:

I am confirming the information discussed during our telephone conversation today regarding the hearing you requested in your appeal of the administrative detention of **[insert description of food]** located at **[insert location]**.

I am granting your request for a hearing and providing additional information about the hearing. The hearing you requested will be held on **[insert date]** at **[insert time]** at the **[insert Division Office, street address, city, state, and Zip Code]**.

The hearing will be a closed hearing because the proceedings constitute an open investigatory record (21 CFR 16.60(a)). This means that only you, your counsel, witnesses, and employees as well as FDA representatives will be allowed to attend.

Under 21 CFR 1.403 a hearing on appeal of a detention order shall be conducted in accordance with 21 CFR part 16 – Regulatory Hearing Before the Food and Drug Administration with the following exceptions:

1. The detention order under 21 CFR 1.393, rather than the notice under 21 CFR 16.22(a), provides notice of opportunity for the hearing and is part of the administrative record of the regulatory hearing under 21 CFR 16.80(a).
2. A request for a hearing must be addressed to the FDA Division Director in whose division the article of food involved is located.
3. The provision in 21 CFR 16.22(b), providing that a person not be given less than three (3) working days after receipt of notice to request a hearing, does not apply.
4. The provision in 21 CFR 16.24(e), stating that a hearing may not be required to be held at a time less than two (2) working days after receipt of the request for a hearing, does not apply.
5. 21 CFR 1.406, rather than 21 CFR 16.24(f), describes the statement that will be provided to an appellant where a detention order is based on classified information.

6. 21 CFR 1.404, rather than 21 CFR 16.42(a), describes the FDA employees, e.g., Division Directors or other officials senior to a Division Director, who preside at hearings.
7. The presiding officer may require that the hearing be completed within one (1) calendar day, as appropriate.
8. 21 CFR 16.60(e) and (f) do not apply to the hearing. The presiding officer must prepare a written report of the hearing. All written material presented at the hearing will be attached to the report. The presiding officer must include as part of the report of the hearing a finding on the credibility of witnesses (other than expert witnesses) whenever credibility is a material issue, and must include a proposed decision, with a statement of reasons. The hearing participant may review and comment on the presiding officer's report within 4 hours of issuance of the report. The presiding officer will then issue the final Agency decision.
9. 21 CFR 16.80(a)(4) does not apply to the hearing. The presiding officer's report of the hearing, and any comments on the report by the hearing participant under 21 CFR 1.403(h), are part of the administrative record.
10. No party shall have the right under 21 CFR 16.119 to petition the Commissioner of Food and Drugs for reconsideration or a stay of the presiding officer's final Agency decision.
11. If FDA grants a request for an informal hearing on an appeal of a detention order, the hearing must be conducted as a regulatory hearing pursuant to regulation in accordance with 21 CFR part 16, except that 21 CFR 16.95(b) does not apply to the hearing. With respect to the regulatory hearing on an appeal of a detention order, the administrative record of the hearing specified in 21 CFR 16.80(a)(1), (a)(2), (a)(3), and (a)(5), and 1.403(i) constitutes the exclusive record for the presiding officer's final decision on an administrative detention. For purposes of judicial review under 21 CFR 10.45, the record of the administrative proceeding consists of the record of the hearing and the presiding officer's final decision.

I am authorized by 21 CFR 10.19 and 21 CFR 16.60(h) to waive, modify, or suspend any provision under 21 CFR part 16. I am modifying 21 CFR 16.60(b), which provides that all parties may confront and conduct reasonable cross-examination of any person (except for the presiding officer and counsel for the parties) who makes any statement on the matter at the hearing. Reasonable questioning will be allowed instead.

If feasible, at least one (1) day before the hearing, you are to provide the Division Director with written notice of, or a copy of, if the Division Director could not reasonably be expected to obtain a copy, any published articles or written information that you intend to present or rely upon at the hearing, as required by 21 CFR 16.24(g). You may provide this information by facsimile: **[insert number]**, electronically: **[insert e-mail]**, or courier: **[insert name and address of Division Director]**.

Any written communication you forward or present to me must be sent by you to all other participants to the hearing as required by 21 CFR 16.44(c).

You are requested to provide at the hearing a brief summary of any lengthy documents you intend to present at the hearing.

If you have any additional questions on the procedures I will follow at the hearing, you may contact me at **[insert phone number]** prior to the hearing.

Sincerely yours,

[Presiding Officer]

Exhibit 5-12 MODEL LETTER DENYING HEARING – Administrative Detention of Food

(Division/OE Letterhead)

Date

Mr. John E. Smith
XYZ, Inc.
123 Smith Lane
Anywhere, USA

RE: Administrative Detention Order DO **[insert #]**

Dear Mr. Smith:

This is a follow-up to our telephone conversation today regarding the hearing you requested as part of your appeal of the administrative detention of **[insert description of food]** located at **[insert location]**.

I am denying your request for a hearing because you have not raised a genuine and substantial issue of fact (21 CFR 16.26(a)). Specifically, **[insert reason why no genuine and substantial issue of fact was raised by the appellant]**.

Sincerely yours, Presiding Officer

Exhibit 5-13A

MODEL LETTER – FINAL DECISION ON APPEAL OF ADMINISTRATIVE DETENTION ORDER – CONFIRMATION

Administrative Detention of Food

[Division/OE Letterhead]

Date

Decision on Appeal –Confirmation

Administrative Detention Order DO **[insert #]**

Mr. John E. Smith
XYZ, Inc.
123 Smith Lane
Anywhere, MS

Dear Mr. Smith:

I am confirming the administrative detention order for **[insert description of food]** located at **[insert location]** because **[insert reason why confirming detention]**.

[If information that supports the administrative detention is, in whole or in part, CLASSIFIED information, insert the following:]

My decision is based **[in whole or in part]** on classified information.

[If information that supports the administrative detention is not CLASSIFIED information, insert the following:]

My decision is based on information you submitted in your appeal [and information presented by all parties at the hearing on the appeal].

The administrative detention is effective until **[insert date]**, unless FDA issues a detention termination notice prior to that date. It is a prohibited act under section 301(bb) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 331(bb), to move an article of food that is subject to administrative detention or to alter or remove any mark or label that identifies the article of food as administratively detained.

Sincerely yours,

[Presiding Officer]

Exhibit 5-13B

MODEL LETTER – FINAL DECISION ON APPEAL OF ADMINISTRATIVE DETENTION ORDER – REVOCATION

Administrative Detention of Food

[Division/OE Letterhead]

Date

Decision on Appeal – Revocation

Administrative Detention Order DO **[insert #]**

Mr. John E. Smith
XYZ, Inc.
123 Smith Lane
Anywhere, MS

Dear Mr. Smith:

I am revoking the administrative detention order for **[insert description of food]** located at **[insert location]** because **[insert why the order is being revoked]**. The administrative detention is terminated as of this date and the food is released. You may remove the labels and tags relating to the detention and return the tags to the Division Director.

[If information utilized to support the administrative detention is, in whole or in part, CLASSIFIED information, insert the following:]

My decision is based **[in whole or in part]** on classified information.

[If information utilized to support the administrative detention is not CLASSIFIED information, insert the following:]

My decision is based on information you submitted in your appeal **[and at the hearing on the appeal]**. Thus, FDA no longer has reason to believe the food is adulterated or misbranded.

Sincerely,

[Presiding Officer]

Exhibit 5-13C

MODEL LETTER TERMINATING APPEAL – Administrative Detention of Food
[Division/OE Letterhead]

Date

Mr. John E. Smith
XYZ, Inc.
123 Smith Lane
Anywhere, USA

RE: Administrative Detention Order DO **[insert #]**

Dear Mr. Smith:

Your appeal of the administrative detention of [insert description of food] located at [insert location] has been terminated because a [seizure action under section 304(a) of the Federal Food, Drug, and Cosmetic Act or an injunction under section 302 of the Federal Food, Drug, and Cosmetic Act] has been filed in court regarding the article of food involved in the detention order (21 CFR 1.402(c)) ([name of case]).

If you have any questions on this termination of your appeal, you may contact the Division at **[insert phone number]**.

Sincerely yours,
[Presiding Officer]

Exhibit 5-14

MODEL GENERAL SUMMARY OF INFORMATION Administrative Detention of Devices

Division Director Letterhead

Date

Ace Plastic Company
11124 Railroad Street
Ogallala, Nebraska 69158

Dear Sir:

This is a General Summary of Information in Support of Detention DN 60011. We intend to present the following information to support our action:

1. Form FDA 483 list of observations issued to Albert C. Edwards, owner of Ace Plastic Company.
2. Establishment Inspection Report dated February 20, 1980.
3. Collection Report for sample of syringes.
4. Pages from Quality Control Log of Ace Plastic Company dated February 18, 1980.
5. Testimony of Sidney H. Rogers, Investigator, reporting his observations and his discussion with Mr. Edwards.

Sincerely yours, Division Director

Exhibit 5-15**MODEL COMPREHENSIVE STATEMENT* Administrative Detention of Devices**

Date

Ace Plastic Co.
11124 Railroad Street
Ogallala, Nebraska 69150

Dear Sir:

The following is a Comprehensive Statement of the Basis for Detention Order DN 60011.
FDA Investigator _____ observations:

Black unidentified spots on the needles and holes in the individual protective packaging of the sterile 2cc syringe led him/her to believe that the devices are adulterated and misbranded resulting in issuing Detention Order number DN 60011 made these observations during his/her (date) inspection of your establishment.

The black spots on the needles and holes in the packages lead us to believe the product is adulterated within the meaning of (1) Section 501(a)(2)(A) of the Federal Food, Drug, and Cosmetic Act (the Act) in that the device has been prepared, packed, or held under insanitary conditions whereby it may have been rendered injurious to health; and (2) within the meaning of Section 501(c) of the Act in that its quality falls below that which it purports or is represented to possess. Further, these same observations lead us to believe that the product is misbranded per Section 502(a) of the Act because the label states the product to be sterile and the holes in the protective wrapper allow the product to be exposed to contamination.

*To be used when the detention order (FDA 2289 Detention Notice) may not serve as the Comprehensive Statement because the "reason for detention" is not described in sufficient detail. When the detention order may serve as the Comprehensive Statement, the letter need only include a copy of the detention order and reference the "reason for detention" as the Comprehensive Statement.

Exhibit 5-16

EXAMPLES OF DETAILED STATEMENTS Administrative Detention of Devices

EXAMPLES OF STATEMENTS UNDER ITEM #15, "REASON FOR DETENTION" THAT PROVIDE SUFFICIENT DETAIL FOR THE FDA 2289 ORDER TO SERVE AS A COMPREHENSIVE STATEMENT:

1. 21 USC Section 351(c) charge.

- Detention order cites adulteration within the meaning of Section 351(c) because the quality of the device falls below that which it claims to possess.
- Comprehensive statement expands upon the charge in the detention order by adding: "...because the labeling specifies that the device measures "x" within ± 3 percent but tests conducted by FDA show that the device only measures "x" within ± 25 percent."

2. 21 USC Section 351(h) charge.

- Detention order cites adulteration within the meaning of Section 351(h) in that the methods used in, etc. (tracking in plain language the applicable portion of the statute) are not in conformity with GMP requirements under 21 USC Section 360j(f) as set forth in 21 CFR Part 820.
- Comprehensive Statement expands upon the charge in the detention order by adding: "...because (citing applicable sections of the GMP regulations and deviations from them, working directly from the FDA 483 but using common, non-statutory language."

3. 21 USC Section 352(a) charge.

- Detention order cites misbranding within the meaning of Section 352(a) in that the labeling for the device, which states that the device will cure the common cold, is false or misleading.
- Comprehensive statements expand upon the charge in the detention order by adding: "...because..."

The same approach should be followed in comprehensive statements where the detention order cites misbranding within the meaning of 21 USC Sections 352(f), (j), etc. The comprehensive statement simply summarizes the factual basis of division's case. If this kind of format is used for a comprehensive statement, the general summary of the information which the division will present in support of the detention (21 USC Section 321(x)(3)) need not consist of anything more than a list of documents (FDA 483, EIR, CR, Analyst Worksheet), including affidavits (for example, where the charge is based on the absence of an approved PMA or an IDE — see 21 USC Section 351(f)).

Exhibit 5-17

MODEL HEARING CONFIRMATION LETTER Administrative Detention of Devices

Division Letterhead

Date

Mr. Albert C. Edwards
President
Ace Plastic Company
11124 Railroad Street
Ogallala, Nebraska 69158

Dear Mr. Edwards:

I am confirming the information listed below discussed during our telephone conversation of today.

The hearing you requested on the appeal of the administrative detention of your devices will be held on ____ at the Kansas City division office, 1009 Cherry Street, Kansas City, MO at 9:00 a.m.

The hearing will be a closed hearing because the proceedings constitute an open investigatory record. This means that only you, your counsel, witnesses, and employees as well as FDA representatives will be allowed to attend.

The regulations on administrative detention 21 CFR 800.55 states that 21 CFR Part 16 will be followed in conducting the hearing, however, the regulations make the following exceptions to Part 16:

1. 21 CFR 16.22(a), concerning the issuance of a separate notice of opportunity for a hearing, is not applicable since the Detention Notice also serves as that notice.
2. 21 CFR 16.22(b), concerning the appeal being sent to the Presiding Officer, is not applicable since the regulations require the appeal to be sent to the Division Director of the division where the devices are located.
3. 21 CFR 16.24(e), concerning not holding the hearing within two (2) days of the appeal, is not applicable because of the short time frames involved. We can hold the hearing within two (2) days of your appeal.
4. 21 CFR 16.42(a), concerning those persons who may act as the Presiding Officer, is not applicable because I have been designated by regulations as the Presiding and Deciding Official.

I am authorized by 21 CFR 10.19 and 21 CFR 16.60(h) to waive, modify, or suspend any provision under 21 CFR Part 16. I am waiving or modifying the following provisions:

1. 21 CFR 16.60(f), which requires the presiding officer to make a recommended decision with statements of reasons to the deciding official, is not applicable because I am the Deciding Official as well as the Presiding Officer in this instance.

2. 21 CFR 16.95(b)(1) and (2) which state that the Administrative Record of a Regulatory Hearing (21 CFR 16.80(a)) is the exclusive record and basis respectively for the decision. The decision will not be based on any material that is not part of the administrative record. I am modifying 21 CFR 16.95(b)(1) and (2), however, because the decision will be based in most cases, on all information presented to me prior to or during the hearing. The decision will not be based on the following information or documents if they are not received or completed by me within the time period necessary for me to review or complete them prior to making a decision as required by the Act or regulation:

a. Information and views I have permitted to be submitted after the hearing, are not part of the official record unless the post hearing submissions and information is submitted within the time specified by me.

b. Any transcript of the hearing.

c. My Report of the Hearing and any comments on the report.

3. That part of 21 CFR 16.60(b) is waived which provides that all parties may confront and conduct reasonable cross-examination of any person (except for the presiding officer and counsel for the parties) who makes any statement on the matter at the hearing. Reasonable questioning will be allowed instead. Reference congressional intent: House of Representatives Report no. 94-853 and 21 CFR 16.5 and 16.60(h).

If feasible, at least one (1) day before the hearing, you are to provide the Division Director with written notice of, or a copy of if the Director could not reasonably be expected to obtain a copy, any published articles or written information you intend to present or rely upon at the hearing as required by 21 CFR 16.24(g).

Any written communication you forward or present to me must be sent by you to all other participants to the hearing as required by 21 CFR 16.44(c).

You are requested to provide at the hearing a brief summary of any lengthy documents you intend to present at the hearing.

If you have any additional questions on the procedures I will follow at the hearing, you may contact me prior to the hearing.

Sincerely yours,

Albert Smith
Division Director

Exhibit 5-18
MODEL ORDER 1/
Administrative Detention of Devices

Division Letterhead

Date

Order

Ace Plastic Company
11124 Railroad Street
Ogallala, Nebraska 69158

Dear Sir:

Based on my review of the material (make brief reference to the documents used by the presiding officer, (e.g. FDA 483, analyst worksheet, published article, CR, EIR, etc. and testimony) presented in the appeal of Detention Order number _____, I hereby order that the Detention Order be confirmed (revoked) because there is (insufficient) reason to believe that the devices are adulterated (misbranded) within the meaning of Section _____ of the Federal Food, Drug, and Cosmetic Act in that _____.

Albert Smith
Division Director

1/ Short Form: To be used when separate written decision/report of the hearing must be prepared later, due to short time frame for the order.

2/ Delete "of section_", and "in that ____" if the detention is revoked.

EXHIBIT 5-19

**MODEL ORDER OF RETENTION, RECALL, AND/OR DESTRUCTION
ORDER OF RETENTION, RECALL, AND/OR DESTRUCTION**

Date Issued: MMM DD, YYYY

Issued To: Name of Responsible Individual

Title

Establishment Name

Address

CITY, ST, ZIP CODE Dear [NAME],

The Food and Drug Administration (FDA) conducted an inspection of your facility at [ADDRESS if different than above] on [MM DD, YYYY], covering the manufacture of human cell, tissue, and cellular and tissue based products (HCT/Ps) subject to Title 21, Code of Federal Regulations, Part 1271 (21 CFR Part 1271). Our review of the information and records examined and collected during the inspection show that certain HCT/Ps received and distributed by your organization may be in violation of 21 CFR Part 1271, as indicated below:

[LIST VIOLATIONS]

- Between [DATE] and [DATE], [QUANTITY/TYPE] HCT/Ps from NNN donors were distributed which were repeatedly reactive for HBsAg/HIV by EIA (21 CFR 1271.85). (Example)

Pursuant to 21 CFR 1271.440, the above referenced HCT/Ps must be:

- Recalled (if distributed), within five (5) working days of receipt of this order, under the supervision of an authorized official of the FDA, and/or
- Destroyed by an acceptable method of disposition, within five (5) working days of receipt of this order, under the supervision of an authorized official of the FDA, or
- Retained until it is recalled, destroyed, the safety of the HCT/P is confirmed, or an agreement is reached with the FDA for its proper disposition under the supervision of an authorized official of the FDA.

[NAME OF FIRM], its owners, employees, and agents shall not distribute or dispose of the HCT/P in any manner except to recall and destroy it consistent with the provisions of the Order. Any other arrangements for ensuring the proper disposition of the HCT/Ps must be agreed upon in writing by [NAME OF FIRM] and an authorized official of the FDA. Such arrangements may include assurance that the HCT/P has been recovered, processed, stored, and distributed in conformance with the attached regulations (21 CFR Part 1271).

All actions taken pursuant to this Order, or otherwise related to the products subject to this Order, shall be taken under the supervision of an authorized Official of the FDA.

Within five (5) working days from the receipt of this Order, the recipient of the written Order or prior possessor of such HCT/P may appeal the Order to the Division Director, [NAME], Division, Food and Drug Administration, [ADDRESS, CITY, STATE, ZIP CODE] and request a hearing on the matter in accordance with 21 CFR Part 16 (copy attached). Such manner of appeal is described in 21 CFR 1271.440(e) of the attached regulations. Failure to request a hearing within the specified time period constitutes a waiver of the right to a hearing.

Please contact [NAME], Compliance Officer, at [TELEPHONE NUMBER], to arrange for supervision of the disposition of the products.

[SIGNATURE BLOCK] Division Director

Attachments (2)
21 CFR Part 1271
21 CFR Part 16

cc: Name and Address of any other HCT/P manufacturer or organization with interest in/jurisdiction over this HCT/P.

HFM-360
HFM-100
HFC-210
HFC-230
GCF-1

Exhibit 5-20: Disqualification Proceedings Flowchart

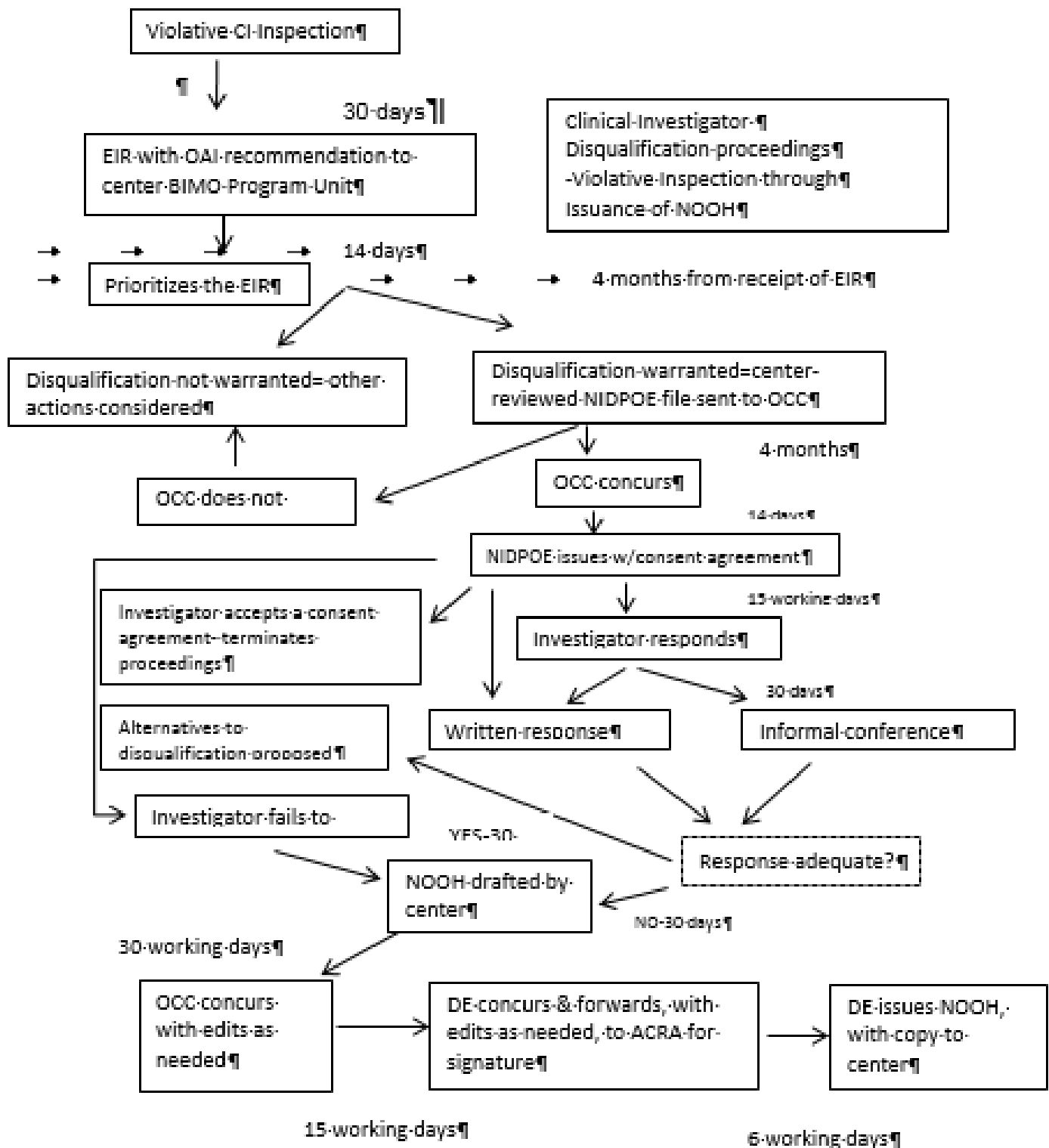


Exhibit 5-21

Sample NIDPOE

[Date]

CERTIFIED MAIL - RETURN RECEIPT REQUESTED

[*Clinical Investigator's Name and Address*]

**NOTICE OF INITIATION OF DISQUALIFICATION PROCEEDINGS AND OPPORTUNITY
TO EXPLAIN**

Dear [Clinical Investigator's Name]:

Between [*inspection start date*] and [*inspection ending date*], Food and Drug Administration (FDA) (hereafter referred to as the "Agency") investigators conducted an inspection of the following clinical study in which you participated: [*title of clinical study*]. This inspection was conducted as part of the FDA's Bioresearch Monitoring Program that includes inspections designed to monitor the conduct of research involving investigational products.

[*For drugs, biologics, devices*] Based on our evaluation of information obtained by the Agency, we believe that you have [repeatedly and/or deliberately violated regulations governing the proper conduct] [and] [repeated and/or deliberately submitted false information in a required report] of clinical studies involving [an investigational new drug] [an investigational device] as published under *Title 21, Code of Federal Regulations (CFR), Part [312, 812]* (copy enclosed).

[*For new animal drugs*] Based on our evaluation of information obtained by the Agency, we believe that you have [repeatedly and/or deliberately failed to comply with the conditions of the exempting regulations] [and] [repeated and/or deliberately submitted false information in a required report], as published under *Title 21, Code of Federal Regulations (CFR), Part 511.1(b)* (copy enclosed).

This letter provides you with written notice of the matters complained of and initiates an administrative proceeding, described below, to determine whether you should be disqualified from eligibility to receive test articles as set forth under 21 CFR [312.70, 812.119, 511.1(c)], and disqualified from eligibility to conduct any clinical investigation that supports an application for a research or marketing permit for products regulated by FDA including drugs, biologics, devices, new animal drugs, food, including dietary supplements, that bear a nutrient content claim or a health claim, infant formulas, food and color additives, and tobacco products.

A listing of the violations follows. The applicable provisions of the CFR are cited for each violation.

[Insert List of Violations]

This letter is not intended to be an all-inclusive list of deficiencies with your clinical studies of investigational [*name of investigational product*]. It is your responsibility to ensure adherence to each requirement of the law and relevant regulations.

On the basis of the above listed violations, FDA asserts that you have [repeatedly and/or deliberately failed to comply with the cited regulations] [*for new animal drugs*: failed to comply with the conditions of the exempting regulations] [and] [repeatedly and/or deliberately submitted false information] and it proposes that you be disqualified as a clinical investigator.

You may reply to the above stated findings, including an explanation of why you should remain eligible to receive test articles and not be disqualified as a clinical investigator, in a written response or at an informal conference in my office. This procedure is provided for by regulation 21 CFR [312.70, 812.119, 511.1(c)].

Within fifteen (15) working days of receipt of this letter, write or call me at [*Center contact phone number*] to arrange a conference time or to indicate your intent to respond in writing. Your written response will need to be forwarded within thirty (30) working days of receipt of this letter. Your reply should be sent to [*Center contact*].

Should you request an informal conference, we ask that you provide us with a full and complete explanation of the violations listed above. You should bring with you all pertinent documents. A representative of your choosing may accompany you. Although the conference is informal, a transcript of the conference will be prepared. If you choose to proceed in this manner, we plan to hold such a conference within thirty (30) days of your request.

At any time during this administrative process, you may enter into a consent agreement with FDA regarding your future use of test articles. Such an agreement would terminate this disqualification proceeding. Enclosed you will find a proposed agreement between you and FDA.

The [*center name*] ("the Center") will carefully consider any oral or written response. If your explanation is accepted by the Center, the disqualification proceeding will be terminated. If your written or oral responses to our allegations are unsatisfactory, or we cannot come to terms on a consent agreement, or you do not respond to this notice, you will be offered a regulatory hearing before FDA, pursuant to 21 CFR Part 16 (enclosed) and 21 CFR Part [312, 812, 511.1]. Before such a hearing, FDA will provide you notice of the matters to be considered, including a comprehensive statement of the basis for the decision or action taken or proposed, and a general summary of the information that will be presented by FDA in support of the decision or action. A presiding officer who has not participated in this matter

will conduct the hearing. The Commissioner will determine whether you will remain entitled to receive test articles. You should be aware that neither entry into a consent agreement nor pursuit of a hearing precludes the possibility of a corollary judicial proceeding or administrative remedy concerning these violations.

Sincerely yours,

[Designated Center Signatory + title] Enclosures (2)

[To blind copy electronically, send to the relevant party at firstname.lastname@fda.hhs.gov; for hardcopy distribution at the White Oak (WO) campus, include the building and room numbers]

OCC; WO31/WO32

DFOI; ELEM-1029

OGCP; WO32-5129

ORA, Division of Enforcement; WO32

[Originating Center- Center files and distribution]

[Relevant Division Office- Division Personnel, including the Division Director; Director, Investigations

Branch; and the Division Investigator(s)] CDER, OSI; WO51

CBER, BIMO group; HFM-664

CVM, BIMO group; HFV-234

CDRH, BIMO group; WO66, BIMO@cdrh.fda.gov

CFSAN, BIMO group; HFS-205

Exhibit 5-22**Sample Consent Agreement****Agreement with Respect to Use of Investigational Products**

The [Center name] ("the Center") of the United States Food and Drug Administration (FDA) and [clinical investigator's name] hereby agree as follows:

1. [Clinical investigator's name] conducted investigational clinical studies, including the following:

2. Between [inspection start date] and [inspection ending date], FDA conducted an investigation of the [number or identify] clinical studies performed by [clinical investigator's name]. As a result of the investigation, FDA determined that these studies contained sufficiently serious deficiencies to warrant the initiation of proceedings to have [clinical investigator's name] declared ineligible to receive investigational [article(s)], pursuant to 21 U.S.C. [appropriate section]. Specifically, FDA concluded that [clinical investigator's name] has:

3. By letter dated [date of NIDPOE letter], the Center provided [clinical investigator's name] with written notice pursuant to 21 CFR [312.70, 812.119, 511.1(c)], of the foregoing violations and the information which led the Center to believe that [clinical investigator's name] [violated FDA regulations governing the use of investigational [article]] [has submitted false information in a required report].
4. In the written notice, the Center also invited [clinical investigator's name] to attend an informal conference to respond to the allegations or to provide a written response to the allegations.
5. [Clinical investigator's name] does not wish to contest the above allegations.
6. Beginning on the date this agreement is executed by the parties, [clinical investigator's name] is not eligible to receive investigational drugs, animal drugs, biologics, devices, or food additives, and is not entitled to conduct any further studies, intended or required for submission to FDA, of investigational articles regulated by FDA. [Clinical investigator's name] agrees to return to the sponsors of the investigational clinical studies in which [he] [she] participated, any and all remaining investigational articles in [his] [her] possession, custody, or control.
7. [Clinical investigator's name] waives [his] [her] opportunity to provide a written explanation and [his] [her] opportunity to attend an informal conference, and to any regulatory hearing pursuant to 21 CFR Part 16 and 21 CFR [312.70, 812.119, 511.1(c)].

8. This consent agreement terminates the administrative proceeding in this present matter, which included the opportunity for an informal conference or a written explanation and a regulatory hearing pursuant to 21 CFR Part 16 and 21 CFR [312.70, 812.119, 511.1(c)].
9. This agreement does not preclude the United States or any other Agency or private entity or person from bringing other proceedings relating to the matters underlying this agreement, and FDA's acceptance of the terms of this agreement may not serve as a defense in any proceedings that the United States or any other Agency or private entity or person may initiate against *[clinical investigator's name]*.
10. *[Clinical investigator's name]* acknowledges that double jeopardy would not attach should the United States bring any criminal charges against [him] [her] in connection with any matter relating to the agreement.
11. By this agreement, *[clinical investigator's name]* is disqualified as a clinical investigator. Disqualification pursuant to this agreement has the same legal effect as being disqualified pursuant to 21 CFR [312.70, 812.119, 511.1(c)] after a Part 16 hearing.
12. FDA is authorized to and will notify the sponsors of the investigational clinical studies in which *[clinical investigator's name]* has participated as an investigator. FDA also will notify the Institutional Review Board (IRB) with authority to oversee clinical studies performed by *[clinical investigator's name]* that *[clinical investigator's name]* has entered into this consent agreement. The notifications may contain a statement of the basis for *[clinical investigator's name]* not being eligible to receive or study investigational articles and the subsequent steps the sponsors and IRB should take.
13. FDA may make copies of this agreement available to the sponsors, IRBs and other interested parties.
14. With respect to this agreement, *[clinical investigator's name]* shall abide by the decisions of FDA; these decisions shall be considered the final decisions by FDA in this matter. FDA's decisions under this agreement shall be reviewed by any reviewing court, if necessary, under the standards set forth in 5 USC 706(2)(A).
15. *[Clinical investigator's name]* name will be added to the list of clinical investigators' entitled "Clinical Investigators- Disqualification Proceedings", which is available to the public on the web pursuant to the Freedom of Information Act (5 USC 552).

Agreed to:

[Clinical investigator's name]

Date

[Designated Center signatory + title]

Date

Exhibit 5-23

Sample Notice of Opportunity for Hearing (NOOH)

[Date]

CERTIFIED MAIL- RETURN RECEIPT REQUESTED

[Clinical Investigator's and/or his/her counsel's Name & Address]

NOTICE OF OPPORTUNITY FOR HEARING

Dear [Clinical Investigator and/or his/her counsel]:

The [Center name] ("the Center"), Food and Drug Administration (FDA) has information indicating that you [repeatedly and/or deliberately violated Federal regulations] [and] [repeatedly and/or deliberately submitted false information in a required report] in your capacity as an investigator in clinical trials with [an investigational new drug] [investigational new animal drug] [an investigational device]. The [violations] [and] [submission of false information] provide(s) the basis for withdrawal of your eligibility as a clinical investigator to receive [investigational new drugs] [investigational new animal drugs] [investigational devices].

Pursuant to section [312.70, 812.119, 511.1(c)] of Title 21, Code of Federal Regulations (CFR), the Center informed you, by letter dated [date of NIDPOE letter], of the specific matters complained of and offered you an opportunity to respond to them in writing or at an informal conference. That same letter gave you the option of entering into a consent agreement with the Agency, thereby terminating any administrative proceedings against you. [State how the investigator responded to this offer whether by not responding, responding in writing, or attending an informal conference]. [The Center has concluded that your [written explanation] [explanation offered at your informal conference] is unacceptable because it fails to adequately address the violations set forth below. [By failing to respond to the letter of [date of NIDPOE letter], you waived your opportunity to provide a written response or for an informal conference.]

Accordingly, you are being offered an opportunity for a regulatory hearing pursuant to 21 CFR Part 16 and [312.70, 812.119, 511.1(c)], on the question of whether you are eligible to receive [investigational new drugs] [investigational new animal drugs] [investigational devices]. You have the right to be advised and represented by counsel at all times. Any regulatory hearing on this matter will be governed by the regulations in 21 CFR Part 16 and the Agency's guidelines on electronic media coverage of administrative proceedings, 21 CFR Part 10, Subpart C. Enclosed you will find copies of these regulations.

A listing of the specific violations follows. These are the matters that will be considered at the regulatory hearing. Applicable provisions of the CFR are cited for each violation.

[Set out violations in numbered paragraphs. Cite CFR provision for each violation.]

Your request for a hearing should be made, in writing, within ten (10) working days of receipt of this letter and should be directed to [*name of DE director*], Director, Division of Enforcement, ORA, Telephone [*DE phone number*], Fax [*DE fax number*]. If no response to this letter is received by that time, you will be deemed to have waived any right to a regulatory hearing, and a decision in this matter will be made based on the facts available to the Agency. No hearing will be held.

A request for a hearing may not rest upon mere allegations or denials but must present specific facts showing that there is a genuine and substantial issue of fact that warrants a hearing. Pursuant to 21 CFR 16.26, a request for a hearing may be denied, in whole or in part, if the Commissioner or his delegate determines that no genuine and substantial issue of fact had been raised by the material submitted. A hearing will not be granted on issues of policy or law. Written notice of a determination of summary judgment will be provided, explaining the reasons for denial of the hearing.

If you wish to respond but do not desire a hearing, you should contact [*Name of DE director*] within the time period specified above and send a written response containing your reply. The letter should state that you waive your right to a hearing and that you want a decision on the matter to be based on your written response and other information available to the Agency.

The Agency's offer to enter into a consent agreement attached to the Notice of Initiation of Disqualification Proceedings and Opportunity to Explain letter dated [*date of NIDPOE letter*] remains available. Entering into a consent agreement would terminate the administrative proceedings, but would not preclude the possibility of a corollary judicial proceeding.

No final decision by FDA has been made at this time on your eligibility to continue to use [investigational new drugs] [investigational new animal drugs] [investigational devices]. Moreover, there will be no prejudgment of this matter if you decline to enter into a consent agreement and decide instead either to request a regulatory hearing or to request that the decision be based on information currently available to the Agency.

Please inform [*name of DE director*] within ten (10) working days of whether you wish to request a hearing or to have this matter resolved by consent agreement or information available to the Agency.

Sincerely,

[Name]
Associate Commissioner for Regulatory Affairs

Enclosures (3)

[To blind copy electronically, send to the relevant party at firstname.lastname@fda.hhs.gov; for hardcopy distribution at the White Oak (WO) campus, include the building and room numbers] OCC; WO31/WO32
DFOI; ELEM-1029

OGCP; WO32-5129

ORA, Division of Enforcement; WO32

[Originating Center- Center files and distribution]

[Relevant Division Office- Division Personnel, including the Division Director; Director, Investigations Branch; and the Division Investigator(s)]

CDER, OSI; WO51

CBER, BIMO group; HFM-664

CVM, BIMO group; HFV-234

CDRH, BIMO group; WO66, BIMO@cdrh.fda.gov

CFSAN, BIMO group; HFS-205

Exhibit 5-24

MODEL LETTER GRANTING HEARING – Administrative Detention of Drugs

[Division/DE Letterhead]

Date
Mr. John E. Smith
XYZ, Inc.
123 Smith Lane
Anywhere, MS

RE: Administrative Detention Order DO **[insert #]**

Dear Mr. Smith:

I am confirming the information discussed during our telephone conversation today regarding the hearing you requested in your appeal of the administrative detention of **[insert description of drug]** located at **[insert location]**.

I am granting your request for a hearing and providing additional information about the hearing. The hearing you requested will be held on **[insert date]** at **[insert time]** at the **[insert Division Office, street address, city, state, and Zip Code]**.

The hearing will be a closed hearing because the proceedings constitute an open investigatory record (21 CFR 16.60(a)). This means that only you, your counsel, witnesses, and employees as well as FDA representatives will be allowed to attend.

I am authorized by 21 CFR 10.19 and 21 CFR 16.60(h) to waive, modify, or suspend any provision under 21 CFR part 16. I am modifying 21 CFR 16.60(b), which provides that all parties may confront and conduct reasonable cross-examination of any person (except for the presiding officer and counsel for the parties) who makes any statement on the matter at the hearing. Reasonable questioning will be allowed instead.

If feasible, at least one (1) day before the hearing, you are to provide the Division Director with written notice of, or a copy of, if the Division Director could not reasonably be expected to obtain a copy, any published articles or written information that you intend to present or rely upon at the hearing, as required by 21 CFR 16.24(g). You may provide this information by facsimile: **[insert number]**, electronically: **[insert e-mail]**, or courier: **[insert name and address of Division Director]**.

Any written communication you forward or present to me must be sent by you to all other participants to the hearing as required by 21 CFR 16.44(c).

You are requested to provide at the hearing a brief summary of any lengthy documents you intend to present at the hearing.

If you have any additional questions on the procedures I will follow at the hearing, you may contact me at **[insert phone number]** prior to the hearing.

Sincerely yours,

[Presiding Officer]

Exhibit 5-25

MODEL LETTER DENYING HEARING – Administrative Detention of Drugs

(Division/OE Letterhead)

Date

Mr. John E. Smith
XYZ, Inc.
123 Smith Lane
Anywhere, USA

RE: Administrative Detention Order DO **[insert #]**

Dear Mr. Smith:

This is a follow-up to our telephone conversation today regarding the hearing you requested as part of your appeal of the administrative detention of **[insert description of drug]** located at **[insert location]**.

I am denying your request for a hearing because you have not raised a genuine and substantial issue of fact (21 CFR 16.26(a)). Specifically, **[insert reason why no genuine and substantial issue of fact was raised by the appellant]**.

Sincerely yours,

Presiding Officer

Exhibit 5-26

MODEL LETTER – FINAL DECISION ON APPEAL OF ADMINISTRATIVE DETENTION ORDER – CONFIRMATION

Administrative Detention of Drugs

[Division/OE Letterhead]

Date

Decision on Appeal –Confirmation

Administrative Detention Order DO **[insert #]**

Mr. John E. Smith
XYZ, Inc.
123 Smith Lane
Anywhere, MS

Dear Mr. Smith:

I am confirming the administrative detention order for **[insert description of drug]** located at **[insert location]** because **[insert reason why confirming detention]**.

[If information that supports the administrative detention is, in whole or in part, CLASSIFIED information, insert the following:]

My decision is based **[in whole or in part]** on classified information.

[If information that supports the administrative detention is not CLASSIFIED information, insert the following:]

My decision is based on information you submitted in your appeal [and information presented by all parties at the hearing on the appeal].

The administrative detention is effective until **[insert date]**, unless FDA issues a detention termination notice prior to that date. It is a prohibited act under section 301(r) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 331(r), to move a detained drug in violation of a detention order under section 304(g).

Sincerely yours,

[Presiding Officer]

MAN-00000#

Exhibit 5-27

MODEL LETTER – FINAL DECISION ON APPEAL OF ADMINISTRATIVE DETENTION ORDER – REVOCATION

Administrative Detention of Drugs [Division/OE

Letterhead]

Date

Decision on Appeal – Revocation Administrative

Detention Order DO **[insert #]**

Mr. John E. Smith XYZ, Inc.
123 Smith Lane
Anywhere, MS

Dear Mr. Smith:

I am revoking the administrative detention order for **[insert description of drug]** located at **[insert location]** because **[insert why the order is being revoked]**. The administrative detention is terminated as of this date and the drug is released. You may remove the labels and tags relating to the detention and return the tags to the Division Director.

[If information utilized to support the administrative detention is, in whole or in part, CLASSIFIED information, insert the following:]
My decision is based **[in whole or in part]** on classified information.

[If information utilized to support the administrative detention is not CLASSIFIED information, insert the following:]
My decision is based on information you submitted in your appeal **[and at the hearing on the appeal]**. Thus, FDA no longer has reason to believe the drug is adulterated or misbranded.

Sincerely,

[Presiding Officer]

Regulatory Procedures Manual

Chapter 6: JUDICIAL ACTIONS

NOTE: For actions resulting from a Current Good Manufacturing Practice (CGMP) or Quality System (QS) inspection of a domestic or foreign drug, biologics, or medical device facility, the firm's profile status information in the Field Accomplishment and Compliance Tracking System (FACTS) should be appropriately updated at each stage in the review process. See "Firm Profile Updates in FACTS" in RPM Chapter 4 for more information.

This chapter contains the following sections:

Section	Topic	Page
6-1	SEIZURE.....	4
6-1-1	Purpose	4
6-1-2	General Guidelines for Seizures.....	4
6-1-3	Types of Seizures.....	8
6-1-4	Direct Reference Seizure Authority.....	10
6-1-5	Approval Process for Seizure and Injunction Cases	10
6-1-6	Responsibilities for Seizure Actions	16
6-1-7	Update Inspections	19
6-1-8	Seizure Accomplishment and Close-Out Documentation.....	20
6-1-9	Disposition of Seized Articles.....	21
6-1-10	Costs of Supervision.....	27
6-1-11	Monitoring Seizure Actions.....	28
6-1-12	Seizures Involving Other Agencies	28
6-1-13	Issuing Press Releases.....	28
6-2	INJUNCTIONS	29
6-2-1	Purpose	29
6-2-2	General Guidelines for Injunctions	29
6-2-3	Definitions.....	30
6-2-4	General Considerations	31
6-2-5	Adequate Notice Preceding Injunction Actions	32
6-2-6	Prerequisites for a TRO or Preliminary Injunction	34
6-2-7	Refreshing Evidence - Updating Inspections.....	35

6-2-8	Approval Process for Seizure and Injunction Cases	36
6-2-9	Responsibilities for Injunction Actions	36
6-2-10	Cover Letter to DOJ	38
6-2-11	Complaint for Injunction	39
6-2-12	Declarations	39
6-2-13	Consent Decree.....	42
6-2-14	Costs of Supervision.....	42
6-2-15	Compliance Follow-Up	43
6-2-16	Vacating Injunctions.....	46
6-2-17	Issuing Press Releases.....	47
6-3	INSPECTION WARRANTS	47
6-3-1	Purpose	47
6-3-2	Inspection Warrants.....	47
6-3-3	Responsibilities.....	48
6-4	SEARCH WARRANTS.....	53
6-4-1	Purpose	53
6-4-2	Search Warrants.....	53
6-4-3	Procedures	53
6-5	PROSECUTION	53
6-5-1	Purpose	53
6-5-2	Referral of Criminal Matters to the Office of Criminal Investigations	53
6-5-3	Special Procedures and Considerations for <i>Park</i> Doctrine Prosecutions...	54
6-5-4	Communication Between OCI and Other FDA Components	56
6-5-5	Processing a Summary and Recommendation	57
6-5-6	Criminal Prosecution after Section 305 Notice.....	57
6-5-7	Criminal Prosecution without Section 305 Notice	59
6-5-8	Contempt of Court; Violation of Probation.....	59
6-5-9	Development of Felony Violation	60
6-5-10	Referrals for Criminal Investigation	61
6-5-11	Information and Indictments	62
6-5-12	Grand Jury Investigations and Secrecy.....	63
6-5-13	Preparation of Summary and Recommendation	63
6-5-14	Submission of Summary and Recommendation Documents.....	70
6-6	CIVIL PENALTIES – ELECTRONIC PRODUCT RADIATION CONTROL	71

6-6-1	Purpose	71
6-6-2	Scope	71
6-6-3	Legal Authority.....	72
6-6-4	Criteria For Recommending Civil Penalties	72
6-6-5	Penalties	76
6-6-6	Director Responsibilities.....	77
6-6-7	CDRH Responsibilities	79
6-6-8	DE Responsibilities	79
6-6-9	OCC Responsibilities.....	80
6-6-10	Appeals	80
6-6-11	Consent Decree of Civil Penalty	80
6-6-12	Case Termination	80
6-6-13	Injunction and Civil Penalties	80
6-7	EXHIBITS	82
	Exhibit 6-1.....	84
	Exhibit 6-2.....	97
	Exhibit 6-3.....	98
	Exhibit 6-4.....	100
	Exhibit 6-5.....	102
	Exhibit 6-6.....	106
	Exhibit 6-7.....	108
	Exhibit 6-8.....	109
	Exhibit 6-9.....	110
	Exhibit 6-10.....	111
	Exhibit 6-11.....	116
	Exhibit 6-12.....	121
	Exhibit 6-13.....	122
	Exhibit 6-14.....	123
	Exhibit 6-15.....	124
	Exhibit 6-16.....	125
	Exhibit 6-17.....	126
	Exhibit 6-18.....	127
	Exhibit 6-19.....	172
	Exhibit 6-20.....	179

Exhibit 6-21	183
Exhibit 6-22	184
Exhibit 6-23	192
Exhibit 6-24	194
Exhibit 6-25	196
Exhibit 6-26	202
Exhibit 6-27	203
Exhibit 6-28	204
Exhibit 6-29	205
Exhibit 6-30	213

6-1 SEIZURE

6-1-1 Purpose

This section provides procedures and instructions for initiating, reviewing, approving, effecting, monitoring, and closing out seizure actions filed under 21 U.S.C. 334.

The United States of America, as plaintiff, proceeds under the Supplemental Rules for Certain Admiralty and Maritime Claims (Supplemental Rules) by filing a Complaint for Forfeiture and obtaining a warrant for arrest, directing the United States Marshal to seize (take possession or place in constructive custody of the court) the article. The theory in a Complaint for Forfeiture is that the article seized is the defendant, and that the government asks the court to condemn the article and declare forfeiture for violation of the law by the article itself. Any interested party, owner, or agent may appear to claim the article by filing a verified claim stating the nature of his/her interest in the article.

Only a proper claimant may litigate on behalf of the seized article. If there is no proper claimant, the United States is entitled to condemnation and forfeiture by default.

6-1-2 General Guidelines for Seizures

Before initiating a seizure case, the compliance officer and ORA management will name a lead coordinator from the affected ORA program or division unit. ORA management will include involved program division directors (PDDs). If the PDD is not located where the action is to take place, the PDD should inform the appropriate district director (DD) before the action occurs.

In this chapter, PDD means the appropriate program division-level official(s) or designee. The PDD must consider several factors.

A. Prior Warning

See procedures under RPM [Chapter 10 - Other Procedures](#), 10-2 "Prior Notice," and RPM [Chapter 4 - Advisory Actions](#), 4-1 "Warning Letters" and specific compliance program and policy guides.

B. Voluntary Hold Or Embargo

If there is concern that the product will be distributed before seizure can be affected, FDA will determine if the dealer will voluntarily hold the product or if an embargo will be necessary. State embargoes should be requested only when there is assurance that the seizure will be approved by the Agency, or when Direct Reference criteria have been met. See [6-1-4, Direct Reference Seizure Authority](#).

For counterfeit drugs and the equipment used to make them, the FDA can first seize and then file a complaint later. See 21 U.S.C. 334(a)(2) and 372(e)(5).

Also, there are provisions in the statute providing for administrative detention of devices, drugs or tobacco products [21 U.S.C. 334(g)], and food [21 U.S.C. 334(h)]. The [RPM Chapter 5](#) sections "Administrative Detention of Food" at 5-3, "Administrative Detention of Drugs at 5-5, and "Administrative Detention of Devices" at 5-6 contain the specifics of the administrative detention procedures.

C. Size Of Lot To Be Seized

Where the retail value of the lot in question is less than two thousand dollars (\$2,000) and when the violation does not involve a hazard to health, refer the facts relating to the violative goods to state or local officials wherever possible.

In some instances, lots larger than \$2,000 may also be disposed of by state or local action and lots smaller than \$2,000 may be seized. For example, seizure of lots valued at under \$2,000 may be appropriate when: there is a documented hazard to health; when the violative product will be incorporated into other products, thus receiving more extensive distribution (e.g., flour containing pesticides is used as an ingredient in baked goods); or when the seizure is necessary to establish a legal precedent.

Certain compliance policy guides, such as the [Compliance Policy Guide \(CPG\) "Sec. 120.500 Health Fraud – Factors in Considering Regulatory Action,"](#) may also have governing limits or conditions for seizure action.

D. Violations Which Appear Easily Corrected

On occasion, seizures may be instituted against articles for violations that could have been easily corrected by the owner without litigation, such as violations of the [Fair Packaging and Labeling Act \(FPLA\)](#). If seizures of this nature are questioned by U.S. Attorneys and judges, it may be pointed out that the violator has refused to correct after prior notice and that, when informal procedures are followed, the expenses incurred to ensure that the goods were in fact brought into compliance would be borne by the government, rather than the violator. In addition, when informal reconditioning is attempted, the violator may ship the goods without bringing them into compliance.

21 U.S.C. 334(d) sets forth the procedure to be followed for attempted reconditioning of articles found in violation. The bond required of the claimant and the supervisory powers given to FDA at the claimant's expense is intended to minimize the chances that the seized goods will be marketed without being brought into compliance.

E. Violations When Agency Has Other Means Of Control

Seizure may not be the most appropriate means of control when the Agency has control over products through other means. An example would be halting a sponsor's unlawful shipments of unlicensed biologics due to possible interference with an ongoing attempt to obtain a license.

F. Voluntary Reconditioning (except for unapproved drugs)

Voluntary destruction of violative lots before seizure should be encouraged; however, any person destroying a lot should be made aware of the [National Environmental Policy Act \(NEPA\)](#) requirements. A copy of the requirements may be obtained from the ORA Safety Management Officer, listed on the FDA Intranet page for "Safety Councils & Committees/EHS Network."

Under no circumstances should FDA witness the voluntary reconditioning of unfit goods, regardless of the nature of the violation or the size of the lot. If a lot is reconditioned, do not recommend seizure unless it is confirmed by examination that the lot is still in violation. If the goods are unapproved drugs, reconditioning is not considered.

G. Continuing Violations

When considering a seizure case for which there is evidence (or the likelihood) of repeated or continuing violations, ORA should also consider whether the public could be better protected by alternative or simultaneous injunctive action. Consideration may also be given to initiating seizure to quickly obtain control of the

articles and, either attempting to obtain injunctive relief in a consent decree or amending the complaint for injunctive relief.

H. Section 702(b) Samples

Section 702(b) of the Federal Food, Drug and Cosmetic Act (also known as the FD&C Act [21 U.S.C. 372(b)]) requires that a part (portion) of the sample of a food, drug, or cosmetic collected for analysis must be provided, upon request, to any person named on the label or the owner thereof, or his attorney or agent. The regulation at 21 CFR 2.10(c) provides certain exceptions to this requirement, but duplicate samples must be available, unless exempted. Failure to provide a part of the sample may jeopardize the seizure action as well as any future action based on analysis of that sample.

I. Preservation Of Shipping Records

The Interstate Commerce Commission regulations (49 CFR 1220.6) require common carriers to keep their records only for one to three years, depending on the type of carrier and record to be kept.

Contested seizure cases or prosecutions following the seizure are often delayed and may not go to trial until more than three years after the shipments were made. In such instances involving shipments by common carrier, steps should be taken to preserve the records that will be essential to prove interstate shipment at the time of trial.

J. Venue, (Place Of Trial) In Actions Arising Under The Federal Food, Drug, And Cosmetic Act

"Venue" means the place or locality of trial. In all seizure actions arising under the Act, the case is initially brought in the court where the goods are located. The court in which the seizure is accomplished has jurisdiction.

21 U.S.C. 334(a) states an article may be seized and condemned by any district court of the United States in whose jurisdiction the article is found.

It is possible under 28 U.S.C. 1404(b) to obtain a transfer of proceedings *in rem* from one judicial division to another judicial division within the same judicial district without the consent of the government.

21 U.S.C. 334(a) and (b) describe situations in which venue can be changed.

21 U.S.C. 334(a) applies to situations in which the number of proceedings is limited by law, i.e., misbranding. 21 U.S.C. 334(b) applies when two or more proceedings involving the same claimant

and the same issues are pending and is concerned primarily with consolidation of cases for trial.

In all requests for change of venue, any FDA staff who become aware of this change should promptly advise the Office of Chief Counsel (OCC) attorney assigned to the case.

6-1-3 Types of Seizures

A. Mass and Open-ended Seizures

The terms “mass” and “open-ended” are used by FDA to distinguish these seizures from “lot-specific seizures,” in which a specific lot or batch of a product is seized. These are internal classifications without independent legal status. They do not appear in the Letter to the U.S. Attorney or in the pleadings, but simply allow the agency to track seizure actions by size and/or impact.

A mass seizure is the seizure of all FDA-regulated products at an establishment/facility. Mass seizures might be conducted when all of the products are held in the same environment (e.g., a filthy warehouse) or are produced under the same conditions (e.g., non-conformance with current Good Manufacturing Practice). A seizure of products in a filthy warehouse is considered a “mass seizure” even though it does not include products that are not susceptible to contamination because of their packaging (e.g., canned goods) or location (e.g., products kept in a freezer or on a floor of the facility where there was no evidence of rodent or insect infestation). Special considerations for mass seizures are described below.

An open-ended seizure is the seizure of all units of a specific product or products, *regardless of lot or batch number*, when the violation is expected to be continuous. An open-ended seizure may be conducted when a specific product is not approved or bears violative labeling, or when the violation otherwise extends to all lots or batches of a product, but not to all of the products in the firm. For example, seizure of all lots or batches of oxygen in a medical gas facility that produces other types of gas would be an open-ended seizure rather than a mass seizure. A mass seizure at this facility would encompass all gasses produced by the firm. Recommendations for open-ended seizures are processed in the same fashion as lot-specific seizures.

B. Multiple Seizures

The term “multiple seizures” is used to describe the seizure of the same product in more than one district court. Multiple seizures may be initiated to prevent the continued distribution or use of violative product at more than one location, particularly product that is dangerous.

Section 304(a)(1) of the Act imposes restrictions on certain multiple seizures, if they are based on the same alleged misbranding and other conditions are not met. Consult this section of the Act, and Division of Enforcement (DE), if necessary, before pursuing an enforcement strategy that will involve multiple seizures of misbranded product.

C. Mass Seizure — Special Considerations

Mass seizures are different from lot-specific seizures because pertinent events and evidence frequently change from the time the investigator documents the violative conditions until the seizure is effected; for example, new lots arrive, FDA-documented lots may have been distributed, and some corrective action may have been taken. These factors can complicate the case and interfere with prompt settlement or other disposition. Thus, prompt action by the agency and the Department of Justice (DOJ) is necessary to effect seizures while the evidence is fresh and accurately reflects the conditions under which the goods are prepared or held.

Therefore, as a general rule, the evidence of violative conditions supporting mass seizure, usually determined on the last day of the Establishment Inspection (EI), should not be more than 30 days old when the case is transmitted to the U.S. Attorney's Office for filing. The 30-day rule does not apply if the deviation is a failure that cannot be corrected within 30 days, for example, the failure to validate a particular procedure or the failure to have had an approval to market a new drug. Provide an explanation in the recommendation why this rule is not applicable when necessary.

Because of the effect that a mass seizure can have on a company, extra care should be taken to ensure that the evidence warrants the proposed action against all articles to be seized. The compliance officer assigned to the case should be thoroughly familiar with the facts. In addition, OCC will prepare a consent decree which may include provisions for injunctive relief, based on material provided by ORA (PDDs as appropriate) and Center.

Special considerations regarding evidence needed in 21 U.S.C. 342(a)(4) mass seizures based on filth are as follows:

1. There must be compelling evidence of significant insanitary conditions (e.g. current live rodent, insect, bird or other vermin activity in the location where the food is to be seized). Physical evidence of filth on each lot of food to be seized is not necessary.
2. The evidence should demonstrate that the infestation has resulted in widespread adulteration under 21 U.S.C 342(a)(4) or

that the live infestation is sufficiently dense and can reasonably be expected to spread to the food to be mass seized.

Examples of mass seizure cases involving 21 U.S.C. 342(a)(4) conditions are available from DE.

6-1-4 Direct Reference Seizure Authority

Direct Reference is an option used when there is clear agency policy, for example, actions based on contamination of certain commodities. Centers have already concurred with stated policy described in documents that provide for Direct Reference. When the CPG (under specific commodities guidance), CPGM, or other guidance provides for Direct Reference, recommendations should be referred directly to DE. Prior to forwarding the recommendation, ORA (PDDs as appropriate) should determine that the article is available for seizure, and that all samples and charges meet the Direct Reference criteria.

6-1-5 Approval Process for Seizure and Injunction Cases

The approval process set forth below applies to both seizure and injunction cases. This process was established to increase collaboration and sharing of evidence at the early stages of case development, to reduce paperwork, to rule-out unsupportable cases, and to shorten approval times for all cases. This process is not meant to diminish the role or responsibility of any participant, nor does it diminish the expectation for quality. ORA is not required to wait until a judicial action is likely to result before communicating concerns to any participants prior to the preliminary assessment (PA) call.

A. Preliminary Assessment (PA) Call:

If all participants have been in communication and are in agreement to move forward with a case, a PA call may be skipped. In such cases, the party proposing the action will prepare a document to be e-signed by the participants and will upload the signed document in MARCS-CMS (CMS) to document concurrence to move forward without performing the PA call. The party proposing the action will inform DE of the decision if it is not one of the involved parties. Given this documentation, the party proposing the action can proceed with uploading the Case Initiation Memo (CIM) and supporting evidence in CMS.

1. Timing:

As soon as practicable after the possibility of conducting a seizure or injunction is first identified, the party proposing the injunction or seizure should arrange a PA call between ORA (PDDs as appropriate) that would be involved in the proposed seizure or injunction, the relevant Center(s), DE, and OCC, or

their designees. When appropriate, the call should occur before the inspection is over. In cases where there is no formal inspection, such as when evidence is developed by an online search, the call should occur after the evidence has been collected.

2. Key Documents:

In advance of the PA call, the party initiating the call should create a preliminary assessment work activity in CMS. CMS is available from FDA's intranet site under *ORA Applications*. The party uploads any evidence supporting a seizure or injunction (e.g., proof of jurisdiction, photographs/ videos, analytical worksheets, the 483, product label and labeling), and labels each entry clearly. Call participants should review the information in CMS information prior to the call when practicable.

3. Participants:

The call should include the PDD as appropriate, the relevant Center(s), DE, OCC Enforcement Advisors and other principals as appropriate. The lead coordinator will select each participant in CMS. A principal may designate a representative authorized to act on behalf of the participant; for example, the Center may designate the appropriate Office of Compliance to represent the Center. OCC may be represented by the appropriate Senior Enforcement Advisor.

4. Topics:

Topics may include: the identity of the firm, type of product involved, problems revealed by the inspection, public health risk, jurisdiction and interstate commerce, potential violations of the statute, supporting evidence, relevant compliance policy documents, prior compliance history, scientific support, and potential for a corporate-wide action.

A suggested PA call agenda check list would include, but not be limited to the following:

- a. PA call-in phone number and pass code
- b. List of ORA attendees (the compliance officer and the investigators would be expected to participate)
- c. List of attendees from the Center(s), DE, OCC Enforcement Advisors, and other officials if necessary (and their telephone numbers to include in CIM)
- d. Establishment(s) name(s), FEI number/registration number, city/state, and brief description of the firm's operation/processing

- e. Product(s) description (thorough), including type of packaging and labeling
- f. The overall and most significant problem(s)
- g. Associated risk(s) and impact
- h. Need for expert and/or health hazard evaluation
- i. The recommended action
- j. Overall charge scheme (e.g., 21 U.S.C. 342 (a)(4) or 355)
- k. A summary of the current significant violations observed, and dates observed
- l. A brief overview of the firm's compliance history, including recalls and reportable events
- m. Relevant compliance policies
- n. Sensitive or controversial issues and concerns
- o. Appropriate notification of and coordination with tribal, state, territories, or local authorities
- p. Supporting evidence in CMS, identified by the naming conventions
- q. Additional evidence possessed by call participants important to the decision whether to proceed with the case (e.g., HACCP plan, process flow, floor plan, photographs, batch records, complaint records, SOPs).

5. Decision:

At the time of the call, the call participants should decide whether to further pursue the seizure or injunction or should identify additional evidence (e.g., sample results that are pending or an expert that is needed). If the participants identified in the PA call decide not to bring a seizure or injunction, the matter will not be processed unless an ***ad hoc*** committee decides otherwise using the procedures described below and in [Chapter 10 - Other Procedures](#), Section 10-8, AD HOC COMMITTEE. The decisions of the participants are not final and may be changed as the case develops based on new information, evidence, or views.

6. Record of call:

The party proposing the action, usually the lead coordinator, will take notes of the views expressed by the participants during the call and will circulate an e-mail or other informal communication briefly summarizing those views to the participants. This summary and any subsequent comments may also be inserted into the Case Initiation Memorandum (CIM) in the appropriate

section, if the decision is to proceed with the case. Please note that these materials may be subject to review in discovery. If you have any questions about what should or should not be shared, please contact OCC.

7. Identify Lead Coordinators and Experts:

Following a decision to pursue a seizure or injunction, the PDD, the Center(s), DE, and OCC should each assign a contact and a single lead coordinator, who will retain those roles of throughout the case wherever possible. The lead coordinator need not have been a call participant. For OCC, the lead coordinators will be the Designated Enforcement Advisor. For the Centers, the lead coordinators may be from the Office of Compliance. The Center must begin to identify, retain, or assign an expert in all cases requiring expert support. Following the call, any new evidence should be uploaded into CMS and a task should be created and the lead coordinators should alert participants to review the new information.

When requesting an expert from the program offices or an outside expert, the center must:

- a. clearly establish what the expert will need to be able to testify about.
- b. review the qualifications of the expert to determine if the expert has the appropriate knowledge and experience based on the facts in the case.
- c. Once the expert has an opportunity to review the evidence, discuss with the expert his/her opinion of the case and identify the strengths and weaknesses in the case. If there are weaknesses identified by the expert, the Center must clearly delineate them to OCC and advise if the Center believes the case should proceed.

8. New Evidence:

Following the call, any new evidence or information should be uploaded into CMS and a task should be created; the lead coordinators should alert participants to review the new information. Notify OCC using the address "[OC OCC Case](#)." mailbox in Outlook.

B. Case Initiation Memorandum (CIM)

As soon as practicable and, at the latest, within 10 working days of the last day of inspection, date of receipt of sample analysis, or date of evidence collection, the party proposing the action should draft a CIM that includes the views of the participants. The party proposing the action should upload the CIM and supporting

evidence into CMS and should notify participants. Notify OCC using the address "[OC OCC Case](#)." mailbox in Outlook. The lead coordinator should convert the PA Work Activity to a case in CMS for concurrent review by the Center, DE and OCC. The Center, DE, OCC, and other participants will not be expected to write separate memoranda, but an expert opinion may need to be obtained and if so, should be added to CMS.

See Exhibit 6-1 for the Format for CIM.

C. Concurrent Review and Use of CMS:

Generally, the lead coordinators should review the CIM and supporting evidence concurrently. They should use CMS to transfer, store, and retrieve relevant documents, set up tasks and log activities.

Each participant must approve the action with regards to the areas within its responsibilities for the case to move forward in the absence of the ad hoc proceeding. If a lead coordinator or any participant believes the case should not move forward, he or she should advise the others assigned to the case as soon as possible. If agreement cannot be reached, the participant(s) with the dissenting view could then write a brief memorandum requesting review by an **ad hoc** committee. See RPM [Chapter 10 - Other Procedures](#) section 10-8, AD HOC COMMITTEE. At the time the request for an **ad hoc** committee is made, the review clock will be tolled and remain tolled until the dispute is resolved. The committee will immediately establish a time schedule for its review of the case. The time schedule and the decision remarks made by the **ad hoc** committee should be made available in CMS.

If the lead coordinators or the **ad hoc** committee decide to proceed with a seizure, the Division will prepare the final letter and legal pleadings and upload them for OCC review. Upon OCC clearance, the Division will submit the legal pleadings and United States Attorney letter, along with an evidentiary package, to the US Attorney's Office/DOJ for filing with the Courts. If the lead coordinators or **ad hoc** committee decide to proceed with an Injunction, OCC will draft the DOJ referral letter and legal pleadings and upload them in CMS. OCC will submit the letter, legal pleadings, and evidentiary package to the Office of Consumer Protection Litigation (OCPL)/DOJ for further review and concurrence. The final signed USA Attorney letter and the filed complaint will be uploaded by the lead coordinator in CMS.

For seizure actions, the Division seizing office is expected to submit via CMS the final Letter to the U.S. Attorney and Complaint for Forfeiture in the form required by the local judicial district in order to assure that there is a clear understanding of the scope and basis

for the seizure action. For Injunction actions, OCC will draft the legal pleadings.

Except for the CIM, formal memoranda are not required; however, it is expected that there are times when additional written documents or opinions may be needed to move the action forward. The participants may use their discretion as to the written form used for such documents, which should be brief and generated within the established time frames. The need for these documents will be determined on a case-by-case basis. To the extent possible, though, the goal is to keep required writing to a minimum.

All written opinions will be available in CMS.

D. Deadlines:

The default timeframe for the two-step process is 10 working days from the last date of the Establishment Inspection (EI), or sample analysis, or evidence collection for the lead coordinator to submit a CIM and 13 working days from the date of the CIM until the time the case and all material or significant evidence including the expert opinion is submitted to DOJ. The deadline may be extended on a case by case basis where circumstances warrant an extension (e.g., because of laboratory results that require additional time, especially complex or voluminous evidence, or an unavoidable logistical delay).

If the deadline is extended, the requestor develops a time extension plan (TEP) for the case which includes deadlines for specific tasks and uploads it in CMS. In emergency situations, the deadline would be shortened as needed. Where possible, the review of routine cases should be completed in the most expeditious manner possible; routine cases may require less than the total of 23 working days.

1. CIM Submission:

The lead coordinator should submit a CIM and all available material and evidence within 10 working days of the last day of inspection, date of receipt of sample analysis, or date of evidence collection.

2. CIM review:

The concurrent review and submission of the case and all material or significant evidence including the expert opinion to DOJ or the onset of negotiations for a consent decree with a firm's counsel should occur within 13 working days after submission of the CIM.

6-1-6 Responsibilities for Seizure Actions

A. Division and Program Responsibilities:

Prior to creating a PA work activity in CMS, the compliance officer will consult with the director of the compliance branch (DCB) and other ORA management (PDD as appropriate) to obtain support for the proposed action. The compliance officer will then create the PA work activity and upload key documents that support the most significant violations, initiate the PA call and PA Work Activity in CMS, and upload a document describing summary views expressed during the PA call.

If the participants agree that a seizure is warranted, the lead coordinator is responsible for writing and uploading the CIM into CMS and notifying the participants. Notify OCC using the address "[OC OCC Case](#)" in Outlook. The contents of the CIM are described below. See also [subsection 6-1-5](#) and [Exhibit 6-1](#).

Additional responsibilities may include:

1. Significant changes to the fact pattern that take place after the initial preliminary assessment call should be communicated to the lead coordinator as soon as possible. The lead coordinator is responsible for uploading the new information and evidence as soon as possible. A new task should be created, and participants should be alerted about the changes.
2. The seizing office must determine whether the lot is available for seizure and must determine which cases require an inspection to refresh evidence (in conjunction with the Center, OCC and DE).

The seizure recommendation should not be forwarded to the U.S. Attorney unless the lot is available. The lead coordinator must prepare the appropriate number of copies of the complaint and the letter to the U.S. Attorney on OCC letterhead. The U.S. Attorney letter will be signed for the Chief Counsel by the Program Compliance Branch Director with his/her initials next to the signature. The documents will then be hand delivered, if practicable, to the U.S. Attorney. All documents should be available in CMS and the parties should be notified when these documents have been made available.

3. When it receives notice that a seizure will be executed, the seizing office is responsible for promptly notifying the appropriate Centers, DE, OCC and any other offices or other tribal, state, local and territorial officials that may be involved in the case, with a copy to the designated OCC contact persons, DoJ/OCPL, and FDA's Office of Media Affairs. The seizing office is also responsible for adding an activity note in CMS and

updating the date fields. ORA (PDD), Centers and DE will work together to determine whether a press release should be drafted, consistent with the procedures outlined in [Exhibit 6-10](#) of this Chapter, Procedures for Issuing Press Releases on Enforcement Actions (Seizures & Injunctions). If a press release is issued, it should be uploaded in CMS.

4. The seizing office is responsible for ensuring appropriate follow-up on seizure actions until the action is adjudicated, and for promptly notifying ORA offices (PDDs and DDs as appropriate, and DE), the appropriate Center, and OCC of the current status of the case. The seizing office should log its activities using the activity notes.
5. The seizing office is responsible for uploading “filed legal documents” and identifying the dates on which the documents were filed in CMS.

B. Center Responsibilities:

1. Appropriate Centers are responsible for providing and obtaining technical/scientific review and support of the case, for assuring that the case meets regulatory policy requirements and for providing a clear indication of scientific support for each charge and each article and for making any medical or technical changes in the complaint for Forfeiture.
2. The Center is responsible for preparing for and participating in the PA call, assigning a lead coordinator (who will retain that role throughout the review process), assigning a technical/scientific expert and retaining and obtaining the concurrence of an outside expert when needed, providing views to ORA for incorporation into a subsequent summary of the PA call in CMS, and providing input for the CIM to include with specificity those charges that can be supported, those that cannot and the rationale within the time frames outlined above.
3. The Center, with input from ORA PDDs as appropriate, and OCC as appropriate, is responsible for determining whether outside experts are necessary to support a case and, if so, for promptly taking steps to secure such support. See RPM [Chapter 10](#) subsection 10-10 “Expert Support for Cases” for further information, including information on paying for expert support.
4. In those situations where an expert memorandum or declaration is needed in order to move the action forward, such as in GMP, HACCP, or similar complex cases, a brief memorandum would be provided by the expert. Experts to be used, whether from the Center or outside, should prepare a brief statement that they

have read the EIRs, CIM, and analytical worksheets, and that based on this review they can support the following conclusions that are specifically listed. If they cannot support any particular conclusions, those should also be listed. The document should state that they are prepared to testify to the above conclusions (in court and by sworn declaration). The Center lead coordinator should upload the expert's CV and bibliography into the CMS case file. The concurrent review process encourages increased communication and collaboration and should allow for early identification of this need for a written opinion/commentary, as well as other requirements needed to move a case forward.

Note: Referral of the case will not be delayed by the Center if an expert has not been identified. However, the Center must be actively pursuing this matter and providing status reports to OCC. The Center will alert DE and OCC promptly if there is difficulty in processing an FDA approval to retain an outside expert. However, OCC may not be able to proceed without the support of expert opinion.

5. Each Center is responsible for monitoring industry-wide state of compliance to determine whether an enforcement strategy should be developed or revised. Consideration should be based on priorities, prior similar actions, nature and scope of the industry. This is necessary to avoid multiple seizures which may have little effect on correcting the problem. In cases involving widespread problems, single device seizures, or multiple seizure campaigns, the seizure should fit into the overall enforcement strategy to correct the problem.

C. ORA Division of Enforcement (DE) Responsibilities:

1. Reviewing, and providing input to the case team as needed during the concurrent review process.
2. Ensuring uniform application of policy and procedures across FDA Centers.
3. Reviewing final agency action; remaining involved in further actions after seized goods are claimed to provide expertise in development of a potential consent decree. NOTE: The Division should discuss the consideration of any regulatory action with the Center, DE and OCC.

D. Office of Chief Counsel (OCC):

1. For seizures, OCC will participate in concurrent review and provide final legal review of legal documents prepared by the Division. OCC will provide the legal assistance necessary for presentation of the action, including direct assistance to the U.S. Attorney and the ORA compliance staff.

2. OCC will insert the FDC number in the letter to the U.S. Attorney, and make any other necessary changes in the documents.
3. Upon approval, OCC will send the approved documents (complaint and letter and ancillary documents) to the Division where the seizure will be made, with a copy to the Center, DE, DOJ/OCL, and FDA's Office of Media Affairs.

E. New Information:

If significant changes to the fact pattern take place after the initial call, Centers and ORA offices should immediately notify the lead coordinators and indicate the location of the new information in CMS. Examples include correspondence from the regulated entity or its counsel, memoranda of meetings, requests for meetings, or additional evidence that has come to light since the referral to headquarters.

F. Independent Judgment:

All reviewing officials (whether in the program, division, center, or DE) are expected to exercise independent judgment as to whether an action or a specific charge should be approved or not approved.

6-1-7 Update Inspections

In situations in which there is a question about the continued existence of a violative condition at a firm or about the availability of violative goods to be seized, ORA staff may be asked to conduct an update inspection (or a buy, sample collection, or similar activity) to confirm that the product or problem affecting products still exists. If the Center, DE, and OCC agree that the evidence must be updated for an action to be brought, the Division will update the inspection assignment in coordination with the Center (If necessary) and upload the assignment in CMS. The Division will create a task to perform an update inspection in CMS and provide instructions in the task instructions text box.

NOTE: As a general rule, the evidence of violations, when presented to the U.S. Attorney, should be no older than 60 days. For mass seizures or seizures based on GMP violations, there should not be more than 30 days from the last date of the inspection to the time the case is submitted to the U.S. Attorney's Office. If the violations are such that ORA or the Center can provide assurance that the articles to be seized could not be brought into compliance within these time frames, the request for update may be waived.

The update (and any resulting report) will focus on documenting the continued existence of originally identified problems. The update findings and the lead coordinator's comments should be transmitted concurrently to DE, the Center, and OCC via CMS.

6-1-8 Seizure Accomplishment and Close-Out Documentation

After seizure has been approved, it is the seizing office's responsibility to provide all litigation support, monitoring and follow-up, to encourage expeditious handling of the seizure, to track the action to its conclusion, and to report current status to the program, OCC, the U.S. Attorney, the Center, the PDD, DE, and the DD as appropriate.

A. Contacts with the U.S. Attorney

Seizure actions involving health hazards require prompt action. The [U.S. Attorney's Manual](#) states that forfeiture actions should be commenced as soon as possible, particularly where continued distribution of the article may threaten the health of the public.

The compliance officer should encourage the U.S. Attorney to promptly file the complaint and to forward a copy of the filed complaint, with the civil number and the date of filing, to OCC and to ORA. The lead coordinator should forward a copy of the filed complaint to DE, the Center, and OCC.

B. Contacts with The U.S. Marshal

After filing the Complaint for Forfeiture, the lead coordinator may arrange with the U.S. Marshal to effect seizure when, in the judgment of ORA, such arrangements are needed to ensure that the seizure is carried out satisfactorily.

ORA may have to use its personnel to expedite seizures in the following situations:

1. When a question of the proper identity of the lot exists (e.g., commingled lots or complicated labeling).
2. When a mass seizure is involved.
3. Lack of cooperation by the dealer, 18 U.S.C. 401 provides as follows:

"A court of the United States shall have power to punish by fine or imprisonment, at its discretion, such contempt of its authority, and none other, as –

* * *

(3) Disobedience or resistance to its lawful writ, process, order, rule, decree, or command."

Under this statute, interference with a U.S. Marshal in locating goods may be charged as contempt of court. The facts should be referred to the U.S. Attorney and OCC.

NOTE: Considerable time can be expended in assisting the U.S. Marshal's Service in effecting seizure and taking inventory of the goods. The standard FDA consent decree provides that

the government shall recover from the claimant court costs and fees, and storage and other proper expenses. The term "other proper expenses" found in 21 U.S.C. 334(e) constitutes an adequate basis for recovery of the costs involved in assisting the Marshal in effecting and taking inventory of the goods seized. The actual hourly salary rate of the investigators rather than the rate for supervision of reconditioning should be charged.

C. Seizure Action Report

As soon as the articles have been seized, the seizing office will promptly notify the OCC attorney, the center, the lead coordinator, and DE of the amount and value of each lot seized, and the Marshal's return date. The division should upload a copy of the email in CMS under the "Final" Tab.

The information necessary to complete this report is obtained by the investigator accompanying the U.S. Marshal or directly from the Marshal. Use Form FD-487. See [Exhibit 6-2](#). If the seizure is not accomplished, the report should so state and explain briefly why the lot was not available or could not be attached. If the article is still violative, provide all known details as to where it went and how to trace or identify it.

The U.S. is required by Supplemental Rule C (4) to give public notice through advertisement before the article may be forfeited. In most districts, the Marshal's office contracts for this at the direction of the U.S. Attorney.

6-1-9 Disposition of Seized Articles

A. Potential Claimant's Disposition Options Overview

Following seizure of any products there are three avenues available to a potential claimant. The claimant may:

1. Do nothing, in which case the article will be disposed of by default;
2. File claim to the article and enter into a Consent Decree, admitting the violation, agreeing to pay costs, and seeking to destroy or rehabilitate the article; or,
3. File claim to the article and contest the action by filing an answer to the complaint.

Regardless of which avenue is chosen, it is the responsibility of the seizing office to monitor all activity to ensure a proper termination of the seizure action and to document the activity with supporting evidence placed in CMS. The Center, DE, and OCC Attorney should be promptly advised of all events in the case.

NOTE: Any decree entered in a seizure case must contain a provision condemning the article as being in violation of the law. Without such a provision, there is no authority for the court to order destruction of the article or to permit its reconditioning.

The avenues available to a potential claimant are addressed more specifically below.

B. Disposal

If no claimant appears in the case, the government will move for default, condemnation, and forfeiture or destruction under a Default Decree (see [Exhibit 6-3](#)). The Decree is prepared by OCC. The Decree may be entered after the return date has expired (see RPM "Responsibilities in Default and Consent Decrees").

To prevent premature defaults, OCC prefers the use of a 30-day time frame following seizure as the return date. Local rules may differ in your area.

When a Default Decree is entered, the U.S. Marshal disposes of the article. This disposal may take various forms, including the following:

1. **Constructive Destruction** - The article is destroyed by using it for a constructive purpose, such as donating misbranded but wholesome food to charity.
2. **Sale** - If the article may be legally sold, the Marshal may sell it to recover costs. Products in violation of the laws we administer normally would not be offered for sale after seizure.
3. **Conversion** - Human food may often be converted to animal food, rather than destroyed. If conversion is the method of destruction, ensure that the product is physically treated to prevent its diversion to human food. Unless a recent precedent for conversion of a product to animal food is on file, the Center for Veterinary Medicine must approve of the reconditioning process.
4. **Destruction** - The article may be destroyed by burning, burial, or dumping. Ensure that the method of destruction is appropriate under NEPA, and that the article cannot be retrieved.

NOTE: Any Default Decree should contain a statement that the destruction of the article will be in accordance with relevant laws including NEPA. When questions arise concerning environmental impact, contact the ORA Safety Management Officer, listed on the FDA Intranet page for "Safety Councils & Committees/EHS Network," for assessment of the proposed method of destruction.

C. Consent Decree of Condemnation

1. Claim - Any potential claimant must first file with the court a proper, verified claim stating his/her interest in the property. Only after a proper claim has been filed may there be negotiations concerning disposition of the seizure. Should more than one claim be filed, the court may have to rule on who is the proper claimant (see [Exhibit 6-4](#)). Any FDA staff who learn that a claim has been filed should notify the OCC attorney immediately and send a copy of the claim by facsimile as soon as it is obtained.
2. Consent Decree - Should a claimant appear, it may agree to the entry of a Consent Decree providing for attempted reconditioning of the article under seizure. See "Compliance Officer and OCC Attorney Responsibilities in Default and Consent Decrees" in 6-1-9 item 10 below. In the event that this method of response is chosen, there are several steps which the claimant must follow. These are discussed below:

The claimant (BUT ONLY THE CLAIMANT) may consent to the entry of a decree condemning the article under seizure and providing for attempted reconditioning or conversion. No discussion as to the provisions of a Consent Decree is to be undertaken before a claim is filed and concurrence from OCC has been obtained. See [Exhibit 6-5](#).

The Consent Decree must provide for the following items:

- a. Condemnation of the article as being in violation of the law.
- b. A penal bond approximately twice the retail value of the article under seizure.
- c. Provisions for payment of costs for storage and handling by the U.S. Marshal and for supervision by FDA before release of the product.
- d. A provision that claimant will attempt to bring the article into compliance under the supervision of, and to the satisfaction of, FDA. See the RPM "Compliance Officer and OCC Attorney Responsibilities in Default and Consent Decrees" in 6-1-9 item 10 below.

NOTE: If recurrence of the same violations that resulted in the seizure is likely, consider including injunctive provisions to the decree.

D. Bond

Following entry of the decree, the claimant is required to post a penal bond (see [Exhibit 6-6](#)). This bond should be twice the retail value of the goods. Its purpose is to ensure that the claimant

complies with the conditions of the decree and performs the reconditioning in a satisfactory manner. If the bond is set too low, it might be profitable for the claimant, after securing release of the product from the marshal, to sell the product without bringing it into compliance.

E. Bond Forfeiture Procedures

When part of the seized article disappears, or the terms of the decree are not complied with, the government may move for forfeiture of the entire bond. If, in the opinion of ORA, a bond action should be sought, submit a recommendation for such action, along with the facts, to OCC for preparation of the necessary papers.

If a claimant chooses, claimant may contest the action, in part or in its entirety. To do this the claimant must:

1. File a proper, verified statement of interest to the article, and
2. File an answer within 20 days after filing the claim denying any or all of the allegations in the government's complaint.

Should a contest arise, the matter will be handled the same as any civil trial and will conclude by a decision of the court after appropriate consideration of the case.

F. Reconditioning Operations

Upon entry of a court order permitting attempted reconditioning of seized articles, the seizing office will make the necessary arrangements for supervision with the claimant to ensure compliance with the decree. Before the reconditioning operation is begun, the lead coordinator should make sure that the claimant has in its possession a formal release by the U.S. Marshal.

Reconditioning may be achieved by various means such as: segregation of codes, cleaning, reworking, relabeling, or physically modifying for use as animal feed, or fertilizer that brings the article into compliance with the law.

1. Reprocessing by Reworking or Cleaning. - Unless ORA has a recent precedent case of a similar nature, proposals for reprocessing must be referred to the appropriate Center for consultation.
2. Relabeling - All proposals for relabeling of drugs, devices, tobacco products, cosmetics, special dietary foods, and fortified or infant foods, must be sent to the appropriate Center for prior comment unless guidelines exist. Other foods may be relabeled when ORA has a clear precedent for the use of the proposed labeling, but doubts should be resolved by referral to the Center.

3. Denaturing - If there are outstanding instructions for the denaturing of the product involved, these should generally be followed. If no instructions exist, or if in ORA's judgment the guidelines should not be followed, the proposal should be referred to the appropriate Center for consideration.
4. When a court order is entered permitting release of seized articles to a claimant for reconditioning, it should provide for supervision of the reconditioning operation by the FDA, at the claimant's expense. As instructed in the [Investigations Operations Manual](#) Section 2.4.8, the investigator supervising the operation is required to submit a detailed report.
5. When the court's decree permits the seized articles to be moved to another division for reconditioning operations, the division in which the operation is to be performed will supervise the reconditioning operation. In such cases, the seizing office should determine that the bond has been posted and the articles released by the U.S. Marshal before permitting the goods to be shipped. The seizing office will forward to the lead coordinator a copy of the decree and other pertinent data, before the seized article begins its physical move.

NOTE: All dispositions of seized goods other than destruction are to receive Center concurrence, unless otherwise noted.

G. Post Seizure Samples

When ORA is considering a related criminal case or when additional analysis is necessary, determination should be made as to whether adequate reserve samples are available for court use. If not, steps should be taken to obtain additional samples before the Default Decree or Consent Decree of Condemnation is entered and the articles are destroyed.

If, after a seizure, the claimant obtains a court order to take a sample from the seized lot, the order should provide for a like sample to be drawn simultaneously by the government. Unless there is an immediate need for examination of the sample, it should be held, under seal, by the seizing office.

H. Notice to Claimant and Notice to U.S. Attorney

Upon completion of the reconditioning, prepare a Notice to Claimant listing the charges to be paid. See [Exhibit 6-7](#). If no response is received in 30 days, send a second notice. See [Exhibit 6-8](#). Upon receipt of payment (check made payable to the "United States Treasury"), the seizing office will advise the U.S. Attorney that the bond may be canceled insofar as FDA is concerned. See [Exhibit 6-9](#). Copy OCC but do not send a copy of this letter to the claimant or its attorney.

- I. Compliance Officer and OCC Attorney Responsibilities in Default and Consent Decrees
 1. General Principles: The general rules that follow (which are subject to exceptions in unusual cases) are intended to reflect two principles.
 - a. Every person in the agency, including the compliance officer in ORA, the Center compliance officer, the DE case reviewer, and the attorney in OCC has a legitimate interest in seeing that a seizure is processed correctly. Therefore, there should be full consultation (notification is not consultation) about the handling of a case, and each should respect the interest and expertise of the others.
 - b. The maintenance of good working relationships with U.S. Attorneys' offices is a matter of concern to both ORA and OCC. U.S. Attorneys' offices should be made aware that they can call upon the assistance of officers in ORA Divisions and Programs and OCC attorneys at headquarters; both ORA and OCC must affirmatively include the other in dealings with U.S. Attorneys' offices.
 2. Requirements:
 - a. All default decrees and consent decrees submitted to a U.S. Attorney's office for filing in court and decrees drafted by a U.S. Attorney's office and submitted to FDA for comment shall be cleared through the assigned OCC attorney and the Center case officer, after full consultation with the compliance officer and the DE case reviewer.
 - i. In the case of a default decree, the consultation and clearance shall at least consist of a telephone conversation among the attorney, Center case officer, DE case reviewer, and the compliance officer. They shall determine what additional consultation, if any, is needed.
 - ii. In the case of a consent decree, a copy of the decree shall be sent to the OCC attorney, DE case reviewer and Center case officer.
 - b. Where OCC is asked by the ORA office or by the U.S. Attorney's office to prepare a decree, the OCC attorney shall consult fully with the compliance officer, DE case reviewer, and with the Center, concerning the decree and, after reaching agreement with the parties involved, shall transmit the prepared decree directly to the U.S. Attorney's office, with a copy to the compliance officer and Center.

- c. No negotiation about the potential modes of compliance for consent decrees shall be conducted with any prospective claimant until after a proper claim has been filed.
- d. Compliance officers shall not negotiate disposition of a filed case without prior approval of an attorney in OCC. Any such negotiation shall be conducted by an attorney from OCC with DoJ.
- e. As soon as it appears to the compliance officer that special local customs or procedures may affect any case (for example, giving seized articles to charity), the compliance officer shall advise the OCC attorney of the local peculiarity. In participating in the disposition of cases involving a default or consent decree, OCC attorneys shall be sensitive to relevant local customs, and shall respect such customs except when they are contrary to law or agency policy.
- f. When an attorney believes that a local custom is contrary to law or agency policy, the attorney shall bring the matter to the attention of responsible officials in the manner that will interfere as little as possible with effective working relationships between OCC, ORA, and the U.S. Attorney's office.

6-1-10 Costs of Supervision

The following rates shall be used in billing a claimant for supervisory services in connection with reconditioning, relabeling, or disposal of seized articles under a Consent Decree.

Investigation time - 267% of GS 11/4

Analytical time - 267% of GS 12/4

The above time is figured at an hourly rate.

Per Diem - Specific rates (41 CFR Part 301) paid to employee, in high cost areas, per diem is higher

Travel - Current Rate per mile (plus tolls)

Miscellaneous expenses - Actual cost

The minimum charge for services shall be not less than the charge for one hour. Additional charges shall be in multiples of one-hour, disregarding fractions of less than 1/2 hour, as follows:

1 to 1 hour 29 minutes - 1 hour charge

1 1/2 to 2 hours - 2 hour charge

6-1-11 Monitoring Seizure Actions

The seizing office should monitor the seizure action regularly to ensure the expeditious progress of the action. Actions taken during the course of the seizure adjudication should be processed through the ORA compliance officer to ensure up-to-date monitoring, accurate record keeping in CMS, and timely reporting. NOTE: The consideration of any regulatory action should be discussed among the ORA Program, DE, OCC and the Center.

6-1-12 Seizures Involving Other Agencies

When the proposed seizure may involve another agency of the Federal Government, contact the appropriate Center for administrative clearance with the pertinent agency. Also see Memoranda of Understanding on the FDA Collaboration [webpage](#).

A. National Marine Fisheries Service - U.S. Department of Commerce

If the Center advises that the lot was involved in inspection or certification by National Marine Fisheries Service - U.S. Department of Commerce, include the following statement in the seizure recommendation and proposed letter to U.S. Attorney:

"Although packed under inspection (or under Certificate No. __), the Center for Foods and Applied Nutrition has discussed this matter with NMFS and that agency has no objection to seizure." See Memorandum of Understanding [225-75-7001](#), [225-86-2000](#), and [225-09-0008](#).

B. U.S. Department of Agriculture

After clearance as under NMFS, include a similar statement in the seizure recommendation. See Memorandum of Understanding [225-80-2000](#) and [225-12-0007](#).

C. Federal Trade Commission

See Memorandum of Understanding [225-71-8003](#).

D. Environmental Protection Agency

See Memorandum of Understanding [225-73-8010](#).

E. Department of Labor

See Memorandum of Understanding [225-74-6008](#).

6-1-13 Issuing Press Releases

The recommendation to issue a press release is made jointly by the OCC attorney assigned to the case, the ORA case officers (the compliance officer and/or DE), and the Center office of compliance. The decision to issue a press release is made by FDA's [Office of Public Media Affairs](#) in accordance with the Transparency Initiative. The roles and responsibilities

of these offices in making these decisions, and in drafting, clearing, and issuing press releases are described in “[Exhibit 6-10 - Procedures for Issuing Press Releases on Enforcement Actions \(Seizures & Injunctions\)](#).” Follow these procedures and the accompanying models for drafting press releases concerning seizures and injunction actions. Upload the press release in CMS.

6-2 INJUNCTIONS

6-2-1 Purpose

The purpose of this section is to provide instructions and define responsibilities for those ORA units involved in the development, preparation, processing, and follow-up of injunctions.

6-2-2 General Guidelines for Injunctions

Before initiating an injunction case, the compliance officer and ORA management will name a lead coordinator from the affected ORA program or division unit. ORA management will include involved PDDs as appropriate.

PDD means the appropriate program division-level official(s) or designee. The PDD must consider several factors.

An injunction is a civil judicial process initiated to stop or prevent violation of the law, such as to halt the flow of violative products in interstate commerce, and to correct the conditions that caused the violation to occur. See 21 U.S.C. 332; Rule 65, Rules of Civil Procedure. If a firm has a history of violations, and has promised correction in the past, but has not made the corrections, the injunction is more likely to succeed. However, the freshness of the evidence is critical.

For an injunction action to be credible in the eyes of the DOJ, the U.S. Attorney, and the court, the evidence must be current. Timeliness is an important factor when considering an injunction action, with or without a Motion for Preliminary Injunction, or a temporary restraining order (TRO). However, case quality and credibility must not be sacrificed to meet guideline time frames. The purpose of the guideline time frames is to limit, as much as can reasonably be expected, the need to update evidence. Updating entails extra work at all levels of the case development and review process and, more importantly, delays obtaining an injunction, which is intended to stop violations that adversely affect the safety or quality of products in commerce.

Once a complaint for injunction is filed by the United States, a hearing may be placed on the court calendar at any time with extremely short notice. It is imperative that the compliance officer maintains close contact

with the OCC attorney and the Assistant U.S. Attorney to be aware of any hearings on FDA actions.

When an injunction is granted, FDA has a continuing duty to monitor the injunction and to advise the court if the defendants fail to obey the terms of the decree.

Should the decree be violated, the agency must consider a civil or criminal contempt of court, or other regulatory action, in as timely a manner as used in initiating the injunction. It is, therefore, mandatory that FDA personnel responsible for initiating injunctions also adhere to the implementation procedure in "Compliance Follow-up."

6-2-3 Definitions

A. Temporary Restraining Order

Temporary restraining orders are court enforced orders entered to control an emergency situation. A TRO seeks immediate, temporary relief (for a period of 10 days, which may be extended for 10 additional days) prior to the hearing for preliminary injunction.

FDA recommends a TRO when the agency believes that the violation is so serious that it must be controlled immediately. A request for a TRO also has the effect of expediting review of the underlying injunction case by the court. An inadequately documented TRO request may result in the court viewing the entire injunction action as lacking credibility.

At the court's discretion, the TRO request may be subjected to a hearing, which may be *ex parte* (without the defendants' presence), by reviewing the documents and questioning government counsel, the FDA investigator, the compliance officer, or other FDA personnel.

B. Preliminary Injunction

Whether or not a TRO has been obtained, a Motion for Preliminary Injunction is subject to a full hearing in which (1) evidence by affidavit, or (2) testimony of witnesses is presented, depending on the practice of the court. Once the motion is granted, or the defendants consent to the entry of a decree, the preliminary injunction is in effect.

A preliminary injunction may stand indefinitely on the court record until the case is settled or a permanent injunction has been entered, after trial or further briefing. A preliminary injunction may be dismissed, or further proceedings for permanent injunction may be set by the court, at the request of either party, at any time.

C. Permanent Injunction

A Decree of Permanent Injunction may be entered at any time after the complaint is filed, either following a hearing or as a result of a negotiated settlement. Defendants in an injunction proceeding may consent to a Decree of Permanent Injunction just as they consent to a Consent Decree of Condemnation in a seizure action.

Should the defendant not consent to such a decree, a trial is held in which, to prevail, the government must prove each element of its case by a preponderance of the evidence. As its name implies, a Decree of Permanent Injunction remains in effect until it is dissolved by an order of the court.

6-2-4 General Considerations

A. When an Injunction May Be Considered

An injunction may be considered for any significant out-of-compliance circumstance, but particularly when a health hazard has been identified. Proceeding by injunction does not preclude institution of additional or concurrent action such as recall, publicity, seizures, embargo by cooperating officials, or criminal prosecution.

In considering an injunction, the agency must evaluate the seriousness of the offense, the actual or potential impact of the offense on the public, whether other possible actions could be as effective or more effective, the need for prompt judicial action, and whether it will be able to demonstrate the likelihood of the continuance of the violation in the absence of a court order. Injunction will be the action of choice when:

1. There is a current and definite health hazard or a gross consumer deception requiring immediate action to stop the violative practice and a seizure is impractical; or
2. There are significant amounts of violative products owned by the same person, a voluntary recall by the firm was refused or is significantly inadequate to protect the public, and a seizure is impractical or uneconomical; or
3. There are long-standing (chronic) violative practices that have not produced a health hazard or consumer fraud, but which have not been corrected through use of voluntary or other regulatory approaches.
4. With respect to a and b above, it is helpful, but not mandatory, to show that there has been a history of prior violations, and that previous attempts to correct them through alternative warnings or sanctions have not been effective. A showing of a violative history should be made whenever possible, but especially in

those cases where an imminent danger to health cannot be alleged.

B. Injunctions in Multiple Jurisdictions

When similar violative practices are found at two or more facilities under the same corporate management, the ORA office where the corporate office is located should evaluate the compliance histories of corporate facilities located in other product and geographic jurisdictions to determine whether there are patterns of violations or trends that indicate the presence of systemic problems that should be addressed on a multi-jurisdictional basis.

The Centers, ORA offices, programs, and divisions, and DE have a significant role in assessing these situations and in developing and coordinating a regulatory approach. The initial and continuing roles of the various offices in multi-jurisdictional injunctions are described in the procedures titled "Injunctions (Multi-jurisdiction)." See [Exhibit 6-11](#). These procedures were developed to facilitate planning, and the timely preparation, processing and review of these types of cases. They must be followed as soon as a potential Multi-jurisdiction injunction is identified by ORA or the Center. At its discretion, the recommending ORA office may invoke these procedures for a single federal district injunction involving multiple Centers.

6-2-5 Adequate Notice Preceding Injunction Actions

A. Identifying Individuals

FDA strengthens its injunction actions by demonstrating in the complaint that FDA made and has documented a conscious effort to get the objectionable products or practices corrected without court involvement. For example, the defendants were notified of the violations (by letter, FDA 483, meeting, telephone call) and, despite having an opportunity to correct the violations, failed to do so. Prior notice is not a legal requirement, but can demonstrate a defendant's resistance to compliance and enhance the agency's request for court intervention.

Although there is no legal requirement to name individuals in complaints for injunction, the agency believes that by doing so, individuals not named in the complaint will be more inclined to prevent violations from occurring in the first instance (general deterrence) and that named individuals will be more inclined to take immediate and active interest in seeing that the violation ceases (specific deterrence). Also, the identification of the responsible persons will prevent their pretense that they were not subject to the injunction, and will help prevent circumvention of the injunction by changing the name of the corporation. Therefore, the individuals

who have the authority and responsibility to correct or prevent the violations should be named as defendants.

During its normal case-development process, FDA will therefore strive to identify the individuals with the authority to take corrective actions and prevent future violations and to develop evidence proving the individuals' authority and responsibility. Such individuals may be located at the sites of the actual or potential violation, at other offices and sites, or both. When there are questions concerning individual responsibility during the review process, assignments should be issued requesting further documentation. One principal purpose of these efforts is to ensure that individuals standing in positions of authority with respect to actual or potential violative conditions will be provided with adequate notice concerning the evidence found by FDA. The management officials believed by FDA to have the highest level of authority in an organization should always receive notice.

B. Methods of Giving Notice

Notice may take a variety of forms including letters and notices from other government agencies, recalls, issuance of FDA 483s, post-inspection discussions, meetings, and telephone calls. All persons receiving notice and the circumstances (date, time, place, and substance) of notice should be documented. Recognizing that firms under FDA jurisdiction include those ranging from owner-operator to large conglomerates and that the nature of violations will vary; what is deemed adequate notice will differ from case to case. Factors to be considered in determining adequacy include, but are not limited to, complexity of the organizational structure, duties and authority of persons believed to be responsible, nature of the violation, compliance history, and the length of time elapsed between notice and filing of the case. Also, see RPM [Chapter 10 - Other Procedures](#), 10-2 "Prior Notice" and 10-3 "Regulatory Meetings."

The factors listed below will apply in determining the adequacy of notice. Agency records should show that sometime during case development:

1. The individuals with authority to prevent or correct violations have been given appropriate notice of the general conditions that are violative.
2. There is sufficient information to conclude that proper action to correct the violations has not been taken or will not be taken promptly.
3. Reasonable efforts on the part of the agency were made and documented to get the objectionable product and practice

corrected without court involvement. Any attempts by the proposed defendants to correct the problem should also be reported.

NOTE: There may be cases where exceptions to the need to show notice through factors 1 through 3 are justified. Justification for such exceptions must accompany the case submission.

6-2-6 Prerequisites for a TRO or Preliminary Injunction

Note: Injunctions that include requests for a TRO have the highest priority ranking of all legal actions. Ensuring that criteria for TROs have been met and that strategies will be developed to halt the violative conduct usually requires knowledge of FDA issues and experience. For this reason, it is recommended that experienced compliance and legal personnel be involved in all TRO recommendations.

These persons should also be available from each reviewing unit to hand carry the case to each succeeding level, for review.

A. Timeliness

As a general rule, a request for a TRO should be processed through the agency so that it may be filed no later than 30 days after FDA's most recent evidence that the violation is occurring.

Also, as a general rule, a request for a preliminary injunction is untimely if the evidence to support it is over 60 days old at the time of filing. The freshness of the evidence is important when the case includes a Motion for Preliminary Injunction, because the government is requesting that the matter be moved ahead of other cases on the court's calendar because of its urgency.

B. Seriousness of the Violation

In addition to considerations of timeliness, if there is a public health threat, that factor is something that should be emphasized. It is very important to remember that we do not need to show potential harm, but if that factor is present, it is very compelling. If the threat is severe enough, the court would consider a TRO for immediate relief.

The magnitude of the violation is another consideration. If the defendant is a small company with just a few employees and the violations cause little or no public health risk, a court may not grant preliminary relief, but may be receptive to granting a permanent injunction. If the violations are significant and the defendant is a major presence in the industry, the fact that the violations may have far-reaching consequences may be a compelling factor in support of preliminary relief, even if there is no direct evidence of harm.

C. Adequate Notice

To avoid the need for updating the evidence in requests for TRO or preliminary injunctions, the agency is committed to prompt review when all of these prerequisites are met. The absence or weakness of a prerequisite may preclude review of the request and the transmission of the case to DOJ until the information is obtained, unless adequate justification for its omission has been provided.

When initiating requests for injunction with a TRO and in implementing compliance follow-up, all personnel will perform the investigational, analytical, and administrative tasks with a high degree of urgency. Advance notice to all involved units is necessary, so that plans for expedited processing and review may be agreed upon and accomplished.

A request for a TRO or preliminary injunction must be accompanied by an affidavit from the program division directors (PDD and where appropriate (for example new drug violations), the affidavit of center personnel attesting to certain facts. Supporting affidavits of experts should be obtained as soon as possible either by ORA or by the Center.

Expert witness support is necessary in all cases except when the violations are so gross and apparent that a reasonable judge who is not familiar with the technical or scientific issues in the case would not hesitate to grant the relief without expert testimony. Because expert testimony takes time to obtain, ORA or the center should begin identifying suitable candidates and forwarding the necessary background material to them at the earliest possible time. Please note that any materials provided to experts must be shared with the defendants in discovery. If you have any questions about what should or should not be shared, please contact OCC.

6-2-7 Refreshing Evidence - Updating Inspections

The referral of a Complaint for Injunction to DOJ should follow closely in time the last evidence of violations (inspectional evidence, laboratory analysis, or undercover buy), or the last communication from the proposed defendants which reveals that the violative conduct will continue. This can be controlled to a certain extent by well-timed reinspection, buys, or similar activities.

Requests for reinspection, undercover buys, or similar activities should be coordinated with the Center and OCC. Assignments for update inspections will be issued directly from the Center after consultation with OCC. The update findings and ORA's recommendation based upon this most current evidence should be transmitted concurrently to OCC and the center.

6-2-8 Approval Process for Seizure and Injunction Cases

See [subsection 6-1-5](#) for the steps to be included for Injunction cases.

6-2-9 Responsibilities for Injunction Actions

A. Program and Division Responsibilities:

Prior to creating a PA work activity in CMS, the compliance officer should consult with the DCB and other ORA management to obtain support for the proposed action. The compliance officer should then create the PA work activity and upload key documents that support the most significant violations, initiate the preliminary assessment call and PA Work Activity in CMS, and upload a document describing summary views expressed during the PA call.

Note: As described in [subsection 6-1-5](#) above, when the participants have been working closely on a compliance issue that will lead to a possible injunction case, the party proposing the injunction can create an injunction case record in CMS and upload the CIM and supporting evidence into that record instead of creating a preliminary assessment work activity.

ORA, along with the Center, is responsible for identifying the relevant statutes and regulations they seek to charge and with specificity the relief sought.

If the participants agree that an injunction may be warranted, the lead coordinator is responsible for writing and uploading the CIM and supporting documents into CMS. Notify OCC using the address "[OC OCC Case](#)." mailbox in Outlook. The contents of the CIM are described in [Exhibit 6-1](#).

When significant changes to the fact pattern that take place after the initial PA call, these changes should be communicated to the lead coordinator as soon as possible. The lead coordinator is responsible for uploading the new evidence as soon as possible. A new task should be created and participants should be alerted about the changes.

Upon approval and receipt of final documents from OCC, the Division will note the date in CMS that the complaint, transmittal letter and ancillary documents were submitted to the district and should also make PDF versions available in CMS. The Division will upload a PDF version of the signed USA letter and the complaint in CMS.

B. Center Responsibilities:

1. Appropriate Centers are responsible for providing and obtaining technical and scientific review and support of the case, for assuring that the case meets regulatory policy requirements and for providing a clear indication of scientific support for each charge and each article.
2. The Center is responsible for preparing for and participating in the PA call, assigning a lead coordinator (who will retain that role throughout the review process), assigning a technical/scientific expert and retaining and obtaining the concurrence of an outside expert when needed, providing views to ORA for incorporation into a subsequent summary of the PA call in CMS, and providing input for the CIM to include with specificity those charges that can be supported, those that cannot and the rationale within the time frames outlined above.
3. The Center, with input from ORA and OCC as appropriate, is responsible for determining whether outside experts are necessary to support a case and, if so, for promptly taking steps to secure such support. See RPM [Chapter 10](#) section 10-10 “Expert Support for Cases” for further information, including information on paying for expert support.
4. In those situations where an expert memorandum or declaration is needed in order to move the action forward, such as in GMP, HACCP, or similar complex cases, a brief memorandum would be provided by the expert. Experts to be used, whether from the Center or outside, should prepare a brief statement that they have read the EIRs, CIM, and analytical worksheets, and that based on this review they can support the following conclusions that are specifically listed. If they cannot support any particular conclusions, those should also be listed. The document should state that they are prepared to testify to the above conclusions (in court and by sworn declaration). The Center lead coordinator should upload the expert’s CV and bibliography into the CMS case file. The concurrent review process encourages increased communication and collaboration and should allow for early identification of this need for a written opinion/commentary, as well as other requirements needed to move a case forward.

Note: Referral of the case will not be delayed by the Center if an expert has not been identified. However, the Center must be actively pursuing this matter and providing status reports to OCC. The Center will alert DE and OCC promptly if there is difficulty in processing an FDA approval to retain an outside expert. However, OCC may not be able to proceed without the support of expert opinion.

5. The Center is responsible for reviewing ORA's proposal regarding conduct to be enjoined, ensuring that the proposal is adequate and reasonable.
6. The Center is responsible for identifying which statutes and regulations they seek to charge, and with specificity the relief sought.
7. Each Center is responsible for monitoring industry-wide state of compliance to determine whether an enforcement strategy should be developed or revised. This includes a multi-facility firm that may lead to a Multi-jurisdictional injunction action. See [Exhibit 6-11](#). Consideration should be based on priorities, prior similar actions, nature and scope of the industry.

C. ORA Division of Enforcement (DE):

1. Reviewing and providing input to the case team as needed during the current review process.
2. Ensuring uniform application of policy and procedures across FDA Centers.
3. Reviewing final agency action, remaining involved in further actions and monitoring after an injunction is entered and determining which cases require an update inspection (in conjunction with the Division, OCC and the Center).

D. Office of Chief Counsel Responsibilities:

For injunctions, OCC will participate in concurrent review and provide legal review, prepare pleadings and other legal documents, and provide legal assistance necessary for presentation of the action, including direct assistance to the Office of Consumer Litigation and/or the U.S. Attorney's Office and the compliance staff.

Upon approval of an action, OCC will transmit the final complaint, transmittal letter and ancillary documents electronically to the ORA Division where action will be taken, with a copy to the designated Center and DE contact persons, DOJ/OCL, and FDA's Office of Media Affairs.

6-2-10 Cover Letter to DOJ

The cover letter transmitting the case to DOJ/Office of Consumer Litigation, Civil Division, will be prepared by OCC and will identify the action sought (TRO, preliminary injunction or permanent injunction), briefly summarize the case, highlighting legal, evidentiary, and tactical issues worthy of note including the significance of the evidence.

6-2-11 Complaint for Injunction

OCC will prepare the Complaint for Injunction, in accordance with the requirements of the Federal Rules of Civil Procedure and any particular requirements of the relevant district court.

The complaint will generally include sections covering jurisdiction, venue, identification of defendants, a statement explaining the nature of the products involved, the purpose of the law that is being violated, a summary of evidence of the violations alleged, a brief reference to prior inspections, prior warnings, and historical non-compliance, and a short-form prayer for relief. See [Exhibit 6-19](#).

6-2-12 Declarations

Most jurisdictions will accept declarations in support of a motion for preliminary relief or for a TRO. If the court requires live testimony in support of a motion for TRO or preliminary injunction, the declaration may be converted to testimony. Please note that declarations are testimony given under oath. Declarants should be prepared to testify in court to all statements made in a declaration.

NOTE: 28 U.S.C. 1746 provides for the optional use of declarations in lieu of affidavits, thereby avoiding the need for a notary public. This is particularly useful for experts and resident investigators when a notary is unavailable. Declarations filed under 28 U.S.C. 1746 have exactly the same legal weight and significance as affidavits. Where either an affidavit or declaration is used, follow Exhibit 6-20. The 28 U.S.C. 1746 declaration should state, "Pursuant to 28 U.S.C. 1746, I declare under penalty of perjury that the foregoing is true and correct. Executed on (date)."

If the court requires affidavits from investigators or analysts or others having firsthand knowledge of the facts, they should be furnished by the ORA office or persons performing the work. However, where significant information is discovered in the course of the inspection and is not contained in the FDA 483 or other document, but is within the personal knowledge of the investigator, that observation, discussion of event, or incident should be the subject of a brief declaration by the investigator. Where a separate declaration is used for an investigator, the relevant FDA 483 issued by that investigator should be attached thereto. In some cases, a declaration may also be necessary for the investigator to summarize and explain the significance of the most recent inspectional findings consistent with his or her experience as an FDA investigator.

The only declarations that will routinely be used in support of injunctions are the declarations of:

- A. the PDD, or their designee;

- B. an investigator (where necessary to support information in the complaint not contained in the FDA 483 or to summarize the significance of the findings);
- C. appropriate Center official (to document such things as the lack of an NDA or the failure to register a product or facility); and
- D. experts.

The declarations should be factual and, except in the case of declarations by experts, not contain conclusions, or opinions. In all cases, each declaration must provide clear, succinct, and strong factual support for the complaint.

The declarations should set forth the identity of the declarant; his/her position with FDA and his/her duties in that position. If it is an expert's declaration, his/her qualifications to draw conclusions or offer opinions must be summarized at the beginning of the declaration and should be supported with an attached copy of the expert's curriculum vitae.

Because the granting or denial of a TRO or preliminary injunction may rest upon the sufficiency of the declarations submitted with the complaint, care should be taken to ensure that every statement in the complaint is covered with equal or greater specificity in the declaration. Violative conditions unrelated to the charge should not be included. Unimpressive violative conditions should not be included; however, a number of less impressive violative conditions may often be grouped to become more impressive when their combined effect is to make a potentially hazardous condition.

NOTE: Listing a series of minor infractions has the effect on a court of minimizing the significance of the case and distracting the focus away from the significant problems.

The facts in the PDD's declaration are derived from a review of documents contained in the ORA files and the declaration should so state. A PDD or investigator may not rely on oral statements made to him or her by other agency personnel.

- A. The following specific information should be covered in the declaration:
 - 1. statement of the position occupied by declarant;
 - 2. duties of the declarant in that position;
 - 3. legal status or business of the defendant firms;
 - 4. address of business;
 - 5. identity of individual defendants, where they perform their duties, and in at least as much detail as in the complaint, their authority and responsibilities;

6. a statement that the defendants are doing (or do) interstate business in a product known as (brand name);
7. the label and labeling of the products (If the labeling is available, it should be attached to the declaration, appropriately identified. If exhibits are not available, relevant portions of the labeling should be quoted when applicable to the charges in the complaint);
8. if relevant to the charges, establishment inspections performed and the facts revealed thereby;
9. a statement that samples from recent interstate shipments have been obtained, briefly citing the labeling accompanying the shipments, if pertinent;
10. sample evidence (include the name of product sampled, and the laboratory findings that confirm the alleged violations);
11. prior actions such as warnings, notice, seizures, and FDA attempts to obtain correction, broken promises or other evidence of bad faith, such as statements by defendants clearly showing an intent to continue the violations, in detail as pertains to each defendant; and,
12. a statement that, despite the previous actions, the defendants are still engaged in violative conduct.

NOTE: All declarations should be prepared in final form, but not be signed, and should be double-spaced. They represent the facts that can be sworn to by an individual. However, changes made in a case during the review process may require changes in the declarations.

- B. To ensure that the declarations remain accurate, the following will apply:
1. The declarant will carefully review the final copy before the case is submitted.

The only signed version should be the final version after all changes have been agreed upon, reviewed, and cleared by the signer.
 2. If substantive changes are made in the declaration, the reviewing office proposing the change will check with the PDD to ensure the individual can attest to the truthfulness and accuracy of the added material. OCC will be responsible for incorporating all approved changes into the final.
 3. In no case will a declaration be modified without the knowledge and express consent of the declarant.

6-2-13 Consent Decree

OCC will prepare the proposed consent decree, using the section in the CIM titled "Violations," and additional information provided by the Center.

ORA and the Center are jointly responsible for providing OCC with the information necessary to support the specific substantive relief sought. See [Exhibit 6-18](#).

In drafting a consent decree, OCC will seek Center approval on matters germane to its original review, including reconditioning or reprocessing plans, CGMP requirements, reviews of the corrective actions of defendants, recalls, cessation of product manufacturing or distribution operations, and measures that could affect availability of medically necessary products. OCC will seek the approval from ORA (the PDD as appropriate) on matters requiring ORA follow-up activities, such as reinspection frequency and rates, reviews of defendant's corrective actions if any were requested by Center, and witnessing destruction and disposition of goods.

Also, during litigation, representatives of those offices with a direct interest in the case will keep each other informed of developments, including changes proposed by DOJ attorneys, to ensure that a consent decree is filed that are acceptable to the agency (PDD, Center, and OCC).

FDA should not seek relief if it cannot be obtained (e.g., do not propose to allow reconditioning of a product if it cannot be accomplished). Also, if the relief provides for the company to obtain a consultant, do not require, as part of the relief that FDA approve of the consultant.

6-2-14 Costs of Supervision

All injunction actions resulting in consent decrees should provide for the payment of costs incurred in conducting all inspections pursuant to the decree. Court orders may also provide for the payment of costs incurred in conducting inspections pursuant to the order.

The following charges apply to all injunctions:

Investigation time: 267% of GS-11/4 hourly rate

Analytical time: 267% of GS-12/4 hourly rate

Per diem actually paid to an FDA employee will be paid at the current existing rates expressed in GSA's Federal Travel Directory.

Miscellaneous expenses: actual cost

The minimum charge for services shall be not less than the charge for one hour. Additional charges shall be in multiples of one-hour, disregarding fractions of less than 1/2 hour, as follows:

1 hour through 1 hour, 29 minutes - charge 1 hour

1-1/2 hours through 2 hours, 29 minutes - charge 2 hours

Consult with OCC before notifying the firm by letter that it may resume operation (see Exhibit 6-12) and before sending any bill setting forth charges for any inspection conducted pursuant to the decree or order (see Exhibit 6-22). Do not use a letter to notify either the firm or the U.S. Attorney that costs have been paid, because such letter may be misconstrued in a way that could have adverse consequences.

Ensure documentation justifying the charges is maintained as part of the legal file and discussed with OCC.

6-2-15 Compliance Follow-Up

Once the injunction has been granted, the Court and the public rely on FDA to conscientiously monitor the defendants' compliance and to advise the Court on compliance with the terms of the injunction.

It is the responsibility of ORA (the PDD as appropriate) to ensure that prompt attention is given to the following:

- A. Consult with OCC as to service of copies of the court's decree.
- B. Determine the firm's plans to bring the operation into compliance and, where applicable, the plans for destruction, reconditioning, or recall of material on hand and finished goods in the market place.
- C. Where the injunction contains a provision for the firm to designate an expert to supervise compliance with the terms of the decree, it should specify that the expert must certify in writing to FDA that the terms of the decree have been complied with before FDA makes any inspection, and that the firm must submit a written list of corrections to FDA.
- D. Find out whether the firm has hired a qualified expert, and determine his/her qualifications. FDA does not approve or disapprove of experts selected by defendants when defendants are required by a consent decree to retain expert consultants. However, FDA may elect not to accept a consultant's report of findings. FDA acceptance of the consultant's findings may include consideration of such factors as the adequacy, completeness, or accuracy of the filed report, if an obvious conflict of interest is uncovered, or if the consultant's competency does not meet a regulatory standard, for example, as required in the drug CGMP regulations at 21 CFR 211.22. ORA should share the follow up findings with the Center either by email or telephone.

- E. Monitor status of the accomplishment of the above. Promptly advise OCC and the appropriate Center of any problems regarding non-compliance with the decree. Maintain close contact, including visits, as necessary, to ensure that the firm is brought into compliance before operations subject to the injunction are resumed.

NOTE: Inspections made under an injunction are performed under the authority of the appropriate Act and the decree entered by the court. When visiting the firm, provide a copy of the decree and FDA 482 to managerial personnel and document that you have done so. This will facilitate any contempt action that may be necessary.

Following determination by ORA that the defendants appear to be in compliance with the requirements of the "unless and until" provisions of the decree, the defendants should be so notified in writing and advised that such determination does not, however, relieve them of their responsibility for compliance with the Act or other provisions of the decree that continue in effect. See [Exhibit 6-12](#) Model Letter Acknowledging Compliance. Consult with OCC before notifying the firm by letter ([Exhibit 6-12](#)) that it may resume operations and before sending an initial bill setting forth the charges for all work performed to get the firm in compliance ([Exhibit 6-21](#)).

NOTE: If a copy of the above letter is furnished to the U.S. Attorney, it may inadvertently trigger a dismissal action unless the U.S. Attorney is also reminded that there are other provisions of the injunction that remain in effect.

If ORA's follow-up discloses that the firm has met the provisions of the decree and notice has issued, the lead coordinator will schedule a follow-up inspection to be performed in 3 to 4 months and quarterly thereafter until the firm maintains a continuous state of compliance for one year. The firm shall be inspected at least annually thereafter. Discretion is permitted to provide flexibility with timing of inspections to coincide with different seasons (dry, rainy, etc.), as appropriate, to inspect under varying operating conditions. Deviation from this schedule is appropriate in those instances where plant operations are on a seasonal. In that event, the firm shall be scheduled and inspected at the beginning of the next operating season.

Should any reinspection or analysis of samples disclose that the defendants are not meeting the terms of the decree, a variety of regulatory actions are available to FDA, including:

1. Reinstatement of Decree

Motion to petition the Court to implement the shutdown provisions of the decree, based on the fact that defendants

regressed from an in-compliance state (as certified in formal notice) to an out-of-compliance state. The effect of this action is to again close the firm until corrections have been made and verified. If the decree allows for a recall, upon request by FDA, this, too, may be considered.

2. Seizure

3. Civil Contempt

A civil contempt is a forward-looking action to force compliance, requesting the court to impose a penalty upon the defendant for continued noncompliance. The penalty may be monetary or confinement of individual defendants for each day or for each violative act until the terms of the decree are met.

4. Criminal Contempt

A criminal contempt action is not to coerce compliance, but to punish prior behavior. The penalty does not depend upon future actions.

5. Prosecution

6. Civil money penalties (for example, for medical devices or tobacco products)

7. Administrative sanctions such as Withdrawal of Applications.

NOTE: The foregoing regulatory actions may be applied individually, sequentially, or concurrently. The consideration of any regulatory action should be discussed with the Center, DE, and OCC.

Recommendations for any action taken as the result of a violation of a decree shall be processed with the same urgency as the original injunction, and in accordance with the procedures in this chapter. The compliance office will prepare a recommendation. For criminal contempt, see the RPM subsection 6-5-8 "Contempt of Court; Violation of Probation". For prosecution see subsection [6-5-6 "Criminal Prosecution After 305 Notice."](#) Should contempt be the action of choice, the lead coordinator will also prepare a Petition for Order to Show Cause why the defendants should not be held in contempt. See Exhibits [6-22](#) and [6-23](#).

Change in ownership or identity of defendant firm should be noted. In the case of a change in ownership or corporate identity of the firm, report detailed facts on the changes to the Center and the OCC for a determination whether the new ownership or corporate entity are covered by the injunction. Rule 65(e), Federal Rules of Civil Procedure, discusses persons covered by injunctions.

- F. If a firm under injunction goes out of business, take the following steps:
1. Maintain the file as an open injunction for one year.
 2. Check the status of the firm at the end of six months and one year after being reported out of business.
 3. Make an effort to determine whether the firm has moved to another location and another ORA office should be notified of the status of the firm. Notify any such office about the injunction.
 4. If the injunction is against an individual as well as a firm, determine the individual's present occupation, and whether or not it is similar to the type of business for which he/she was enjoined. If so, notify the Center and OCC.
 5. If the firm remains out of business after one year, notify OCC and the appropriate Center of your intention to close the file in 60 days unless either component has further information which requires consideration.
 6. After the 60-day waiting period, if no further information is received, and the injunction was a preliminary one, notify the U.S. Attorney in writing that the firm has ceased operations and the government recommends closing the injunction file.

6-2-16 Vacating Injunctions

FDA does not ordinarily initiate requests to vacate injunctions whether issued by consent decrees or court orders. Nor will the agency join with a defendant in filing a motion to request such relief. However, if all of the following apply, FDA may agree to not oppose such a motion:

(1) the agency has recent evidence (e.g., within the last 6-8 months) that the defendant is in compliance with the Act, applicable regulations, and the decree or order; (2) the defendant has remained in continuous compliance with the Act, applicable regulations, and the decree or order for the life of the sunset provision (virtually always five years); and (3) the defendant has given FDA an opportunity to consider whether or not to object to the motion. A long violative history or lack of cooperation by the defendant will also affect FDA's response to a motion seeking to have an injunction vacated.

If a defendant contacts the appropriate ORA office(s) to discuss the possibility of vacating an injunction, the defendant should be instructed to prepare a written request specifically describing the evidence to show how it has met each of the foregoing criteria. ORA and the Center should not discuss their views about vacating a decree with the defendants or their counsel. That request should be forwarded to OCC (Deputy Chief Counsel and Associate Deputy Chief Counsel for Litigation), the relevant Center(s), and DE, together with the PDD's views, which should include a description

of the results of the most recent inspection and the defendant's overall inspection history since the injunction was entered. If OCC, the program/division, the center, and DE do not object to vacating the injunction, OCC will inform the defendant's counsel that FDA will not oppose a motion requesting such relief.

Thereafter, the defendant's counsel should prepare, in draft, a short motion briefly describing the sunset provision, the defendant's compliance therewith, and the fact that FDA has read the motion and does not object to the relief sought. If OCC agrees with the motion, it will take steps to contact DOJ so that the motion may be filed without opposition from the United States.

6-2-17 Issuing Press Releases

The recommendation to issue a press release is made jointly by the OCC attorney assigned to the case, the ORA case officers (the compliance officer or DE), and the Center's compliance office. The decision to issue a press release is made by FDA's Office of Media Affairs in accordance with the Transparency Initiative. The roles and responsibilities of these offices in making these decisions, and in drafting, clearing, and issuing press releases are described in [subsection 6-1-13 "Issuing Press Releases."](#) See [Exhibit 6-10](#). Follow these procedures and the accompanying models for drafting press releases concerning seizures and injunction actions. Upload the press release in CMS.

6-3 INSPECTION WARRANTS

6-3-1 Purpose

To provide procedures for obtaining inspection warrants. Procedures for Search Warrants are discussed in [Section 6-4](#).

6-3-2 Inspection Warrants

FDA does not routinely request inspection warrants in order to conduct investigations or inspections of regulated industry. However, warrants have been used effectively to gather information that has been refused improperly. Inspection warrants should be recommended as soon as possible after a refusal is encountered. A past refusal is not a prerequisite to seeking an inspection warrant. (**NOTE:** "Inspection warrant" and "administrative inspection warrant" have the same meaning.)

Inspection warrants may be sought when inspection has been refused completely or when refusals have been encountered in limited areas; for example, when photography or sample collection has been refused.

There are situations where FDA will seek a preemptive inspection warrant; for example, when there is a history of prior refusals from a firm and FDA

anticipates a current refusal to inspect. Also, FDA may seek a preemptive inspection warrant prior to initiating a scheduled inspection when there is a documented corporate policy mandating refusal in a particular area (such as photography, sample collection, or copying of records), or there is good reason to believe that required information will be refused and that information will then be destroyed before an inspection warrant can be obtained.

Before seeking an inspection warrant, the agency needs to ensure that:

- A. FDA is entitled by statute or regulation to inspect the facility and to have access to the information which has been refused; and
- B. there is a compelling FDA need for that information, and
- C. the firm/individuals have refused to allow inspection or access to information in spite of a clear demonstration or explanation of appropriate statutory authority.

6-3-3 Responsibilities

Recommendations for inspection warrants are given high priority and handled expeditiously by all offices involved in their review. Under ordinary circumstances, OCC is not involved with the procedures for determining the need for an inspection warrant until the responsible center and DE determine that the application should proceed.

A. Division/District

1. Preliminary Steps

When the criteria for requesting an inspection warrant are not clear, the lead coordinator should consult with DE prior to submitting a request for an inspection warrant. DE is located at 10903 New Hampshire Avenue, Silver Spring, MD, 20993 ororaospopenforcementdivio@fda.hhs.gov.

When the PDD decides to recommend an inspection warrant, the lead coordinator should contact DE by telephone, provide advance notice, ascertain the DE contact person, obtain any additional guidance, and upload the documents listed below into CMS (Compliance Management System).

The Lead Coordinator should transfer the case to DE by changing the current owner to DE pursuant to CMS procedures. CMS will automatically send an e-mail to the person in DE designated to receive notification when actions have been submitted to that office. Prior to changing ownership for submission of the action, the Lead Coordinator should identify all potential or suspect adulteration and/or misbranding charges cited in the subject action under the Act/CFR tab in CMS.

2. What to Include

- a. **Cover Memorandum.** The cover memorandum should summarize the circumstance(s) justifying the need for an inspection warrant. The memo must cover the following elements:
 - i. The statutory or regulatory authority to conduct the inspection or to obtain the information.
 - ii. Why there is a compelling need to conduct the inspection or obtain the information.
 - iii. A clear description of the refusals encountered or, if refusals are anticipated, the reasons why a refusal is expected. Include a description of the efforts to explain our statutory authority and the firm's continued refusal in spite of this explanation.
 - iv. Each type of information sought and refused, and an explanation why the information cannot be obtained through other means.
 - v. The status of the inspection (ongoing, terminated, or anticipated)
 - vi. The reason for the inspection; prior warrants obtained; and, if applicable, violations observed.
 - vii. Any situation that may result in a refusal or delay of an inspection conducted under a warrant.
 - viii. Any other pertinent information, for example, that the location is a personal residence or ORA anticipates resistance during execution of the inspection warrant, in which case a strategy for dealing with the anticipated resistance should be outlined.
 - ix. Factors that are known to involve danger to the public, the inspecting persons, or others, for example, weapons, guard dogs, or hazardous chemicals.
- b. **Draft Application for Inspection Warrant.** The application for inspection warrant forms the basis for the agency's request to the Court. If there are multiple locations under the control of the same firm, prepare individual applications and warrants to cover each location. The application must include the following elements:
 - i. The correct address of the premises to be inspected. If the inspection is to extend to a vehicle, a precise description of the vehicle, including the color, make, model, and license number of the vehicle.
 - ii. The statutory authority to inspect the establishment and the items sought.

- iii. Any violations observed during the course of the current investigation or the most recent inspection, specifically citing the language and section of the Act being violated. Although it is not required that a violation has occurred in order to obtain approval of an inspection warrant, DOJ has asked that such information be included in the Application, when available.
- iv. A detailed description of any relevant refusals, including, for example, and not limited to: the individuals making the refusals, their titles, the dates of the refusals, any additional responsible individuals involved in or consulted about the refusals, the reasons given, any written corporate policy regarding the refusal, the names of investigators to whom the refusals were addressed.
- v. A detailed description of the reason for our inspection, or investigation during which the refusal was made, emphasizing that inspection was made at a reasonable time, in a reasonable manner, and describing any agency directives or programs which authorized the inspection and its scheduling.
- vi. A description of the items that will be sought during the execution of the warrant.
- vii. A description of the manner in which the requested inspection will be conducted pursuant to the warrant, such as the use of one or more investigators or U.S. Marshals to accompany the requesting investigator on the inspection, sample collection, and photography, and, where appropriate, copying of records.
- c. A Draft Warrant. Include a draft copy of the inspection warrant.
- d. Other Information and Documentation. Include any pertinent supporting documentation or background information.

NOTE: Recent models of Warrant Applications and Warrants may be available from ORA/DE, oraospopenforcementdivio@fda.hhs.gov.

3. Processing

The lead coordinator should transfer the case to DE by changing the current owner to DE pursuant to CMS procedures. CMS will automatically send an e-mail to the person in DE designated to receive notification when actions have been submitted to that office. Prior to changing ownership for submission of the action, the lead coordinator should identify all adulteration and/or misbranding charges cited in the subject action under the Act/CFR tab in CMS.

The lead coordinator will promptly alert DE of copies of approved, filed warrants uploaded in CMS and keep DE informed of the progress of the inspection under the warrant.

DOJ prefers, and FDA encourages, that U.S. Marshals accompany FDA investigators when warrants are executed. If this presents a problem for ORA staff, DE should be notified immediately. The recommending PDD should anticipate and set forth in the cover memorandum any situation that may result in a refusal or delay of an inspection conducted under a warrant. Whenever possible, an agency decision and implementation strategy regarding anticipated resistance, possible arrests, or use of force during execution of the inspection warrant should be considered and made prior to execution of the warrant.

If problems are encountered during the application for or execution of the warrant, DE should be contacted immediately. If there is a legal issue, contact OCC and DE immediately. A return (a statement indicating completion of the inspection conducted under warrant) must be made to the Court within 10 days of completion of the inspection. The return is a separate document prepared as part of the draft warrant application. It is simply a statement from the Investigator who was authorized to conduct the inspection that the inspection was made on a certain date(s). The document is filled in with the date of inspection, signed by the Investigator, and returned to the Court. A copy of the return should also be uploaded into CMS and a hardcopy should be forwarded to OCC.

B. Division of Enforcement (DE)

When a recommendation for an inspection warrant is transferred from the Program Division to DE, DE maintains case ownership but will send a task in CMS to the responsible Center(s) for concurrent review. The Center and DE will review the recommendation and proposed documents to assess the need for the action, the agency's statutory authority, completeness, accuracy, format, and conformance with current DOJ requirements. The Center indicates the completion of their review by uploading associated documents into CMS and closing the "task" pursuant to procedures in CMS. DE will provide the revised documents to OCC. Throughout the process, DE will monitor and coordinate the concurrent review and processing of the inspection warrant with the recommending Program Division, Center, and subsequently with OCC, and DOJ. If a warrant application is not approved by DE, a written explanation of the decision will be uploaded into CMS and DE will indicate "Non-Concur" in the internal decision field with the reason for non-concurrence, adding the completed date and changing the current

owner to the program or division, as appropriate. The office should close out the case pursuant to CMS procedures.

If through concurrent review by the Center and DE, a warrant application package is approved, DE will revise the documents as needed, upload them into CMS and indicate "Concur" in the internal decision field and add the completed date. DE will forward the revised documents to the Deputy Chief Counsel for Litigation, OCC and a draft DOJ transmittal memorandum for OCC. After review and approval of the warrant application package by OCC, OCC will forward the application package to DOJ and provide the final package to DE for upload to CMS. DE will update the FDA Final Decision to Approved.

Following DOJ review, DE uploads into CMS the DOJ approved (or denied) warrant application package, including any necessary guidance or instructions for the application and execution of the warrant. DOJ coordinates the filing of the application warrant with the Assistant U.S. Attorney's Office. Action ownership in CMS will end with DE.

DE notifies the Director of Office of Strategic Planning and Operational Policy (OSPOP) who notifies the Associate Commissioner for Regulatory Affairs (ACRA) through the Assistant Commissioner for Partnerships and Policy (OPOP) and designated contacts in the FDA [Office of External Affairs](#) and Office of Media Affairs of the strategy and impending action immediately once DOJ agrees to file the application and the filing has occurred or is imminent. DE uploads into CMS the files of all warrant recommendations. OSPOP/DE ensures the ACRA is notified once the inspection warrant has been executed.

C. Center

The responsible center promptly reviews all warrant application documents forwarded to it by DE, ensuring center support (or providing reasons for disapproval) and the accuracy of statutory references, with special emphasis on the authority for access to those items sought to be inspected. Where possible, revisions to documents should be highlighted and uploaded into CMS. Disapprovals are documented in writing and uploaded into CMS over the signature of the Director, Office of Compliance, or his/her designee.

D. Office of Chief Counsel

OCC promptly reviews the warrant and application package for legal sufficiency and transmits the final application package to DOJ. Any disapprovals will be documented in writing and DE will upload them into CMS.

6-4 SEARCH WARRANTS

6-4-1 Purpose

To provide the procedures for obtaining search warrants. Procedures for Inspection warrants in RPM [Section 6-3](#).

6-4-2 Search Warrants

Search warrants are effective tools for obtaining evidence of criminal conduct, and for seizing contraband or the fruits of a crime, property that has been or is intended to be used in the commission of a crime, or the arrest of persons based upon probable cause. See Rule 41, Federal Rules of Criminal Procedure. Also, see [U.S. Attorney's Manual](#). Criminal search warrants are particularly useful when there is reason to believe that relevant evidence may be hidden or destroyed.

6-4-3 Procedures

The Office of Criminal Investigations (OCI) is responsible for reviewing all matters in FDA for which a criminal investigation is recommended and is the focal point for all criminal matters. ORA management must communicate with its local OCI office, as instructed in [subsection 6-5-10 "Referral of Criminal Matters to the Office of Criminal Investigations"](#) below, before pursuing a criminal search warrant.

6-5 PROSECUTION

6-5-1 Purpose

This section establishes operational procedures for the uniform submission and review of prosecution recommendations, including referrals for criminal investigation. A number of different procedures, depending upon the distinguishing case features, are included in order to eliminate unnecessary review and to expedite the case review process.

As described below, all criminal referrals, whether initiated by ORA, the Center, or another FDA Headquarters component, must be sent to OCI for initial review in accordance with this section. If OCI declines the referral, the Center or ORA may pursue the matter through the preparation of a Summary and Recommendation in accordance with [subsection 6-5-5 et seq.](#)

6-5-2 Referral of Criminal Matters to the Office of Criminal Investigations

OCI is responsible for reviewing all matters in FDA for which a criminal investigation is recommended and is the focal point for all criminal matters. FDA personnel must refer all criminal matters, regardless of their

complexity or breadth, to OCI. This includes criminal search warrants, misdemeanor prosecutions, felony prosecutions, referrals for criminal investigation, and meetings associated with section 305.

ORA management must communicate with the local OCI office before pursuing any criminal matter. Designated center and ORA and FDA Headquarters points of contact must communicate with their respective OCI Senior Operations Manager (SOM). This communication is absolutely essential to preclude potential interference with other on-going criminal investigations and to prevent confusion among the components of OCC and DOJ that are responsible for handling FDA's criminal cases.

During this communication, OCI is to be provided with all of the facts of the potential case and any additional information that is relevant to, or could impact, the case in any way. In accordance with [SMG 9111](#), ORA management should notify the local Special Agent in Charge (SAIC), Assistant Special Agent in Charge (ASAIC), or Resident Agent in Charge (RAIC) of the referral via telephone. For referrals of *Park Doctrine* prosecutions, see the procedures below.

For all criminal referrals, OCI will decide promptly whether or not to pursue the case.

OCI will communicate its decision back to the referring Office. If OCI declines to pursue a referral, OCI will promptly convey its decision to the referring office, which may then proceed with the case and submit a formal summary and recommendation for prosecution in accordance with subsections [6-5-5](#) and [6-5-13](#) of this chapter.

6-5-3 Special Procedures and Considerations for *Park Doctrine* Prosecutions

A. Recommending *Park Doctrine* Prosecutions

The *Park Doctrine*, as established by Supreme Court case law, provides that a responsible corporate official can be held liable for a first-time misdemeanor (and possible subsequent felony) under the Act without proof that the corporate official acted with intent or even negligence, and even if such corporate official did not have any actual knowledge of, or participation in, the specific offense. A *Park Doctrine* prosecution, for the purposes of this section, refers to a recommended prosecution of a responsible corporate official for a misdemeanor violation of the Act.

Misdemeanor prosecution under the Act can be a valuable enforcement tool. Such prosecutions are referred to DOJ. Once a person has been convicted of a misdemeanor under the Act, any subsequent violation of the Act is a felony, even without proof that the defendant acted with the intent to defraud or mislead.

Misdemeanor prosecutions, particularly those against responsible corporate officials, can have a strong deterrent effect on the

defendants and other regulated entities. In some cases, a misdemeanor conviction of an individual may serve as the basis for debarment by FDA.

1. When considering whether to recommend a misdemeanor prosecution against a corporate official, consider the individual's position in the company and relationship to the violation, and whether the official had the authority to correct or prevent the violation. Knowledge of and actual participation in the violation are not a prerequisite to a misdemeanor prosecution but are factors that may be relevant when deciding whether to recommend charging a misdemeanor violation.
2. Other factors to consider include but are not limited to:
 - a. Whether the violation involves actual or potential harm to the public;
 - b. Whether the violation is obvious;
 - c. Whether the violation reflects a pattern of illegal behavior and/or failure to heed prior warnings;
 - d. Whether the violation is widespread;
 - e. Whether the violation is serious;
 - f. The quality of the legal and factual support for the proposed prosecution; and
 - g. Whether the proposed prosecution is a prudent use of agency resources.

As the Supreme Court has recognized, it would be futile to attempt to define or indicate by way of illustration either the categories of persons that may bear a responsible relationship to a violation or the types of conduct that may be viewed as causing or contributing to a violation of the Act. In addition, these factors are intended solely to explain the focus for the procedural steps to be addressed by FDA personnel, and do not create or confer any rights or benefits for or on any person, and do not operate to bind FDA. Further, the absence of some factors does not mean that a referral is inappropriate where other factors are evident.

When ORA is considering initiating a referral for a *Park Doctrine* prosecution, the lead coordinator is required to consult with the appropriate center to ensure that the referral will align with agency priorities and that the center will support the referral and provide expert witnesses or other litigation support when necessary. Centers and ORA offices are also encouraged to consult with OCC and OCI HQ SAIC and/or the ASAIC Investigative Operations Division (IOD) early in the process for guidance and recommendations regarding optimal venue.

If ORA or the center is seeking a misdemeanor prosecution under the *Park Doctrine*, the initial referral to OCI should clearly indicate that a *Park Doctrine* prosecution is being sought and the reasons that a *Park Doctrine* prosecution would be beneficial. At the same time that ORA refers a *Park Doctrine* prosecution to the appropriate OCI Office, notice of the referral also should be sent to the SAIC and/or the ASAIC OCI HQ IOD, and the applicable center. Notice of all *Park Doctrine* referrals, whether initiated by the office or the center, should also be sent to the Deputy Chief Counsel and Associate Deputy Chief Counsel for Litigation in OCC, and to the director of DE.

Upon receipt of a *Park Doctrine* referral, OCI will promptly review the referral and will communicate with OCC and the referring office to obtain any information or assistance needed to present the matter for prosecution. In appropriate cases, the assigned OCC attorney and/or a representative from DE or other component should participate in the initial presentation of the *Park Doctrine* matter.

6-5-4 Communication Between OCI and Other FDA Components

The following Staff Manual Guides (SMGs) provide additional information on communications between OCI and other FDA components:

- A. [SMG 9111 Sharing of Information Related to Criminal Violations.](#)
This SMG requires that OCI be notified of potential criminal activity immediately if there is an imminent threat to public health and within 10 business days in all other cases and that OCI evaluate the information within 10 business days and notify the office of its initial assessment. It also addresses information sharing between OCI and other FDA components.
- B. [SMG 9110 Enhanced Communications with the Office of Criminal Investigations \(OCI\) and Improved Alignment of Criminal/Regulatory Priorities and Activities.](#) This SMG provides general procedures for the establishment of regularly scheduled meetings between OCI and center, ORA and other FDA components.

Notify OCI if you receive a request from a law enforcement agency (federal, state/local, or foreign) for non-public information related to a criminal case. Notification should be provided to the SAIC and/or the ASAIC, OCI HQ IOD. This is particularly important if the request relates to grand jury information, judicial proceedings under the Act, or joint investigations with OCI and other law enforcement agencies about violations of the Act. When OCI seeks non-public information on its own initiative or in response to a request described above, provide the information to the SAIC and/or the ASAIC OCI HQ IOD for their review

and determination of appropriate written confidentiality assurances prior to disclosure. Indicate what information is non-public.

6-5-5 Processing a Summary and Recommendation

In cases where OCI has declined to pursue a referral, the recommendation for prosecution or for investigation with a view of possible criminal charges will be prepared in the format of a Summary and Recommendation (S&R). This document is a memorandum containing all information that would permit review and evaluation of the office's recommendation, including the reasons for not including samples or individuals cited in the Section 305 notice (when such a notice is issued) and information concerning any potential weaknesses in the case, anticipated defenses, or reasons why discretion may be exercised not to prosecute a person (such as, extreme age or very poor health).

It is important for the S&R to contain all facts pertaining to the recommendation, since it will be relied upon to determine whether a case is prosecutable and worthy of forwarding to DOJ. In prosecution cases in which FDA forwards counts in an Information or Indictment (as opposed to referrals for criminal investigation), the S&R should present the evidence of **each element** of the offense to be charged.

Where a lead coordinator submitted the original referral or where the referral relates to an inspectional process, each recommendation must be accompanied by the written concurrence of the DD and the Director of DE. The DD's approval must state why prosecution is the action of choice, and DE must concur. This concurrence will appear on the last page of the S&R. Where a center submitted the original referral and the referral relates to a center process, each recommendation must be accompanied by the written concurrence of the director of the center's office of compliance.

See [subsection 6-5-13](#) for detailed guidance for preparing an S&R.

6-5-6 Criminal Prosecution after Section 305 Notice

Criminal referrals for which the agency has provided a notice and opportunity to respond, pursuant to Section 305 of the Act, should follow the procedures described below:

- A. When ORA does not have direct reference authority to issue a Section 305 notice, ORA will submit a citation recommendation to the appropriate center(s) for review, after contacting OCI (as described in "Referral of Criminal Matters to the Office of Criminal Investigations" in [subsection 6-5-2](#) above.

Generally, the citation recommendation includes:

1. the names and responsibilities of each individual and the charges to be presented in the notice;

2. the full background history of notification of the persons to receive a notice; and,
 3. facts supporting the proposed charges, including assurance of interstate documentation. All pertinent evidence, such as work sheets, labels, and inspection reports, should be submitted with the recommendation. The center may request the interstate documentation if a special need to review it exists.
- B. If ORA or the center identifies an issue requiring consultation with DE, OCI, OCC, or an ad hoc committee, the component identifying the issue will obtain prompt resolution as early in the review process as possible.
- C. If, following the meeting held in response to the Section 305 notice, there is no significant change in the facts, as set forth in the citation recommendation, the lead coordinator will notify the center, which will promptly forward the citation recommendation package to DE. Concurrently, a final S&R will be sent by the lead coordinator to DE with copies to the center.

If there is a significant change in the facts or strength of the proposed case, the lead coordinator will submit the prosecution recommendation package to the appropriate center solely to determine whether prosecution remains warranted in view of the new information. If prosecution is warranted, the center will promptly forward to DE the prosecution S&R and the center's approval memo presenting the basis for its decision in light of the new information.

NOTE: When ORA has evidence sufficient to meet the requirements for direct reference authority to issue a Section 305 notice ("direct reference cite authority"), the procedures in # 1 above do not apply (except that OCI must be contacted, as described in "Referral of Criminal Matters to the Office of Criminal Investigations" above). After the Section 305 process has been completed and, if no new information is presented that affects the basis for the direct reference authority, the lead coordinator should promptly submit its prosecution S&R directly to DE for a limited review. The lead coordinator should concurrently send a copy of the S&R to the center.

If the response to the Section 305 notice reveals new information affecting the basis for the direct reference cite authority, the PDD must obtain center review and concurrence concerning that aspect of the recommendation before submitting it to DE.

- D. DE will perform a limited review to determine whether the proposed prosecution conforms to agency policy and enforcement strategies and objectives. If DE concurs in the prosecution recommendation, it

will forward all relevant materials to OCC, along with a memo concerning the issues it has considered and that DE believes OCC should review.

- E. OCC will review the recommendation and, if it agrees that prosecution is supportable, prepare a referral letter and form of Information or Indictment.

6-5-7 Criminal Prosecution without Section 305 Notice

Those instances in which the agency need not issue a Section 305 notice under the Act are codified in 21 CFR 7.84. No Section 305 notice is required in cases brought under Title 18 of the United States Code - as opposed to cases brought under the Act - or in cases exempt under 21 CFR 7.84(a)(2) and (3), based on the agency's belief that the notice might result in alteration or destruction of evidence or flight to avoid prosecution. Nor is a Section 305 notice usually provided when the agency is recommending further investigation.

Criminal referrals not preceded by a Section 305 notice should follow the procedures described below. OCI must be contacted early on in this process, in accordance with the procedures described in "Referral of Criminal Matters to the Office of Criminal Investigations" above.

- A. The PDD is to consult with DE, which will consult with OCC, to determine whether to issue a Section 305 notice or whether an ad hoc committee is needed to decide the issue. If DE and OCC agree that no Section 305 notice should be issued, DE will so notify the director. The lead coordinator will then prepare an S&R and obtain approval from the Region before submitting the S&R to DE, with concurrent copies to the center and OCC for review. The lead coordinator will explain under the heading "No Section 305 Notice" why such notice is not required. Should DE and OCC decide that a Section 305 notice should be issued, DE will so notify the lead coordinator who will then follow the procedure under RPM [subsection 6-5-6, "Criminal Prosecution after 305 Notice"](#).
- B. If the center and DE concur in the recommendation, each will prepare a memo reflecting its views on the relevant issues. The center will forward its memo to DE.
- C. DE will forward all relevant materials and memos to OCC and if OCC agrees that prosecution is supportable OCC will prepare a referral letter and form of Information or Indictment.

6-5-8 Contempt of Court; Violation of Probation

The lead coordinator will prepare an S&R outlining the facts that establish the violative conduct and send it and a copy of the pertinent court order electronically via CMS to DE. Because DE and the relevant center are

expected to conduct concurrent reviews, the S&R should include a request that DE send a task referral pursuant to CMS procedures to the center requesting its review.

Both the center and DE will have 10 working days to review the proposed action and upload their comments into CMS.

If no adverse comment is provided by either the center or DE, or if adverse comment was provided but a consensus to proceed is reached, the lead coordinator will forward its S&R and supporting evidence to DE via CMS for prompt forwarding to OCC for review. If OCC agrees that the action is supportable, it will prepare a referral letter.

6-5-9 Development of Felony Violation

Some investigations may reveal facts supporting potential felony charges under either Title 18 of the United States Code or 21 U.S.C. 333(a)(2). A primary problem associated with these cases is determining the investigational end-point. When such situations are encountered, an *ad hoc* committee should be considered. This is because some potential cases should be referred at an early stage for a grand jury investigation, while FDA can carry others to investigational completion prior to referral.

The following matters, among others, should be considered in these situations:

- A. scope of the investigation;
- B. status of current investigation, including identification of targets and of potential cooperating individuals;
- C. strategy and timing in completing the investigation;
- D. agency compliance policy in the area at issue;
- E. preliminary evidence that violations are intentional;
- F. identification of inspectional or investigational problems;
- G. use of criminal search warrants;
- H. need for or wisdom of a Section 305 notice citation; and,
- I. recommendation for grand jury investigation. See subsection [6-5-12, "Grand Jury Investigations and Secrecy"](#).

For investigations subject to ad hoc committee oversight, the compliance branch in the managing organizational unit will prepare a status report whenever significant progress is made on an investigation or at least every 90 calendar days, whichever occurs first, and distribute it to DE, OCC, appropriate center, and affected program/division offices.

6-5-10 Referrals for Criminal Investigation

A referral from ORA or center to DOJ for further criminal investigation, including an investigative grand jury, should follow the process described below:

- A. The initiating unit, division or center, will notify OCI in accordance with the RPM section "Office of Criminal Investigations." If OCI elects not to pursue the case, then the unit or center may notify DE and request an ad hoc committee meeting and provide a Summary and Recommendation Document (S&R) of the existing evidence. Relevant, organized, and tabbed background material will be assembled by the initiating unit and uploaded with the S&R into CMS. The lead coordinator should transfer the case to DE by changing the current owner to DE pursuant to CMS procedures. CMS will automatically send an e-mail to the person in DE designated to receive notification when ownership of a case has changed to that office. Information should cross reference and cite specific pages of the background material.
- B. Prior to scheduling the meeting, DE will review the background package and ensure that it is in a form that will facilitate review and identification of issues.
- C. DE will promptly notify the committee via e-mail of the availability of the background package in CMS and in the body of the e-mail provide a time and place for the meeting and identify the principal issues to be decided. With very rare exception, a minimum of 10 working days will be provided for members to review the background package; center review will be given high priority and the meeting will not be scheduled until the center is ready to participate. A copy of this e-mail should be uploaded into CMS.
- D. The committee members should be prepared to make agency decisions on the issues, including whether referral should be made on the basis of the evidence in hand, whether additional assignments should first be issued, completed, and reviewed by the committee, or whether a noncriminal disposition should be considered in lieu of or in addition to a prosecution.
- E. Should the committee members concur in the recommendation for referral and believe that there is no need to gather further evidence or for a further meeting, DE will promptly prepare a memorandum of the decision, upload it into CMS and forward a hardcopy to OCC as the agency's recommendation. DE will maintain ownership of the case. OCC will revise ORA's draft of the referral letter, as necessary. DE should upload this draft into CMS.
- F. Should the committee believe that additional investigation is needed, the committee will issue the appropriate assignments,

record them in a memo that is uploaded in CMS and set a tentative date to reconvene. Offices performing the additional work will be responsible for providing written summaries of the results and, when appropriate, recommendations to the committee in advance of the next meeting. These associated documents should be uploaded into CMS. DE will monitor the status of the assignments and schedule via e-mail the follow-up meeting. A minimum of 5 working days will be provided for members to review new information prior to the meeting. DE will prepare a memorandum of any subsequent meeting and upload it into CMS.

- G. If the committee decides, either on the basis of its initial review or on the basis of additional data discussed at a subsequent meeting, that a request for criminal investigation should be referred, DE will promptly forward to OCC any relevant materials that may not have previously been provided along with a written request that OCC refer the matter to DOJ.

NOTE: When FDA participates in investigations in which another Federal agency has the lead and intends to request a criminal investigation, ORA will work directly with the lead agency in developing evidence and in assisting in the investigation. In such cases, the lead coordinator will promptly notify the relevant centers, ORA program and division, DE, OCl, and OCC of the investigation, the roles of the units in the investigation, and whether a grand jury investigation is contemplated.

As soon as the lead coordinator determines that it would like to seek the prosecution of Title 21 or Title 18 charges based upon violations involving FDA regulated articles in an investigation where another Federal agency has the lead, it will notify DE, for an FDC number, the centers, and OCC of its intent to do so and will promptly forward a recommendation to DE, the center or, if appropriate, directly to OCC, to obtain approval to proceed with the case.

In some cases, an ad hoc meeting may be appropriate. If special time constraints are applicable because of the participation of other agencies, the recommendation should so state. Except for possible time constraints, joint investigations should be processed in the same manner as other FDA cases.

6-5-11 Information and Indictments

These documents will usually be prepared by Office of Chief Counsel.

An Information is the formal legal document that is usually used to allege misdemeanor violations. An Indictment is the document in which felony violations are alleged, following presentation to the grand jury. This document is also referred to as a True Bill of Indictment. With the consent

of a defendant, an Information may be presented to a grand jury, even though only misdemeanor violations are alleged.

6-5-12 Grand Jury Investigations and Secrecy

Grand jury investigations are subject to Rule 6 of the Federal Rules of Criminal Procedure. See [Exhibit 6-28](#). The fact of grand jury investigations and the actions of a Federal grand jury are secret. Only persons whose names have been filed with the court pursuant to Rule 6(e) may know about the grand jury's activities, such as whether the grand jury has issued a subpoena to someone. **For this reason, transcripts of testimony given before a grand jury can be read by or discussed only with persons who have been designated under Rule 6(e). Neither FDA colleagues nor supervisors may be advised of the substance of grand jury activities unless they have been designated under Rule 6(e).**

As with any pending investigation, there should be no comment whatsoever to the media or to the general public about the existence or activities of a grand jury. Even if there has already been speculation in the press about a grand jury or reports about it from witnesses called to testify before the grand jury (who are not bound by the rule of grand jury secrecy), no confirmation or other comment on the grand jury should be made.

Strict adherence to the rule of grand jury secrecy protects not only the integrity of the government's investigation and the validity of any indictment the grand jury might return, but the rights of the persons accused.

Compromising the 6(e) rule is a very serious matter and could result in dismissal of the charges, the suppression of valuable information, and/or a contempt citation against persons violating Rule 6(e).

DOJ and the U.S. Attorney may request FDA to provide investigative support to conduct interviews, accompany U.S. Marshals to seize evidence, and so on. Any person who is involved in this type of investigation will be given a 6(e) designation where these actions involve matters occurring before the grand jury.

6-5-13 Preparation of Summary and Recommendation

See [Exhibit 6-24](#) for a model format for the summary and recommendation memorandum and [Exhibit 6-25](#) for an example of a food sanitation case. The Sample Index is an outline of the support samples related to the prosecution.

A. Sample Number, Product, Date Shipped

The order of the counts in an Information or Indictment is variable, but should be determined by the significance or seriousness of the

violations, rather than the sequential order of the sample numbers or the date of sample collection. However, where all samples or schemes have the same degree of seriousness, list in descending chronological order (most recent offense in Count I, next most recent offense in Count II, and so forth. The column headings may be changed to provide whatever information ORA feels is significant. Beneath the sample number indicate the proposed count number. In cases where supporting samples are unnecessary, describe the scheme or violation and outline the elements of the offenses.

B. Citation Under Section 305 Of The FD&C Act

List complete names and addresses of all persons issued Section 305 notices. Prepare brief, concise paragraphs explaining significant new evidence obtained since the Recommendation for Citation was submitted. Also include any changes in the status of responsible individuals or the firm that have occurred since the center approved the issuance of 305 notices or, in the case of direct reference cite authority, since the Section 305 notice issued. See subsection [6-5-6 "Criminal Prosecution after Section 305 Notice"](#). If this is a recommendation without a Section 305 notice, prepare a brief paragraph explaining the facts, including identifying the basis of concurrence with this approach, for example, "Ad Hoc meeting."

C. Legal Status

Prepare a brief paragraph describing the legal status of the firm as of the date of the S&R and at the time of the violations. If there has been a change in the legal status in the interim, furnish complete information concerning the change. As soon as the decision is made to recommend prosecution of a corporation, request certified copies of the Articles of Incorporation and the most recent Annual Corporate Registration. The annual corporate registration may list the current corporate officers at the date of filing. This request may be made in writing as shown in [Exhibit 6-26](#) or in person so that the records are received in a form suitable for introduction into evidence (see [Exhibit 6-28](#)). If the Articles of Incorporation have been received before the recommendation has been submitted, so state in this section and enclose photocopies of the Articles with the recommendation. If they have not been received, include a statement that the Articles of Incorporation have been requested and photocopies will be submitted upon receipt.

When preparing photocopies of certified copies, the removal of any staples nullifies the certification. -- Caution the Legal Secretary/Technician about this.

If a corporation is dissolved, in most states it still legally exists for a period of time specified by the state in which it is incorporated and may be prosecuted during that period. In case of dissolution, submit copies of any notices thereof filed with the state and reports of any actions by the state on such dissolution.

D. Alleged Violation

Prepare a summary of what the case is about. Include a statement on how the problem came to the attention of the agency. List the violations under this heading. In the event the proposed counts are numerous, and the violations involve several different sections of a statute, you may use an outline or tabular form. Adulteration and misbranding charges should be charged in separate counts. In cases involving fraud, a detailed statement of all pertinent data (who, what, when, where, why, and how) concerning the scheme, from its conception through its perpetration, should be prepared.

The following questions should be considered:

1. When was the scheme initially implemented? By whom?
2. What were its primary objectives?
3. What were the methods by which it was implemented?
4. Where was it put into operation and for how long?
5. What was the nature of the scheme, the types of merchandise or service involved?
6. Describe the magnitude, nature, and characteristics of the scheme (for example, number of units shipped, and amount of money involved).
7. Describe the victims as to health, economic status, or other features.
8. Identify for each proposed defendant or target any evidence reflecting that the offense was committed knowingly and willfully (intentionally).
9. Identify potentially cooperative witnesses.
10. Describe any noteworthy investigational problems encountered.

E. History

State briefly the regulatory history of the firm and the individual defendants. Point out any cooperative work FDA has done with the state or other Federal agencies. Indicate any prior Federal action and any state legal action taken against the proposed defendants as well as any previous in rem actions.

F. Prior Notice

As more fully explained in RPM [Chapter 10 - Other Procedures](#) when it is consistent with the public protection responsibilities of the agency and if a violative situation does not present a danger to health or does not constitute intentional, gross or flagrant violations, it is FDA's policy to afford individuals and firms an opportunity to voluntarily take appropriate and prompt corrective action prior to the initiation of enforcement action. If voluntary correction is not achieved, documentation that adequate prior notice was provided strengthens the agency's position in enforcement actions by establishing that responsible individuals continued violating the law despite having been warned by the agency.

Indicate how and to whom prior notice was provided. If formal prior notice has not been given, indicate how the proposed defendants are aware of the consequences of their violative acts, or explain why prior notice is not necessary or appropriate in this situation.

G. Other Correspondence

Provide reference to and copies of any correspondence that the agency (division, program, center, or other headquarters' unit) and state may have regarding matters subject to the recommended action.

H. Witnesses for Inspectional and Analytical Findings

Arrange the samples (if any) by proposed count numbers listing the collecting investigator and the analysts. Identify the documentary and physical evidence associated with each witness and describe how this evidence was obtained, e.g., interview, inspection, surveillance, or other means. For a case with support samples, assign count numbers as in Exhibit 6-25.

I. Other Witnesses

List the names, addresses, telephone numbers, and titles of any other known witnesses, including cooperating subjects of the investigation, FDA representatives from the center, and nongovernment expert witnesses with a summary of their anticipated testimony.

J. Recommendation

List the persons being recommended for prosecution and the corresponding sample numbers (if any) or scheme that is the basis for prosecution. If any such persons have been previously convicted or are the subject of other legal action, include a paragraph stating the nature of the charge, the date the case was terminated, the disposition, the penalty imposed, the jurisdiction, and the case number (and an FDC, lead sample, or other FDA

identifying numbers, if any). Indicate whether warnings were given and summarize the recommended defendant's response or corrective action. Indicate what harm has or can result from the criminal activity at issue, such as, type and total amount of loss, number and type of victims, and similar information. See also the RPM [Chapter 10 - Other Procedures](#), subsection 10-2 Prior Notice.

K. Permanent Abeyance of Samples or Non-Inclusion of Individuals

If ORA decides to place any of the samples listed in the Section 305 notice in permanent abeyance or to not include cited individuals as proposed defendants, the reasons for these decisions should be given in this section. Excluded samples should not be destroyed until the termination of the action by plea or trial. If all samples and individuals listed in the Section 305 notice are included in the prosecution recommendation, this section may be omitted.

L. Sample Data

This section is designed to furnish a brief summary of the available information in the file regarding each sample. Ordinarily, a criminal case should include more than one count and only in very unusual circumstances, which must be explained in the memorandum, will a one-count Information be referred to DOJ.

Thoroughly discuss any potential problem areas with respect to the samples, such as a modification of official analytical methods during analysis, deviations from normal procedures in the collection of the samples, errors in the collection records, seals, analytical records which had to be corrected, or any inconsistencies between affidavits and records.

1. Date lot shipped/received: For 301(a) or (d) violations, state the date the defendants shipped the lot or delivered it for shipment. For 301(k) violations, state the date the defendants received the lot, and for 301(c) violations state the date the lot was received and the date it was delivered or proffered for delivery. Occasionally, the receiving date in a 301(k) violation is not available. In such a case, the date of the offense is the day on which the investigator can testify that she or he saw the subject lot at the proposed defendant's premises. Occasionally, a 305 notice will issue with the date of shipment being the date furnished in an affidavit signed by the dealer, but subsequent investigation uncovers records indicating that the lot was actually shipped or delivered on another date. As long as the 305-notice stated "on or about" with respect to the date, this is acceptable. The correct date will be listed in the Information or Indictment, even if it differs from that listed in the Section 305 notice. Complete information regarding the conflicting dates

should be furnished under the caption "Documentation of Interstate Commerce."

2. Date lot sampled/by whom: If the sampling of the lot takes place over a period of several days, that should be stated here. In the case of a 301(k) violation, if the lot remains in the regular storage area for saleable goods, the Information or Indictment will indicate that it was held for sale between the date of receipt and the last day of the inspection. If the lot is moved to a quarantine area and it is clear that it is not to be sold, the day the product was moved (or destroyed, denatured, or embargoed) will be used in the Information or Indictment. In addition to the name of the collecting investigator, indicate where he or she is located at the time of the writing of the recommendation. If the investigator has transferred to another district, resigned, or retired, he or she should be contacted when the Information or Indictment is submitted to DOJ, advised that prosecution is pending, and requested to keep the PDD informed of his or her location so that the investigator can be contacted if the case goes to trial.
3. Description of lot and sample size: The size of the lot should be listed and, in 301(k) sanitation cases, a brief description of the lot should be given.
For example, the description should contain the statement that the investigator looked at (number of) bags, found urine on (number of) bags, (number of) bags were rodent gnawed, and should indicate whether filth was only on the exterior of the lot or on containers covered by other containers, whether or not the lot was received palletized, whether containers in the lot had been restacked by the firm, etc.
4. Analysts: As with the collecting investigator, the current location of the analysts should be recorded and contact should be made with the analysts when the Information or Indictment is submitted to DOJ.
5. Analytical methods: The method of analysis should be given. If there was any deviation from an official method, complete information concerning the modification and reasons therefore should be given. In the analysis of official preparations, the method in the compendium should be followed.
6. Number of subs analyzed: If every sub has been analyzed, merely state "all." It is incumbent upon the Compliance Branch to ensure that sufficient analytical work has been performed.
7. Analytical findings: The results of each analysis of the product should be listed. If the problems which were encountered necessitated additional work, or deviation in or from an official

method such as new methodology or analysis to resolve discrepancies in analytical results, such matters should be disclosed and discussed. In cases involving filth in foods, the analytical findings should be broken into two groups; those demonstrating actual contamination in the product [402(a)(3)] and those demonstrating 402(a)(4) conditions.

The results regarding the findings of actual product contamination should be summarized basically as follows:

a. Section 402(a)(3) Verification

Subs, _____, and - gnawed -incisor marks - confirmed.

Subs, _____, and- contained rat or mouse excreta or hair - confirmed.

Sub _____ - insects (identities, if possible)

b. Section 402(a)(4) Verification

If there is substantial 402(a)(3) evidence, the subsamples collected from the surface and proximity of the lot need only be briefly summarized, covering each type of 402(a)(4) filth present. This includes rat or mouse excreta, rodent urine, and rodent nesting material as being confirmed or identified.

If the proposed charges differ from the data listed under "Analytical Findings" or the charge sheet that accompanied the 305 notice, the reasons for the differences should be discussed.

8. Section 702(B) Portion: In any case involving analytical work, a portion of the sample usually should be available for the defendant, should he or she request it. Verify whether the section 702(b) sample portion is available, and note the amount available. If a 702(b) portion does not exist, this fact should be conspicuously noted, and an explanation provided.

Some exceptions to the requirement for 702(b) portions are codified at 21 CFR 2.10. If all subs have been analyzed, there is a presumptive 702(b) concern which should be addressed.

NOTE: Filth exhibits do not require a 702(b) portion.

9. Seizure: If the lot forming the basis for a proposed count was seized, list the case number and the FDC number and state the disposition of the seizure.
10. Documentation of interstate commerce: State the name and title of individuals signing dealer statements and affidavits, the name and address of the firm for which they work, and list the documents furnished, including information such as purchase order, invoice, freight bill, and bill of lading numbers, and the

dates they were issued. Interstate commerce witnesses are sometimes called on to testify and supply the original documents in the event the case goes to trial.

11. Remarks: This section should contain detailed information concerning any potential problem areas or weaknesses in the case not covered in the description of the individual counts. Include the ages of the proposed defendants and, if known, any physical problems they may have. Also, indicate that OCI was contacted regarding the case. Finally, state why prosecution is the action of choice.

6-5-14 Submission of Summary and Recommendation Documents

The summary and recommendation (S&R) documents are submitted to the center, DE and OCC, depending upon the instructions described in the applicable case procedure in subsections 6-5-6 "[Criminal Prosecution after Section 305 Notice](#)," 6-5-7 "[Criminal Prosecution Without Section 305 Notice](#)", or 6-5-2 "[Referrals of Criminal Matters to OCI for Criminal Investigation](#)."

A. Prosecutions Requiring Center Approval

1. Submit the S&R (prepared as described in "Preparation of Summary and Recommendation") and the supporting documents listed below by uploading them into CMS.
 - a. Section 305 Notice and Charge Sheet
 - b. Record of Section 305 meeting and any documents presented at the meeting
 - c. Written answer to the Section 305 notice (if meeting was not held)
 - d. Any correspondence or memoranda of telephone conversations with proposed defendants since the Citation Recommendation was submitted.
 - e. Guaranty (if applicable)
 - f. Articles of Incorporation (Photocopy can be submitted in CMS and lead coordinator will maintain the original. DO NOT HOLE PUNCH the original document).

Centers should upload their approval memo into CMS.

NOTE: If the recommendation meets the circumstances outlined in subsection [6-5-13 "Processing a Summary and Recommendation"](#) and does not require further review by the center, submit the S&R and supporting documents to DE as described in "Direct Reference Prosecutions" below.

B. Direct Reference Prosecutions

The S&R prepared as described in subsection [6-5-13 "Processing a Summary and Recommendation"](#) should be uploaded into CMS. The lead coordinator should transfer the case to DE by changing the current owner to DE pursuant to CMS procedures. CMS will automatically send an e-mail to the person in DE designated to receive notification when ownership of a case has changed to that office. The S&R should contain the supporting documents listed above.

6-6 CIVIL PENALTIES – ELECTRONIC PRODUCT RADIATION CONTROL

6-6-1 Purpose

This section provides procedures and instructions for recommendations of civil penalties for violations of Subchapter C - Electronic Product Radiation Control (formerly the Radiation Control for Health and Safety Act of 1968) of Chapter V of the Act.

- A. Please be alerted to the fact that the provisions for penalties for electronic products under Section 539 of the Act are such that they cannot be correlated with penalties for devices under Section 303 of the Act.
- B. Any references simply to **manufacturer** that appear in this chapter include the words **assembler** and **importer**, since those words are included by definition in Section 531(3) [21 U.S.C. 360hh(3)] of the Act in the word **manufacturer**.
- C. Any references to products in this chapter refer to an electronic product as that term is defined in Section 531(2) [21 U.S.C. 360hh(2)] of the Act.

6-6-2 Scope

These procedures are provided primarily for guidance in recommending a civil penalty action; however, instructions for incorporating injunction recommendations in the civil penalty recommendations are included. See [Section 6-2](#).

Injunction considerations are included because there is precedent where the recommended, approved, and executed action was a joint civil penalty and injunction action. See [Exhibit 6-30](#).

Documents attached as exhibits represent only some of the regulatory considerations under the Act. These procedures are designed to provide guidance in recommending an action involving any violation committed under the Act.

6-6-3 Legal Authority

Civil penalties are provided for in Section 539 [21 U.S.C. 360pp] of the Act. Action under this section may be brought in any district court of the United States in which any act or omission or transaction constituting the violation occurred, or in any such court where the defendant is found or transacts business. Process in such cases may be served in any district of which the defendant is an inhabitant, or wherever the defendant may be found.

6-6-4 Criteria For Recommending Civil Penalties

The basic criteria for recommending a civil penalty are as follows:

A. A Violation of The Act Has Been Established and Documented.

NOTE: It is not necessary to show a health hazard to initiate action; such hazards were recognized and implied in the enactment of the Act by Congress.

1. Section 538(A)(1) [21 U.S.C. 360oo(A)(1)] Introduction or Delivery for Introduction into Commerce or Importation into The United States of a Non-Compliant Product
 - a. This prohibited act only applies to a manufacturer, excluding diagnostic x-ray assemblers, of an electronic product.
 - b. A non-compliant product must have been delivered for introduction or introduced into interstate commerce.
 - c. Penalty for committing a violation under this section does not require the manufacturer's prior knowledge of the noncompliant state of the product. Nevertheless, a penalties action is not usually initiated unless a violation has continued after notice/warning to the defendant.
 - d. An exception may be made in the case of manufacturers, where violations are a significant radiation hazard. (If the defendant(s) continue the violative practice(s) after notice/warning has been given, the instances of similar violation occurring prior to the notice/warning then become subject to inclusion as "counts" in the civil penalty action.
 - e. Each violation is based on evidence that the product did not comply with an applicable standard when introduced or delivered for introduction into commerce by the manufacturer. Defects, as defined by 21 CFR 1003.2, are not subject to this charge, unless they constitute non-compliance with a standard.

2. Section 538(a)(2) [21 U.S.C. 360oo(a)(2)] Failure to Give Notification or Take Corrective Action
 - a. The product must be shown to be noncompliant or defective as a result of its design, production or assembly by the alleged violative manufacturer. Significant radiation hazards may be considered for civil penalties without prior notice/warning. In all other circumstances, the manufacturer must have been given a reasonable period of time within which to refute any allegations that the product is noncompliant or defective.
 - b. The agency should be in a position to demonstrate that the manufacturer was aware of the noncompliant or defective product either through the FDA's notification or otherwise if that question is raised.
 - c. The manufacturer should be given a reasonable period of time within which to demonstrate that the noncompliant or defective product does not present a significant risk of injury to any person and apply for an exemption from notification and repair under 21 CFR 1003.30 and Section 535(a)(2) of the Act. An exception may be made in the case of manufacturers, where violations are a significant radiation hazard. In these cases, civil penalty without prior notice/warning will be considered.
 - d. The agency must be able to demonstrate that at least one of the following violations has been committed:
 - i. The manufacturer has not notified the agency of a defect or noncompliance.
 - ii. The manufacturer has not notified the known purchasers of the defect or noncompliance.
 - iii. The failure of the manufacturer to repair, replace or refund the cost of noncompliant or defective products. This may involve either failure to submit a corrective action plan or failure to implement a plan approved by the agency.
 - iv. Charging of purchasers by the manufacturer for the repair, replacement or refund of a noncompliant or defective product, including charges for any portion of an approved corrective action plan.
 - v. This section applies to dealers and distributors of electronic products for which there is an applicable performance standard in that it is a prohibited act for these individuals to fail to furnish the manufacturer with such information as may be necessary to identify

and locate for purposes of Section 535, the first purchasers of noncompliant products.

3. Section 538(a)(3) [21 U.S.C. 360oo(a)(3)] Failure to Maintain Records or Permit Inspection
 - a. The manufacturer must maintain records of the locations of the first purchasers if the product is subject to the distribution recordkeeping requirement as specified in Table 1 of 21 CFR 1002.1. The manufacturer must also maintain records of the locations of any subsequent purchasers which have been provided to the manufacturer by dealers and distributors. However, the manufacturer is not responsible for the location of records of subsequent purchasers which are not provided to it by dealers and distributors. The agency may require the manufacturer to request dealers and distributors to provide this information to it in a corrective action plan in accordance with 21 CFR 1002.41(a)(1) and Section 537(f) of the Act.
 - b. The manufacturer is required to maintain records which demonstrate the adequacy of its manufacturing practices to ensure the agency that its safeguards against hazardous radiation are adequate and that its products comply with an applicable performance standard.
 - c. Dealers and distributors of electronic products subject to the distribution recordkeeping requirement as specified in Table 1 of 21 CFR 1002.1 must maintain records which identify the product and the location of all first purchasers and make these records available for inspection or copying by the agency. Failure to fulfill either of these two requirements would be considered a violation under this section. Dealers or distributors are not, however, required to obtain or maintain this information for subsequent purchasers.
 - d. The manufacturer and dealer or distributors, after having been given reasonable notice, are required to make all required records available for inspection by the agency. The agency is not required to show cause for this request and failure to comply by the responsible person or company is a violation under this section.
 - e. The agency can require a manufacturer to permit the inspection of its facilities as well as its required records if good cause is established.

Grounds for establishing good cause include:

 - i. introduction of noncompliant or defective electronic products into commerce by the manufacturer;

- ii. disapproval of the manufacturer's testing program of products for which there is an applicable standard; or,
- iii. nonsubmission of assurance by the manufacturer in the form of a report of the adequacy of the product safeguards against hazardous electronic product radiation. Failure to permit inspection when good cause is shown is a violation under this section.

Dealers and distributors, other than those who are also considered to be manufacturers, are only required to permit inspection of records described in paragraph iii above.

4. Section 538(a)(4) [21 U.S.C. 360oo(a)(4)] Reporting

- a. It is a prohibited act for applicable manufacturers to fail to provide the agency with product, supplemental, abbreviated, and annual reports in accordance with 21CFR 1002.10, 1002.11, 1002.12, and 1002.13. Normally regulatory action should be pursued where the products have an applicable performance standard or, in the case of flagrant violations, where no standard has been issued for the product.
- b. It is a prohibited act for a manufacturer to fail to provide a report in conformance with guides or instructions which have been prescribed under 21 CFR 1002.7(b).
- c. It is a prohibited act for any manufacturer of electronic products to fail to report an accidental radiation occurrence with its product in accordance with 21 CFR 1002.20.
- d. It is a prohibited act for any assembler of diagnostic x-ray equipment to fail to provide the agency with a report of its assembly of an x-ray system or component in accordance with 21 CFR 1020.30(d) (1). This assembler's report is required in lieu of the reports cited in paragraph (b)(i) above.
- e. It is a prohibited act for dealers or distributors of electronic products for which there is an applicable performance standard to fail to report the information required by 21 CFR 1002.40(b) to the manufacturer of the product in accordance with 21 CFR 1002.41(a)(1) when required for purposes of Section 535 of the Act and when it has been requested by either the manufacturer or the Director of the Center for Devices and Radiological Health (CDRH).
- f. It is a prohibited act for a manufacturer or assembler to fail to report a defect or noncompliance in an electronic product, in accordance with 21 CFR 1003.20.
- g. It is a prohibited act under Section 538 (a)(5)(A) [21 U.S.C. 360oo(a)(5)(A)] for a manufacturer to fail to certify that its product is in compliance with an applicable performance

standard. The manufacturer must furnish the certification in the form of a label or tag, as prescribed by 21 CFR 1010.2.

- h. It is a prohibited act under Section 538(a)(5)(B) for any manufacturer or importer to affix a certification label to a product which is not in compliance with an applicable performance standard or for which the testing program has been disapproved in accordance with Section 534(h) of the Act. The agency must be able to demonstrate that the manufacturer would have known, if it exercised due care, that such certification was materially false or misleading.
- B. Prior notice/warning should have been given to the responsible individuals.

Prior notice may have been by Warning Letter, Notice of Noncompliance Letter, Program Disapproval Letter, or by any other method in accordance with [Chapter 10 - Other Procedures](#).

6-6-5 Penalties

- A. The Act provides that any person who violates any of the prohibited acts shall be subject to a civil penalty of not more than \$1000 for each count, with a maximum of \$300,000 for any person for any related series of violations. Where individual responsibility cannot be proven, civil penalty may be recommended for the firm only.
- B. Counts - A count is based upon a violation with respect to each electronic product involved, or with respect to each act or omission made unlawful by Section 538. This means that the count is not determined by the product alone, but by the number of acts committed in conjunction with each product.

EXAMPLE:

An employee of XYZ Company installs certified components into a diagnostic x-ray system and fails to file a Report of Assembly ([Form FDA 2579](#)) in accordance with the implementing regulations (21 CFR 1020.30(d)). The prohibited act is Section 538(a)(4) of the Act for failure to make or provide a report required pursuant to Section 537(b). The required distribution of these reports is to (1) FDA, (2) the state agency for the installation site, (3) the owner/user of the system, and (4) either the component manufacturer or XYZ Company. The distribution of the forms is required within 15 days from the date of assembly. The responsibility of completing the forms falls on the individual (employee) who actually performs the installation and the supervisor or company president who is responsible for compliance with the standard. In addition, the firm also has an obligation and responsibility in the filing and maintenance of required documents.

Consequently, the following counts in this specific case could be charged:

Firm Violation of Section 538(a)(4) - 1 count

Employee A Violation of Section 538(a)(4) - 1 count

Manager/President Violation of Section 538(a)(4) - 1 count

Total = 3 counts

This specific example provides for a maximum civil penalty of \$3000 for each occurrence of a failure to file the required report. The key to determining the number of counts is the "act or omission made unlawful by Section 538," (i.e., 3 violation instances (counts) are associated with the 1 product involved in the example cited above. Each additional product involved with the same violation would yield 3 additional counts for each occurrence.)

- C. The assembler firm could also be charged under the same section of the Act (Section 538(a)(4)) when the reports continue to be filed in excess of the 15-day time frame. Reports that are more than 30 days late inhibit FDA's ability to test newly installed systems for compliant assembly by the firm. The firm may be attempting to inhibit compliance testing of their systems. However, for each violative product, the charge must be either failure to file or filing the report late. The same installation cannot receive charges under both categories.

6-6-6 Director Responsibilities

- A. The PDD, as appropriate for the action, is responsible for deciding if the circumstances warrant recommendation of a civil penalty. Every effort should be made to determine that all necessary documentation has been obtained, all related samples are included, and the supporting Establishment Inspection Reports (EIRs) are complete.
- B. The lead coordinator should document as fully as possible who was responsible for the violations
- C. The lead coordinator is responsible for seeing that all violations are documented.
1. Documentation for each violative product should consist of the following:
 - a. Sample Collection Report
 - b. Complete interstate documentation where Section 538(a)(1) of the Act is charged.
 - c. Appropriate affidavits by dealers, purchasers, users, etc., where applicable

- d. Copies of appropriate records of proof of sale or installation of equipment, where applicable.
 - e. Copies of appropriate labeling.
 - f. Clear and distinct photographs of labels, and the equipment, where applicable
 - g. Copies of all documents that can be considered prior notice or warning
2. The recommendation packet should consist of the following:
- a. Memorandum of recommendation to CDRH explaining the details of the case. This memorandum should contain the reasons why you believe that civil penalty is the action of choice, and should address the size of the business and the gravity of the violation.
 - b. A draft letter to the United States (U.S.) Attorney, which includes the background of the case, a statement of prior notice/warning, the reasons why we are pursuing this course of action, and the violations alleged.
 - c. A Proposed Complaint for Civil Penalty. This complaint should specify the legal authority for the action recommended, each specific act committed, or, the manner in which the act was committed, when and by whom committed, and the section of the Act violated. The complaint must reflect the basis of each count for which we seek a civil penalty. Where possible, use a chart to reflect instances where more than one count is being charged under a specific prohibited act. The Complaint should also include the amount of civil penalty sought, and a brief description of how it was computed.
 - d. Copies of appropriate sample records.
 - e. Copies of EIRs reporting the violation.
 - f. If an injunction is being sought in the same complaint, an affidavit, as referenced in the RPM subchapter for Injunctions, should be prepared and submitted.
- D. The lead coordinator shall notify CDRH's Field Programs Branch (HFZ-306) that a recommendation is being submitted, and the recommendation shall be submitted by the most expeditious means. An electronic copy on a diskette should also be attached to the recommendation.
- E. If the approved letter to the U.S. Attorney and the Complaint for Civil Penalty are returned to ORA electronically for submission to the U.S. Attorney, it will be the responsibility of the lead coordinator

to see that they are delivered to the U.S. Attorney's office. If the Complaint includes an injunction, the documents should be delivered to the U.S. Attorney's office by the most expeditious and practical means.

- F. The lead coordinator shall be in direct contact with the U.S. Attorney's office with regard to timeliness of filing of the complaint, and scheduling of any hearings, etc.
- G. In the event of any hearings in the action, the lead coordinator shall be responsible for arranging for the presence of any necessary witnesses, funding, and assuring that all necessary documents are available.

6-6-7 CDRH Responsibilities

- A. CDRH is responsible for a timely review of the recommendation and for assuring that all the evidence and supporting documentation are adequate.

If additional information is needed, the lead coordinator will provide the information, or may, if necessary, make a personal visit to CDRH.

CDRH will forward a copy of the lead coordinator's original recommendation to DE, even though it may prepare an amended copy to include any deletions or additions of its own.

- B. CDRH will prepare a memorandum to DE reflecting the issues considered by CDRH in reviewing the case and providing the scientific assurances which support the case.

A copy of CDRH's concurrence memorandum should be sent to the recommending ORA unit, at the time that it is forwarded to DE. In case of disapproval, CDRH shall state clearly the reason for such disapproval and include any guidance necessary for ORA to present an acceptable case. If follow-up for additional information is indicated, CDRH shall be specific as to what is needed, and so advise ORA. If a case is disapproved, a copy of the disapproval memorandum shall be sent to DE.

- C. CDRH will identify a qualified expert(s) for any court cases.
- D. CDRH will provide an affidavit from the CDRH/OC Records Manager for any notification and reporting charges under Sections 538(a)(2) and (a)(4) of the FD&C Act.

6-6-8 DE Responsibilities

DE will be responsible for ensuring that the recommendation complies with agency policy. It will review the proposed letter to the U. S. Attorney and Complaint for Civil Penalty. If it finds that these documents, or any

other required documents, are not satisfactory, it will be responsible for obtaining the necessary and proper document(s) and submitting them to OCC.

DE will be responsible for determining that the necessary distribution is made of the final documents, as approved by OCC to the appropriate offices. Approved actions for submission to the U. S. Attorney shall be forwarded to the ORA lead coordinator by electronic transmission.

6-6-9 OCC Responsibilities

OCC will provide the final legal review of all the documents in the case, and will determine the legal sufficiency of the evidence. It will be responsible for any further changes in the Complaint, and/or letter to the U. S. Attorney, if any. Significant changes will be made in consultation with DE, CDRH and the lead coordinator, as appropriate. OCC shall designate an attorney to be responsible for the case. This attorney will provide legal assistance to the U. S. Attorney's office and the PDD in the disposition of the case.

6-6-10 Appeals

Appeals of any disapprovals will be handled as prescribed by the Appeal Process in Chapter 10 of the RPM.

6-6-11 Consent Decree of Civil Penalty

The defendant may seek to negotiate a penalty below the maximum for each count. Such negotiated settlement should be in the form of a Consent Decree of Civil Penalty. All proposed settlements will be presented to OCC. All negotiations with the defendant's lawyers will be conducted by the lawyer representing the agency, in consultation with DE, the PDD, and CDRH.

6-6-12 Case Termination

Upon notification by the Clerk of the Court that the penalty has been assessed by the Court and the defendants have paid the penalty, the case may be closed.

6-6-13 Injunction and Civil Penalties

Injunctions under this Act are provided for by Section 539(a) of the FD&C Act.

An injunction recommendation should be included with the civil penalty recommendation if the circumstances warrant it. Criteria to be considered for injunctive relief include, but are not limited to, the following:

- A. The manufacturer has repeatedly committed the same violation, or same type of violation.
- B. The violative product could cause significant risk of injury to any person.
- C. The manufacturer is continuing to commit the same violations (e.g., introduction of noncompliant products into commerce) after being advised of the agency's finding and request to cease and desist.
- D. The violator refuses to correct previously cited defective or noncompliant products.

Injunction may be recommended to prohibit certain actions such as the introduction of violative products into commerce, or to require the violator to stop violating the Act by taking positive action to correct the existing violations (e.g. correction of noncompliant or defective products, notification of purchasers, submission of reports and information, providing access for inspection, certification of products, etc.).

A recommendation memorandum to CDRH will contain the same information as the recommendation for a civil penalty, but will include a statement recommending an injunction, and giving the reasons for the recommendation.

The letter to the U. S. Attorney and the Complaint will contain the same background information, but will include the additional request for an injunction. The subject of the recommendation will address itself to both the civil penalty and the injunction; and the Complaint will be entitled "Complaint for Injunction and Civil Penalty."

Whenever the civil penalty recommendation includes an injunction request, the recommendation will contain the information requested by this chapter, but will be processed according to the RPM subchapter on "Injunctions." The counts involved in the action will be the same as described in this chapter.

6-7 EXHIBITS

These exhibits include a number of models and examples. They should be used only as guides and, with the possible exception of legal citations, should not automatically be used verbatim in any case. Examples from recent cases may be found on ORA's intranet site. The compliance officer may request examples of inspection warrants, and other examples not available on ORA's intranet site, from DE, oraospopenforcementdivio@fda.hhs.gov.

EXHIBIT 6-1

6-1A CMS INSTRUCTIONS (removed)

6-1B CASE INITIATION MEMORANDUM

EXHIBIT 6-2 SEIZURES - U.S MARSHAL LETTER

EXHIBIT 6-3 FORM OF DEFAULT DECREE OF CONDEMNATION

EXHIBIT 6-4 FORM OF CLAIM

EXHIBIT 6-5 FORM OF CONSENT DECREE OF CONDEMNATION

EXHIBIT 6-6 FORM OF BOND

EXHIBIT 6-7 NOTICE TO CLAIMANT

EXHIBIT 6-8 SECOND NOTICE

EXHIBIT 6-9 LETTER TO CANCEL BOND

EXHIBIT 6-10 PROCEDURES & MODELS FOR ISSUING PRESS RELEASES

EXHIBIT 6-11 INJUNCTIONS (MULTI-JURISDICTION)

EXHIBIT 6-12 MODEL LETTER ACKNOWLEDGING COMPLIANCE

EXHIBIT 6-13 DRUG/GMP/ADULTERATION/MISBRANDING CASE –
INTRODUCTORY LANGUAGE FROM A COMPLAINT

EXHIBIT 6-14 FOOD ADULTERATION CASE – INTRODUCTORY LANGUAGE FROM
A COMPLAINT

EXHIBIT 6-15 DRUG GMP CASE – DESCRIPTION OF CHARGE FROM A
COMPLAINT

EXHIBIT 6-16 DIRTY WAREHOUSE CASE – DESCRIPTION OF CHARGES FROM A
COMPLAINT

EXHIBIT 6-17 MISBRANDING (343(A) AND 352(A)) CASE - DESCRIPTION OF
CHARGE FROM A COMPLAINT

EXHIBIT 6-18 EXAMPLES OF CONSENT DECREE PROVISION

EXHIBIT 6-19 EXAMPLES OF COMPLAINT PROVISION

EXHIBIT 6-20 AFFIDAVIT/DECLARATION

EXHIBIT 6-21 MODEL LETTER BILLING CHARGES

EXHIBIT 6-22 PETITION FOR ORDER TO SHOW CAUSE

EXHIBIT 6-23 ORDER TO SHOW CAUSE

EXHIBIT 6-24 FORMAT FOR PROSECUTION SUMMARY AND RECOMMENDATION

EXHIBIT 6-25 MODEL PROSECUTION SUMMARY AND RECOMMENDATION
MEMORANDUM

EXHIBIT 6-26 MODEL LETTER REQUEST FOR ARTICLES OF INCORPORATION

EXHIBIT 6-27 RULE 44 - PROOF OF OFFICIAL RECORD

EXHIBIT 6-28 RULE 6. THE GRAND JURY

EXHIBIT 6-29 EXAMPLE OF LETTER TO THE DEPARTMENT OF JUSTICE, RE:
INJUNCTION AND CIVIL PENALTY

EXHIBIT 6-30 EXAMPLE OF COMPLAINT FOR INJUNCTION AND CIVIL PENALTY

Exhibit 6-1

6-1-A: CMS INSTRUCTIONS: [See the CMS User Guide on the FDA Intranet](#)

Exhibit 6-1B: CASE INITIATION MEMORANDUM OUTLINE

- A. **POINTS OF CONTACT** List of Primary Center, Division, Program, and DE contacts with phone numbers (on the top of the very first page). Identify any OCC attorneys who have been consulted on the case.

NOTE THAT THE FORMAT MUST BE AS A NOTE/REFERRAL TO OCC TO ASSERT THE APPROPRIATE PRIVILEGES TO PROTECT IT FROM DISCOVERY

- B. (Attachment A “LEAD “ASSIGNMENT to CIM ELEMENTS)

1. BRIEF Executive Summary (Description of Evidence): limit to 3 or 4 sentences to identify type of product, conduct and nature of the case. Just need the big picture, for example: “This is a proposed permanent injunction against a cheese manufacturer whose products have been found to be contaminated with listeria in the past and who has a lengthy history of egregious sanitation and CGMP deficiencies” OR “This is a proposed mass seizure of food products stored in a facility infested by rodents.
2. Product Information (Obtain this information from the Center)
 - a. Examples: Approvals (IND, NDA, 510(k), PMA, IDE, Licensed, OTC Monograph), if relevant to charges
 - b. Product Classification or Type e.g., Rx, OTC, Device Class, if relevant
 - c. Product Labels and Labeling (hyperlink to Photos and Draft Complaint)
3. Organizational Chart (hyperlink to EIR and/or Org. Chart)
 - a. Include a BRIEF description of most responsible person(s)
 - b. Identify proposed defendants including a hyperlink to evidence used to support that this is most responsible person (hyperlink to affidavit and articles of incorporation)
 - c. Name of current counsel, if known
 - d. Corporate Relationships (subsidiaries/parent companies)
4. Current Inspection

Rather than a “cut and paste” of the FDA 483 observations, list the most significant observations/ violations categorized by the type of violation (e.g., filth, CGMP, labeling violations etc.) with reference or hyperlink to details in the EIR AND to the RELEVANT exhibits (Please do not reference ALL EIR exhibits).

<INSERT AUTHOR(s) NAME and
DIVISION/PROGRAM/CENTER/DIVISION.

Further Guidance:

- a. FDA 483 observation would be explained within the context of the larger system to frame its significant impact on production, product safety and public health. Provide critical insight and context for the observations explaining its impact on the product or process. For example, rather than “we observed a hole in the roof of the facility,” explain “we observed water dripping onto the food being processed from a hole in the facility’s roof. When including hyperlinks to the evidence please identify the location of key information supporting the FDA 483 observation. For example, the hyperlink to a 42 page laboratory analysis worksheet would identify the page(s) where key evidence is located.
- b. All documented evidence should be in finalized form (including signatures, as appropriate) whenever possible.
- c. If the EIR has not been finalized provide a “separate” document that captures this information. <INSERT AUTHOR(s) NAME, DIVISION/PROGRAM/CENTER/DIVISION>
- d. FDA 483 Observation Table (Tables of Evidence/Attachment B). If the firm has offered to correct the violations, explain the impact on the firm’s/product’s state of compliance, the risk to public health risk and the regulatory strategy.
<INSERT AUTHOR(s) NAME and
DIVISION/PROGRAM/CENTER/DIVISION>
- e. Comparison of Firm’s Repeat Observations (Tables of Evidence/Attachment B). When possible, include a table with observations from past inspections to demonstrate recurring violations (rather than a narrative of each inspection). Insert hyperlinks in the table or “list of observations” in the report and the exhibits
<INSERT AUTHOR(s)NAME and DIVISION/PROGRAM/
CENTER/DIVISION>

5. Center Office of Compliance Concurrence and Expert Information

<INSERT AUTHOR(s) NAME and CENTER/DIVISION>

- a. Charges that the Center preliminarily supports (to be later confirmed through technical/expert support memorandum)

public health significance of violations<INSERT AUTHOR(s) NAME and CENTER/DIVISION>

- b. Weaknesses- please include Center's weaknesses in the combined "ANTICIPATED DEFENSES" (Potential Weaknesses)* IN THE SECTION BELOW
- c. Preliminary Risk Assessment (Counter-arguments to Public Health significance) (to be confirmed through technical/expert support memorandum) <INSERT AUTHOR(s) NAME and CENTER/DIVISION
- d. The Center's review of the Firm's FDA 483 response. If incomplete, the status is indicated in Attachment B table, "Firm's Stated or Observed Corrective Actions."
<INSERT AUTHOR(s) NAME and CENTER/DIVISION.
- e. List of most similar precedent cases (Seizure or Injunction or CMP)
- f. The Center's technical /expert evaluations (e.g., GMP; new drug) (separate) is needed but if incomplete would not delay the issuance of the CIM

<INSERT AUTHOR(s) NAME and CENTER/DIVISION

- i. Table format (Attachment B) for e.g., GMP violations is VERY useful; effective and efficient way to compare current violations with those seen in the past, Focus on major violations, categories of violations, and link observations to particular locations and dates. If more than one, identify the expert (Attachment B) with the particular charges for which each will testify.

<INSERT AUTHOR(s) NAME and CENTER/DIVISION>

- ii. If in-house experts, provide a CV and direct phone number and a summary of the expert's views, prioritizing the supportable violations in order of severity and explaining the significance of each violation.
- iii. For outside experts, provide a CV, email address, and phone number, and confirmation that the expert has been retained and commitments as to date we can expect expert's evaluation if not already completed.
- iv. Results of database search if charge involves filing or registering with FDA or obtaining approval from the agency or literature search (GRAS/E) when new drug charges are included.

<INSERT AUTHOR(s) NAME and
CENTER/DIVISION>

- v. HHE if applicable.

<INSERT AUTHOR(s) NAME and
CENTER/DIVISION>

- vi. Review by drug shortage staff or evaluated as
medically necessary (device) when appropriate
(Center).

<INSERT AUTHOR(s) NAME and
CENTER/DIVISION>

6. Judicial District

7. Interstate commerce, hyperlink the key single documents (not
an entire CR e.g., doc. Sample/product label) Specify whether
the hyperlinked documents are for finished products or
components (and if components, the names of the associated
finished products);

<INSERT AUTHOR(s) NAME and DIVISION/PROGRAM/
CENTER/DIVISION>

8. Complaints-Summary of any consumer complaints and/or
injuries or whistleblower reports

<INSERT AUTHOR(s) NAME and DIVISION/PROGRAM/
CENTER/DIVISION>

9. Regulatory History (hyperlink to finalized documents, where
possible and appropriate)

<INSERT AUTHOR(s) NAME and
DIVISION/PROGRAM/CENTER/DIVISION>

- a. BRIEF SUMMARY of inspection history including inspection
classification with emphasis on recurring violations (should
be no more than one or two paragraphs) (Cross Reference
TABLES OF EVIDENCE, Attachment B as needed)
- b. Recalls (most recent first and should identify products)
- c. Warning or Untitled Letters AND response(s) (Cross
Reference TABLES OF EVIDENCE, Attachment B as
needed)
- d. Regulatory meeting minutes
- e. Written responses from firm (to inspections, 483s, warning or
untitled letters) (Cross Reference TABLES OF EVIDENCE/
Attachment B as needed)

- f. FDA evaluation of firm's responses (Cross Reference TABLES OF EVIDENCE/ Attachment B as needed)
 - g. Other written correspondence from firm or its counsel re: the violations at issue. Please include a table (Cross Reference TABLES OF EVIDENCE/ Attachment B as needed) identifying any correspondence received from the firm
 - h. Please include a table with the firms corrective actions (Cross Reference TABLES OF EVIDENCE/Attachment B) e.g., stated in the firm's 483 response or other correspondence or during the re-inspection) as well as FDA's evaluation of the correction (whether it was adequate
<INSERT AUTHOR(s) NAME and CENTER/DIVISION>
10. Relief requested (Use drafts from RPM as a starting point and filed cases as models) although we will rely on OCC to draft the consent decrees, there are certain substantive provisions which must be drafted by the centers and ORA divisions or programs, as they describe the particular technical and scientific steps that must be taken to bring an operation into compliance. We are including samples in the RPM Chapter 6 of usual requirements for a variety of FDA's more typical types of cases. Please note that these are examples only, not boilerplate, and are intended to set out the level of detail that the centers and ORA will need to contribute to the scientific/technical aspects of the relief, in lieu of preparing a draft consent decree. The assigned center and ORA personnel must adapt these provisions to the particular circumstances of each case. In reviewing these samples, employees are not limited to linking the specific relief to a particular type of case. For example, in these examples, audit requirements are set out in the CGMP sections, but there may be situations in which a food sanitation case will need that type of relief. Similarly, the examples do not encompass every type of violation seen in FDA's cases, but they should provide sufficient guidance to assist in generating the operative portion of the decree in cases involving other types of violations
<INSERT AUTHOR(s) NAME and DIVISION/
PROGRAM/CENTER/DIVISION>
11. Proposed charges and consent decree provisions (Reference the RPM) Look at all the CDs to pick and choose what will get them to the goal (take a look at the precedent cases)
12. Anticipated Defenses [Division/Program/ Center/OCC]: Any potential weaknesses in case including defense's already known or advanced by the firm or its counsel. Both ORA and the

Center need to provide input on potential weaknesses for the case including any weaknesses that were discussed during the Preliminary Assessment Call.

<INSERT AUTHOR(s) NAME and DIVISION/
PROGRAM/CENTER/DIVISION>

13. Other reports submitted (or confirmation that none were filed) such as Field Alert reports, adverse event reports, medical device reports, post marketing reports.

<INSERT AUTHOR(s) NAME and
DIVISION/PROGRAM/CENTER/DIVISION>

Exhibit 6-1 Attachment A LEAD ASSIGNMENTS to CIM ELEMENTS

	ELEMENT	LEAD
A	POINTS OF CONTACT List of Primary Center, Division, Program, and DE contacts with phone numbers (on the top of the very first page). Identify any OCC attorneys who have been consulted on the case.	
1	BRIEF EXECUTIVE SUMMARY (DESCRIPTION OF EVIDENCE) (limit to 3 or 4 sentences) to identify type of product, conduct and nature of the case. Just need the big picture, for example: "This is a proposed permanent injunction against a cheese manufacturer whose products have been found to be contaminated with listeria in the past and who has a lengthy history of egregious sanitation and CGMP deficiencies" OR "This is a proposed mass seizure of food products stored in a facility infested by rodents ."	
2	PRODUCT INFORMATION (Obtain information from the center) Examples: Approvals [IND, NDA, 510(k), PMA, IDE, Licensed, OTC Monograph], if relevant to charges Product Classification or Type e.g., Rx, OTC, Device Class, if relevant Product Labels and Labeling (hyperlink to Photos and Draft Complaint)	
3	ORGANIZATIONAL CHART (Hyperlink to EIR and/or Org. Chart) Include a BRIEF description of most responsible person(s) Identify proposed defendants including a hyperlink to evidence used to support that this is most responsible person (hyperlink to affidavit and articles of incorporation) Name of current counsel, if known Corporate Relationships (subsidiaries/parent companies)	

	ELEMENT	LEAD
4	CURRENT INSPECTION	
	Rather than a “cut and paste” of the FDA 483 observations, list the most significant observations/violations categorized by the type of violation (e.g., filth, CGMP, labeling violations etc.) with reference or hyperlink to details in the EIR AND to the RELEVANT exhibits (Please do not reference ALL EIR exhibits).	
	FURTHER GUIDANCE: FDA 483 observation would be explained within the context of the larger system to frame its significant impact on production, product safety and public health. Provide critical insight and context for the observations explaining its impact on the product or process. For example, rather than “we observed a hole in the roof of the facility,” explain “we observed water dripping onto the food being processed from a hole in the facility’s roof. When including hyperlinks to the evidence please identify the location of key information supporting the FDA 483 observation. For example, the hyperlink to a 42 page laboratory analysis worksheet would identify the page(s) where key evidence is located	
	If the EIR has not been finalized provide a “separate” document that captures this information	
	FDA 483 Observation Table (Tables of Evidence/Attachment B) if the firm has offered to correct the violations, explain the impact on the firm’s/product’s state of compliance, the risk to public health risk and the regulatory strategy.	
5	Comparison of Firm’s Repeat Observations (Tables of Evidence/Attachment B). When possible, include a table with observations from past inspections to demonstrate recurring violations (rather than a narrative of each inspection). Insert hyperlinks in the table or “list of observations” in the report and the exhibits	
	CENTER OFFICE OF COMPLIANCE CONCURRENCE AND EXPERT INFORMATION	
	Charges that the Center preliminarily supports (to be later confirmed through technical/expert support memorandum) public health significance of violations	
	Please include Center’s weaknesses in the combined “CENTER/DIVISION POTENTIAL WEAKNESSES”* section below	

	ELEMENT	LEAD
	Preliminary Risk Assessment (Counter-arguments to Public Health Significance) (to be confirmed through technical/expert support memorandum) The Center's review of the Firm's FDA 483 response. If incomplete, the status is indicated in Attachment B (table), "Firm's Stated or Observed Corrective Actions." List of most similar precedent cases (Seizure or Injunction or Civil Money Penalty) The Center's technical /expert evaluations (e.g., GMP; new drug) (separate) is needed but if incomplete would not delay the issuance of the CIM Expert Evaluations (e.g., GMP; new drug, GRAS/E,) –vary with type of case. If more than one, identify the expert (Attachment B) with the particular charges for which each will testify. If in-house experts, provide a CV and direct phone number and a summary of the expert's views, prioritizing the supportable violations in order of severity and explaining the significance of each violation For outside experts, provide a CV, email address, and phone number, and confirmation that the expert has been retained and commitments as to date we can expect expert's evaluation if not already completed. Results of database search if charge involves filing or registering with FDA or obtaining approval from the agency or literature search (GRAS/E) when new drug charges are included HHE if applicable Review by drug shortage staff or evaluated as medically necessary (device) when appropriate (Center)	
6	JUDICIAL DISTRICT	
7	INTERSTATE COMMERCE Hyperlink the key single documents (not an entire CR e.g., doc. Sample/product label) Specify whether the hyperlinked documents are for finished products or components (and if components, the names of the associated finished products) Finished Product Interstate Documentation Component Interstate Documentation	
8	SHORTAGE REVIEW by drug shortage staff or evaluated as medically necessary (device) when appropriate	

	ELEMENT	LEAD
9	COMPLAINTS Summary of any consumer complaints and/or injuries or whistleblower reports	
10	REGULATORY HISTORY (hyperlink to finalized documents, where possible and appropriate) Brief Summary of inspection history including inspection classification with emphasis on recurring violations (should be no more than one or two paragraphs) (Cross Reference TABLES OF EVIDENCE, Attachment B as needed) Recalls (most recent first and should identify products) Warning or Untitled Letters AND response(s) (Cross Reference TABLES OF EVIDENCE, Attachment B as needed) Regulatory meeting minutes Written responses from firm (to inspections, 483s, warning or untitled letters) (Cross Reference TABLES OF EVIDENCE/ Attachment B as needed) FDA evaluation of firm's responses (Cross Reference TABLES OF EVIDENCE/ Attachment B as needed) Other written correspondence from firm or its counsel re: the violations at issue. Please include a table (Cross Reference TABLES OF EVIDENCE/Attachment B as needed) identifying any correspondence received from the firm Please include a <u>table</u> with the firm's corrective actions (Cross Reference TABLES OF EVIDENCE/Attachment B) e.g., stated in the firm's 483 response or other correspondence or during the re-inspection) as well as FDA's evaluation of the correction (whether it was adequate	
11	RELIEF REQUESTED (Use drafts from RPM as a starting point and filed cases as models) Specific relief the Center and ORA seeks; e.g., stop distribution, initiate a recall, hire consultant. repair facility Proposed Consent Decree Charges AND consent decree provisions	
12	ANTICIPATED DEFENSES [ORA/CENTER/OCC] Any potential weaknesses in case including defense's already known or advanced by the firm or its counsel. Both ORA and the Center need to provide input on potential weaknesses for the case including any weaknesses that were discussed during the Preliminary Assessment Call.	

	ELEMENT	LEAD
13	OTHER REPORTS SUBMITTED (or confirmation that none were filed) such as Field Alert reports, adverse event reports, medical device reports, post marketing reports.	

Exhibit 6-1 Attachment B - TABLES OF EVIDENCE

FDA 483 Observation Table (Current Inspection) (Example)

483 Observation	Citation	Supporting Documents (Hyperlink)

Comparison of Firm's Repeat Observations (Regulatory History) (Example)

Observation	Inspection #1 [DATE]	Inspection #2 [DATE]	Inspection #3 [DATE]
	FDA 483 # []	FDA 483 # []	FDA 483# []

Center's Significant FDA 483 Observations and Identified Expert Table

483 Observation (Prioritized by Severity)	Citation	Center Supported/ Not Supported	Expert Identified (if Center Supported)

Correspondence Received from the Firm (Example)

Correspondence by Firm or its Agents	ORA Review	Center Review	Did the FDA Respond (Yes or No)	Date FDA Responded
[DATE] & Hyperlink to Correspondence	[DATE] & Hyperlink to review memo or email	[DATE] & Hyperlink to review memo or email		[DATE] & Hyperlink to FDA response

Firm's Stated or Observed Corrective Actions (Example)

FDA 483 Observation # [& Date Observed by FDA]	Firm's Stated Correction	ORA Evaluation of the Correction	Center Evaluation of the Correction

Exhibit 6-2**SEIZURES - U.S MARSHAL LETTER**

Reference: SAMPLE NO.
 FDC NO.
 PRODUCT:

Dear Sir:

Please refer to Complaint for Forfeiture which has been filed in the above referenced matter.

As soon as seizure has been effected, we will appreciate your providing us with the following information, which may be furnished by filling in the captions below, on the extra copy of this letter enclosed for that purpose.

Sincerely yours,

Enclosure
cc this letter
Self-addressed franked envelope

DATE SEIZED:

AMOUNT SEIZED:

RETURN DATE (date after which default will be entered):

SEIZED IN POSSESSION OF:

WHERE STORED AFTER SEIZURE:

SEIZED BY:

U.S. Marshal or Deputy Marshal

FORM FDA 487 (6/82)

Exhibit 6-3**FORM OF DEFAULT DECREE OF CONDEMNATION**

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF MARYLAND

United States of America,	)	No. _____
	)	
Plaintiff,	)	
	)	
v.	)	
	)	
So many cartons, more or less,	)	
of an article of food labeled in part:	)	
	)	
" _____,"	)	
	)	
Defendant.	)	

On _____, 20____, a Complaint for Forfeiture against the above described article was filed on behalf of the United States of America. The Complaint alleges that the article proceeded against is a food which was adulterated when introduced into and while in interstate commerce and is adulterated while held for sale after shipment in interstate commerce within the meaning of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 342(a)(3), in that it consisted in part of a filthy substance by reason of the presence therein of insects. Pursuant to warrant for arrest in rem issued by this Court, the United States Marshal for this district seized the article on _____, 20____.

It appearing that process was duly issued herein and returned according to law; that notice of the seizure of the above described article was given according to law; and that no persons have appeared or interposed a claim before the return day named in the process;

Now, therefore, on motion of _____, United States Attorney for the District of Maryland, by _____, Assistant United States Attorney, for a Default Decree of Condemnation and Destruction, the Court being fully advised of the premises, it is

ORDERED, ADJUDGED AND DECREED that the default of all persons be and the same are entered herein; and it is further:

ORDERED, ADJUDGED AND DECREED that the seized article is a food (or: device, drug, etc.) which was adulterated (or misbranded) when introduced into interstate commerce (or: while in interstate commerce, or: is adulterated while held for sale after shipment in interstate commerce) within the meaning of 21 U.S.C. 342(a)(3), (or appropriate charge) in that it consists in part of a filthy substance by reason of the presence therein of insects, (or enter appropriate statement) and is therefore hereby condemned and forfeited to the United States pursuant to 21 U.S.C. 334(a); and it is further:

ORDERED, ADJUDGED AND DECREED, pursuant to 21 U.S.C. 334(d), that the United States Marshal in and for the District of Maryland destroy the condemned article and make return to this Court. Destruction shall be in a manner that complies with the requirements of the National Environmental Policy Act.

Dated this _____ day of _____, 20__.

United States District Judge

NOTE:

EXHIBITS: Where exhibits of the seized article are desired for use in displays, to illustrate public speeches, or in subsequent prosecution proceedings, the last paragraph of the above decree should be worded:

(for the entire lot) "*** that the United States Marshal in and for the District of Maryland do forthwith deliver same to a representative of the Food and Drug Administration for official use or uses***."

(for a portion of the lot) "*** do forthwith deliver a portion of same to a representative of the Food and Drug Administration for official use or uses and destroy the remainder of same***."

Exhibit 6-4**FORM OF CLAIM**

In the District Court of the United States for the _____
 District of _____, _____ Division. _____,
 Term, A.D., 20____

UNITED STATES OF AMERICA,)
)

v)

No. _____,

CLAIM

Now appears before this Honorable Court
 _____ Company, a corporation duly organized and existing under
 the laws of the State of _____, with its principal place of business in
 the City of _____, State of _____, intervening
 in this proceeding by virtue of its interest as _____, and prays to
 defend the article(s) above described, and makes claim to the article(s) as the
 same is attached by the United States Marshal for this District under process of
 this Court at the instance of the United States of America, libellant;

And the claimant avers that it has a true and bona fide interest in the
 article; wherefore it prays to defend accordingly.

_____ Company

By: _____

 Proctor for Claimant

State of _____)

)

SS:

County of _____)

_____, being duly sworn, deposes and says that he is the _____ of _____ Company, the corporation which is described in and which executed the foregoing Claim; that he has authority to act on behalf of the corporation in this matter and that he signed the Claim pursuant to his authority; that he has read the Claim and knows the contents thereof, and that the same is true to the best of his knowledge, information, and belief; and that he knows the seal affixed to the Claim is the seal of the corporation and was duly affixed as such.

Sworn to before me this _____ day of _____, 20____.

Notary Public

Exhibit 6-5**FORM OF CONSENT DECREE OF CONDEMNATION**

In the District Court of the United States for the _____ District of
 _____ Term, A.D., 20____.

UNITED STATES OF AMERICA	)	
	)	
v.	)	No. _____, _____
	)	Decree of Condemnation
_____	)	

On _____, 20 ____, a Complaint for Forfeiture against the above described article was filed in this Court on behalf of the United States of America by the United States Attorney and the Assistant United States Attorney for this District. The Complaint alleges that the article proceeded against is a food which was adulterated when introduced into interstate commerce within the meaning of the Federal Food, Drug, and Cosmetic Act (Act), 21 U.S.C. 342(a)(3), (or appropriate charge) because it consisted of a filthy substance by reason of the presence therein of insects. Pursuant to a warrant for arrest in rem issued by this Court, the United States Marshal for this District seized the article on _____, 20___. Thereafter, _____ Company of _____, _____ intervened and filed claim to said article. Claimant consents that a decree, as prayed for in the Complaint, be entered condemning the article under seizure.

The Court being fully advised of the premises, it is on motion of the parties hereto:

ORDERED, ADJUDGED AND DECREED that the seized article is a food (or: device, drug, etc.) which was (or is) adulterated (or misbranded) when introduced into interstate commerce (or: while in interstate commerce, or: while held for sale after shipment in interstate commerce) within the meaning of 21 U.S.C. 342(a)(3) (or appropriate charge) because it consists in part of a filthy substance by reason of the presence therein of insects, (or enter appropriate statement) and is therefore hereby condemned and forfeited to the United States pursuant to 21 U.S.C. 334(a); and it is further:

ORDERED, ADJUDGED, AND DECREED, pursuant to 21 U.S.C 334(e), that the United States of America shall recover from said Claimant court costs and fees, and storage and other proper expenses, as taxed herein, to wit, the sum of \$ _____; and

Claimant having petitioned this Court that the condemned article be delivered to it pursuant to 21 U.S.C. 334(d), it is further

ORDERED, ADJUDGED, AND DECREED that the United States Marshal for this District shall release said article from his custody to the custody of claimant for the purpose of bringing the article into compliance with the Act if claimant, within 20 days from the date of this decree, (a) pays in full the aforementioned court costs and fees, and storage and other proper expenses of this proceeding and (b) executes and files with the clerk of this Court a good and sufficient penal bond with surety in the sum of _____ Dollars (\$ _____), approved by this Court, payable to the United States of America, and conditioned on the claimant's abiding by and performing all the terms and conditions of this decree and such further Orders and Decree as may be entered in this proceeding; and it is further

ORDERED, ADJUDGED, AND DECREED that:

1. After the filing of the bond in this Court, the claimant shall, at its own expense, cause the article to be shipped to its plant at _____. When the article arrives at the _____ plant, claimant shall give written notice to the _____ Division, Division of Enforcement, Office of Enforcement and Import Operations, Office of Regulatory Affairs, Food and Drug Administration, Department of Health and Human Services that the article has arrived and that claimant is prepared to bring it into compliance with the law under the supervision of a duly authorized representative of the Department of Health and Human Services (DHHS).

2. The claimant shall at all times, until the article has been released by the DHHS representative, retain intact the entire lot of goods comprising the article for examination or inspection by said representative, and shall maintain the records or other proof necessary to establish the identity of said lot to the satisfaction of said DHHS representative.

*3. The claimant shall not commence bringing said article into compliance until it has received authorization to do so from the DHHS representative.

NOTE: In mass seizure cases, this item should read as follows:

3. The claimant shall not commence bringing the articles into Compliance until the premises have been rendered clean and suitable for the storage of _____ and it has received authorization to do so from the DHHS representative.

4. The claimant shall at no time, ship, sell, offer for sale, or otherwise dispose of any part of the article until the DHHS representative shall have had free access thereto in order to take any samples or make any tests or examinations that are deemed necessary, and shall in writing have released the article for shipment, sale, or disposition.

5. Within 30 days from the date of the filing of the bond in this Court, claimant shall complete the process of bringing the article into compliance with law under the supervision of the Department of Health and Human Services.

6. The claimant shall abide by the decisions of the DHHS representative which decisions shall be final. If claimant breaches any conditions stated in the decree, or of any subsequent decree or order of this Court in this proceeding, claimant shall return the article immediately to the United States Marshal for this District at Claimant's expense, or shall otherwise dispose of it pursuant to an order of this Court.

7. The claimant shall not sell or dispose of said article or any part thereof in a manner contrary to the provisions of the Federal Food, Drug, and Cosmetic Act, or the laws of any State or Territory.

8. The claimant shall compensate the United States of America for cost of supervision at the rate of \$_____ per hour per person for each day actually employed in the supervision of the reconditioning, as salary or wage; where laboratory work is necessary, at the rate of \$_____ per hour per person for such laboratory work; where subsistence expenses are incurred, at the rate of \$_____ per day per person for such subsistence expenses. Claimant shall also compensate the United States of America for necessary traveling expenses at \$.___ per mile and for any other necessary expenses which may be incurred in connection with the supervisory responsibilities of DHHS.

9. If requested by the DHHS representative claimant shall furnish the representative duplicate copies of invoices of sale of the released article, or shall furnish such other evidence of disposition as said representative may request.

The United States Attorney for this District, on being advised by the DHHS representative that the conditions of this decree have been performed, shall transmit such information to the Clerk of this Court, whereupon the bond given in this proceeding shall be canceled and discharged; and it is further

ORDERED, ADJUDGED, AND DECREED that if the claimant does not avail itself of the opportunity to repossess the condemned article in the manner aforesaid, the United States Marshal for this District shall retain custody of said article pending the issuance of an order by this Court regarding its disposition; and it is further

ORDERED, ADJUDGED, AND DECREED that this Court expressly retains jurisdiction to issue further decrees and orders as may be necessary to the proper disposition of this proceeding, and should the claimant fail to abide by and perform all the terms and conditions of this decree, or of such further order or decree as may be entered in this proceeding, or of said bond, then said bond shall on motion of the United States of America in this proceeding be forfeited and judgment entered thereon.

Dated at _____, this _____ day of _____, 20____.

United States District Judge

We hereby consent to the entry of the foregoing Decree.

United States Attorney

Assistant United States Attorney

Proctor for Claimant

Exhibit 6-6**FORM OF BOND**

In the District Court of the United States for the _____ District of
_____, _____ Division. _____ Term,
A.D., 20____

UNITED STATES OF AMERICA,	)	
	)	
v.	)	No. _____,
_____.	)	
	)	Bond
_____	)	

KNOW ALL MEN BY THESE PRESENTS: That
_____, as Principal, and _____, a
corporation duly organized under the laws of the State of _____, and
having a place of business at _____, as Surety, are held
and firmly bound unto the United States of America in the sum of
_____ (\$_____) Dollars, for the payment of which to
the United States of America they bind themselves, their representatives,
successors, and assigns, jointly and severally, firmly by these presents.

WHEREAS, on _____, 20____, a decree was entered in the above-
described proceeding, a copy of which Decree is hereto annexed, marked Exhibit
A, and made a part thereof;

NOW, THEREFORE, the condition of this obligation is such that if the said
Principal shall abide by and perform all the terms and conditions of said Decree
and such further Orders and Decrees as may be entered by the above-
designated Court in this proceeding, then this obligation shall become null and
void; otherwise it shall remain in full force and effect.

And the Principal and Surety covenant and agree that, by entering into and
furnishing this Bond, they submit themselves, and each of them, to the
jurisdiction of the above-designated Court and irrevocably appoint the Clerk of
Said Court as their agent upon whom any papers affecting their liability on said

Bond may be served, that their liability on and under the Bond may be enforced on motion made in and to the Court without the necessity of an independent action, and that the motion and notice thereof may be served on the Clerk of the Court.

Signed with our hands and seals this _____ day of _____, 20__.

By: _____
Principal

By: _____
Surety

Attest:

Secretary

Bond approved _____, 20__.
UNITED STATES ATTORNEY

_____ Division _____ District of _____, 20__.

Exhibit 6-7**NOTICE TO CLAIMANT**

(Sample No.)
FDC _____, Civil # _____
Shelled Walnuts

June 17, 20____
U.S. vs. 12 cases ***** and
9 cases ***** Walnuts

Firm Name
Street Address
City, State, Zip

Dear Sir or Madam:

In accordance with the terms of the decree, these lots of walnuts have been satisfactorily reconditioned and the good portion, consisting of 854 lbs., is released for your disposition. The rejects, consisting of 30 lbs., have been destroyed under the supervision of a representative of this office.

The following supervisory charges were incurred during the reconditioning operations:

Investigator's time	6 hrs. at \$**. ** per hr	\$XXX.XX
Mileage-Govt. car	18 miles at \$0. *** per mile	\$ X.XX
Analyst's time	5 hrs. at \$**. ** per hr	<u>\$XXX.XX</u>
	Total Charges	<u>\$XXX.XX</u>

(* Note: Use rates of reimbursement specified in Consent Decree)

Please remit promptly a money order, bank draft, or certified check for \$XXX.XX, made payable to the United States Treasury, attach to the enclosed copy of this letter, and forward to:

U.S. Food and Drug Administration
_____ Office
Compliance Branch
Street Address
City, State Zip

Upon receipt of your remittance, we shall advise the United States Attorney that, insofar as this office is concerned, the bond posted to cover the decree may be canceled.

Sincerely yours,

Director, Compliance Branch Office

Enc: cc this ltr.
cc: Fiscal Branch

Exhibit 6-8**SECOND NOTICE**

(Sample No.)
FDC _____, Civil # _____
Shelled Walnuts

July 17, 20____
U.S. vs. 12 cases ***** and
9 cases ***** Walnuts

CERTIFIED MAIL - RETURN RECEIPT

Firm Name
Street Address
City, State, Zip

Dear Sir or Madam:

Under date of June 17, 20____, we mailed you "NOTICE TO CLAIMANT" requesting payment for charges incurred in the supervisory operations specified in the terms of the decree entered in the above identified seizure action. You were requested to remit money order, bank draft, or certified check, in the amount of \$XXX.XX, to this office. Remittance has not been received.

This is to inform you that unless payment of the costs specified in our letter of June 17, 20____, is received within two weeks after the date of receipt of this notice, the claim will be referred to the United States Attorney for collection.

Sincerely yours,

Director, Compliance Branch Office

Enc: cc this ltr.
cc: Smith & Smith Attorneys
XYZ Bonding Co.

(Send one month after first Notice; follow up in 2 weeks)

Exhibit 6-9**LETTER TO CANCEL BOND**

(Sample No.)
FDC _____, Civil # _____
Shelled Walnuts

July 25, 20____
U.S. vs. 12 cases ***** and
9 cases ***** Walnuts

Honorable _____
United States Attorney
Street Address
City, State, Zip

Dear _____:

The terms of the Order of Condemnation entered in the above-identified action, providing for reconditioning, have been complied with under the supervision of a representative of this office.

Costs of supervision have been paid, and insofar as we are concerned the bond may be canceled.

Sincerely yours,

Director, Compliance Branch Office

Exhibit 6-10**Procedures & Models for Issuing Press Releases**

Procedures for Issuing Press Releases on Enforcement Actions

(Seizures & Injunctions)

OCC – Office of Chief Counsel

ORA – Office of Regulatory Affairs

DE – ORA's Office (Program and District)

OMA – Office of Media Affairs

AUSA – Assistant U.S. Attorney

A. Before Issuing a Press Release

1. Issuance of Press Releases to Publicize Enforcement Actions – Generally speaking, FDA will issue a Press Release when an enforcement action is taken by the Agency. The release should include a description of the enforcement action, i.e., type of action, basis for action, firm, location, product(s) and firm's geographical market area. In the case of seizure actions, the Letter to the U.S. Attorney and Complaint for Forfeiture should be provided by OCC to OMA for the drafting of the release. In the case of injunction actions, the Complaint for Injunction and/or Consent Decree should be provided to OMA by OCC.
2. Decision to Publicize – Typically, the release will be issued at the national level. If, however, OMA determines that the release is more appropriate for the local level, it will notify OCC (attorney assigned to the case), ORA (ORA Headquarters) and the Center (Office of Compliance) of its decision.

Example of what would be publicized at local level – firms with limited geographic distribution of their products

3. Coordinating with AUSA – The OCC attorney assigned to the case contacts the AUSA to inform him/her of FDA's plans to issue press and to obtain concurrence. If the AUSA plans to issue a release, FDA typically will defer issuance of the release to the AUSA and may request that an FDA quote be included in the DOJ release. The OCC attorney notifies OMA whether the AUSA concurs with FDA issuing press or prefers to issue one itself.

4. Drafting and Clearing the Release – If FDA is issuing the release, the process for drafting and clearing the release starts at OMA.
 - a. OMA creates the first draft of the release using one of the attached model press releases (e.g., injunction or seizure). OMA routes the release for headquarters review and clearance in the following order of offices –
 - i. Center - Center compliance staff will obtain clearance from appropriate Center officials, including the insertion of a quote, as appropriate, into the release about the action that is being taken.
 - ii. ORA – ORA Executive Operations Staff will obtain input from ORA components by circulating the release to the relevant headquarters units and the appropriate ORA offices. Program and District input, when provided, will be routed through the Division of Enforcement (DE) to assure uniformity in enforcement language. Offices will be responsible for coordinating review by State officials if enforcement action involved our state counterparts. When circulating the release for input and comment from ORA components, ORA Executive Operations will attach, if supplied from OMA, the Final Letter to the U.S. Attorney and Complaint for Forfeiture (for seizures) and the File Complaint or Consent Decree (for injunctions). ORA Executive Operations is responsible for coordinating all comments from ORA components. ORA Executive Operations will have the responsibility for obtaining clearance of the proposed quote from the ACRA, ORA Executive Operations staff will obtain final ORA document clearance through the ACRA or his/her designee and send the final ACRA cleared version forward to OMA.
 - iii. OCC lead case attorney - OCC will give the AUSA a copy of the release for review.)
 - b. After the release is cleared through the three offices listed above (Center, ORA, OCC) for technical accuracy, OMA will route it through OMA's standard press release clearance process, which involves top agency officials.
 5. Final Copy of Press Release – OMA takes comments, makes final edits to the release and notifies the above offices, concurrently, as appropriate, for last minute edits.
- B. Issuance of Press Release
1. Local press release – OMA returns final copy of release to the appropriate ORA public affairs specialist (PAS) or compliance

officer to format the release on ORA's letterhead. The PAS issues the release to local Associated Press bureau shortly after enforcement action has occurred – no later than 24 hours after the event. OMA sends copy of release to OMA's Website Management Staff for posting to FDA Website.

2. National press release – OMA will issue and post the release using the same procedures as for other agency releases.
3. In the case of seizures, press does not issue until the seizure action is completed. If the Complaint for Forfeiture was issued under seal, press cannot issue until the seal is lifted. OCC will inform OMA of the appropriate time to release the press statement.

Model Press Release – SEIZURE**(FDA Enforcement Actions)****FDA – Recommended Seizure**

Carried out by United States Marshals Under Court Order

At the request of the Food and Drug Administration (FDA), the U.S. District Court for the (name of district) District of (State) issued a seizure warrant for seizure of (various articles of foods/drugs/etc.) at (name of firm) located in (city, state). The U.S. Marshals Office executed the seizure warrant (state when).

The seized (name of product(s)) are (adulterated and/or misbranded) under the Federal Food, Drug, and Cosmetic Act because (state how the products are adulterated and/or misbranded without reference to statute provisions). (Name of firm) distributed the products in (description of geographical area where products were distributed) through (types of consignees).

FDA inspections of (name of company) revealed (state what was revealed), for which (name of firm) was previously issued a Warning Letter(s) outlining unacceptable practices. The company was given an opportunity to correct the violations, but failed to take appropriate action(s).

This product (poses/does not pose) a public health risk because (describe reason why it does not pose a risk/OR describe the health risk involved, i.e., contaminated product can cause).

(possible quote by FDA official – OMA will handle)

The FDA advises consumers to (describe whatever action(s) is/are recommended by the agency – for example, not to purchase the product, stop using the product, discard the product, return to place of purchase, stop using medicine, do not stop using medicine without consulting a physician, consult a physician, etc.).

The FDA has initiated this action to promote and protect the public health by enforcing the Federal Food, Drug, and Cosmetic Act. FDA's mission includes ensuring the safety or safety and effectiveness of a broad spectrum of regulated products, including food, human and animal drugs, vaccines, blood products, medical devices, electronic products that emit radiation, and cosmetics.

Exhibit 6-10 Model Press Release – INJUNCTION

(FDA Enforcement Actions)

Food and Drug Administration Seeks Injunction Against (name/type of firm(s))

The Food and Drug Administration (FDA) is seeking a (permanent/preliminary/temporary) injunction against (firm's name and address) to (describe purpose of injunction).

The government's complaint, filed by the U.S. Department of Justice in the U.S. District Court for the (name of district) District of (State) charges (name of firm) with violating the Federal Food, Drug, and Cosmetic Act by (describe the charges in plain English). In addition to (name of firm), the complaint names as defendants (name and title of individual(s)).

The complaint asserts that the defendant(s) has/have carried out (describe the violative action(s)) since (the beginning date) despite the FDA's warning(s) that this/these action(s) is/are illegal.

This/these violative action(s) (poses/does not pose) a public health hazard because (describe the reason(s) why).

The FDA advises consumers to (describe whatever action(s) is/are recommended by the agency – for example, not to purchase the product, stop using the product, discard the product, return to place of purchase, stop using medicine, do not stop using medicine without consulting a physician, consult a physician, etc.).

The FDA has initiated this action to promote and protect the public health by enforcing the Federal Food, Drug, and Cosmetic Act. FDA's mission includes ensuring the safety or safety and effectiveness of a broad spectrum of regulated products, including food, human and animal drugs, vaccines, blood products, medical devices, electronic products that emit radiation, and cosmetics.

Exhibit 6-11**INJUNCTIONS (MULTI-JURISDICTION)****INJUNCTIONS
(Multi-jurisdiction)****A. Scope**

These procedures apply to injunction actions where the corporate headquarters and/or the facilities to be enjoined are located in two or more FDA divisions. The procedures describe special coordination requirements for this category of injunctions.

These procedures do not supersede the instructions in section 6-2, INJUNCTIONS. They are supplementary for only multi-division injunctions involving 2 or more facilities in the same corporation. These procedures do not apply to Team Biologics.

At its discretion, the recommending division may invoke these procedures for an injunction in a single jurisdiction or involving multiple Centers.

B. Objectives

Office of Regulatory Affairs (ORA), Centers and other organizations in FDA are involved in the case development activities. A number of case development activities must occur concurrently to ensure high quality work products are generated with adherence to strict timeframes. These procedures are intended to facilitate case processing with respect to:

1. Proactive communication with FDA offices that recommend, review, or concur;
2. Coordination, organization, and scope;
3. Support throughout the case development process;
4. Timelines, milestones, deadlines; and
5. Quality assurance.

C. Responsibilities and Roles

Bringing a timely multi-district injunction of high probative value requires a coordinated team effort. To avoid multiple evidence and review updates, redundant edits of work products, and miscommunications, the stakeholders should assume case ownership and be readily available at all critical stages of case development and review.

1. Program Division Director

The Program Division Director (PDD) will ensure that inspections, investigations, and sample collections that support an injunction action are scheduled and completed with due diligence. In addition, the PDD will have an active obligation to expedite the early alert/notification, establishment inspection report, exhibits, collection reports, investigational memos, compliance recommendation, collateral assignments, et al. The PDD may delegate these activities as appropriate.

2. Director of Compliance Branch

The Director of Compliance Branch (DCB) will provide administrative oversight for case management in the unit. The DCB will ensure continued Division and Program responsiveness to case support needs until the case is finally adjudicated and follow-up obligations are fulfilled. (S)he has primary responsibility to ensure Early Alert/Notification to the Division of Enforcement.

3. Director of Investigations Branch

See “ Early Alert/Notification” section in this exhibit under “Procedure,” below.

4. Director, ORA Division of Enforcement

The Director, Division Enforcement (DE) will provide administrative oversight for Compliance Team Coordinator activities. (S)he will ensure continued responsiveness to case support needs until the case is adjudicated.

5. Compliance_Team_Leader

The Compliance Team Leader will typically be the Compliance Officer in the recommending unit assigned to the case

The Compliance Team Leader has responsibility for initial review of the evidence, drafting a compelling recommendation, and providing overall direction for ORA case development activities. In addition, the Compliance Team Leader will:

- a. Develop strategy in collaboration with the Compliance Team Coordinator and other offices, including the appropriate Center and OCC personnel, early in the process, e.g., even at the pre-inspection stage when there is a history of noncompliance;
- b. Establish deadlines and milestones for meeting timeframes in collaboration with the Compliance Team Coordinator;
- c. Determine resources, including identification of expertise and division of labor, necessary to meet deadlines, milestones, and timeframes;
- d. Identify work sharing projects and communicate to the Compliance Team Coordinator the need for research, models, assistance in drafting

documents or assignments, coordinating conference calls, attending meetings, etc. and other needs that will expedite the case and/or contribute to quality;

- e. Accompany the case to the Center, in appropriate circumstances, unless the PDD, Director of DE, or the Center Office of Compliance Director conclude that it would serve no useful purpose; and,
- f. Provide a copy of the recommendation and all related support documents concurrently to the Center and the Compliance Team Coordinator.

6. Compliance Team Coordinator

The Compliance Team Coordinator will typically be a Compliance Officer in DE. The Compliance Team Coordinator will act as the ORA headquarters facilitator for the case. In addition, the Compliance Team Coordinator will:

- a. Collaborate with and provide assistance to the Compliance Team Leader to ensure all case development needs are met;
- b. Communicate case contact information for each office in the case development chain of command (offices that recommend, review, or concur);
- c. Serve as a liaison to establish open lines of communication within the case development and review team at each phase of case evaluation;
- d. Facilitate timeliness of work products;
- e. Periodically provide a chronology and update of important case events and activities to the case development and review chain of command;
- f. Identify relevant issues, unexpected events, and other factors impacting the case;
- g. Conduct a review of the final case recommendation concurrent with the Center's evaluation for the purpose of providing case liaison;
- h. Issues identified as part of the Compliance Team Coordinator's review will be deferred to the Compliance Team Leader for resolution.

D. Procedure

Early Alert/Notification: As soon as the PDD, DCB, or Director of Investigations Branch (DIB) identifies a **potential** Multi- jurisdictional injunction, they will provide an early alert to the appropriate Center(s) and the Director, Division of Enforcement (HFC-200). The early alert should include:

- 1. The name, address, and FEI numbers of the target corporate office and facilities;
- 2. Date(s) of the planned, in-process, or completed inspections;
- 3. General nature of the violations, e.g., GMPs, HACCP, sanitation, etc.; and,
- 4. Products involved and any special characteristics, e.g., sterile, LACF, medical

necessity, etc.

If a Center or other stakeholder has cause to suspect that a multi-district injunction should be considered, their designee will provide a similar early alert or notification to the Director, Division of Enforcement (HFC-200).

The notification can be made by telephone, email, FAX, or other appropriate electronic communication. Notifications by telephone should be followed up by a written summary that is forwarded to DE (HFC-200) within 2 business days.

The Director, DE will immediately identify a Compliance Team Coordinator and communicate that decision to the appropriate Division, Program, and/or Center contacts.

E. Organizational Case Management Strategy

Each case presents unique factors and circumstances that if managed properly will mitigate delays and evidence development problems.

The Compliance Team Coordinator and the Compliance Team Leader shall jointly identify the ORA/Center/OCC stakeholders and initiate a conference call with them as soon as practical. The purpose is to front-load the case, facilitate communication among the stakeholders, and expedite the case.

The conference call should:

1. Introduce facts and circumstances of the case;
2. Provide an overview of previous regulatory actions, e.g., identify which corporations, facilities and products were involved, the types of actions taken, and similarities in the violations;
3. Discuss support for the injunction;
4. Identify policy implications, e.g., right case, right area;
5. Discuss case strategy and scope, e.g., all or specific facilities, all or certain products; and
6. Identify roles and partnerships, including those of the Program Divisions, the Division of Enforcement, programs, and the relevant Center(s).

The stakeholders will typically include offices that recommend, review, or concur; and those in positions of Compliance Team Leader; Compliance Team Coordinator; DCB; PDDs ; Program Director, Division of Enforcement; Center Office Compliance Director, Center Office of Compliance Division Directors, and other Center Compliance personnel; Deputy Chief Counsel for Litigation; and appropriate OCC Senior Enforcement Advisors(s).

Exhibit 6-12**MODEL LETTER ACKNOWLEDGING COMPLIANCE**

Name
Title
Firm Name
Street Address
City, State, Zip

Re: Injunction
Civil # _____

Dear _____:

This is to advise you of the results of an inspection conducted on (Date), at your fish processing plant at (Location).

A comparison of the conditions at the plant and your expert's certification statement submitted under the terms of the injunction showed that your plant was in compliance on that day.

You may, therefore, resume operations at the plant at (Location).

We wish to remind you that the terms of the injunction under which your firm is operating require that you maintain your plant in a sanitary condition in the future. Our approval of the conditions found on (Inspection Date) should not be construed as approval for any conditions that may be found in the future. Should it be determined during any future inspection that you have failed to maintain the plant in a proper sanitary condition, we will not hesitate to request that the court take whatever steps are necessary to ensure compliance.

Very truly yours,

Director

Exhibit 6-13**DRUG/GMP/ADULTERATION/MISBRANDING CASE – INTRODUCTORY
LANGUAGE FROM A COMPLAINT**

An investigation by the Food and Drug Administration (FDA) of (name of firm, city, state) reveals violations of the adulteration and misbranding provisions of the Federal Food, Drug, and Cosmetic Act, resulting in various injectable drugs being produced contrary to current good manufacturing practices, 21 U.S.C. 351(a)(2)(B); failing to have their purported quality because they are not sterile, 21 U.S.C. 351(b); and falsely stating that they are sterile when they are not, 21 U.S.C. 352(a). We request that proceedings be instituted pursuant to 21 U.S.C. 332(a) to enjoin (name of firm) and (number) of its officers who share responsibility for shipping these adulterated and misbranded drugs in interstate commerce in violation of 21 U.S.C. 331(a) and for adulterating and misbranding these drugs while holding them for sale after shipment in interstate commerce in violation of 21 U.S.C. 331(k). Prior FDA warnings have been unsuccessful in promoting the necessary corrections.

Exhibit 6-14**FOOD ADULTERATION CASE – INTRODUCTORY LANGUAGE FROM A COMPLAINT**

An investigation by the Food and Drug Administration (FDA) of (name of firm, city, state) reveals violations of the adulteration provisions of the Federal Food, Drug, and Cosmetic Act, resulting in human foods becoming adulterated within the meaning of 21 U.S.C. 342(a)(3) and 342(a)(4), in that they have been manufactured under conditions whereby they may have become, and in fact have become, contaminated with filth. We request that proceedings be instituted pursuant to 21 U.S.C. 332(a) to enjoin (name of firm) and (number) of its officers who share responsibility for adulterating food during manufacture in their plant, 21 U.S.C. 331(k), and from shipping adulterated food in interstate commerce, 21 U.S.C. 331(a). Prior FDA warnings have been unsuccessful in promoting the necessary corrections.

Exhibit 6-15**DRUG GMP CASE – DESCRIPTION OF CHARGE FROM A COMPLAINT**

A drug is deemed to be adulterated within the meaning of the Act, 21 U.S.C. 351(a)(2)(B), if the methods used in or the facilities or controls used for its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice. Thus, a drug is adulterated regardless of whether it is physically deficient in some respect. The purpose of the good manufacturing practice provision of the Act is to control the process of drug manufacturing and to attack the production of unreliable drugs in its incipiency, not after the fact. *United States v. Bel-Mar Laboratories*, 284 F. Supp. 875 (E.D.N.Y. 1968); *United States v. An Article of Drug ... White Quadrisect*, 484 F.2d 748 (7th Cir. 1973). Injunctive relief incorporating the statutory language of the Act, 21 U.S.C. 351(a)(2)(B), has been granted by numerous district courts. See for example the following reported cases: *United States v. Dianovin Pharmaceuticals, Inc.*, 342 F. Supp. 724 (D.P.R. 1972), aff'd 475 F.2d 100 (1st Cir. 1973); *United States v. Lit Drug Co.*, 333 F. Supp. 990 (D.N.J. 1971); *United States v. Lanper Co.*, 293 F. Supp. 147 (N.D. Tex. 1968). See also *United States v. Medwick Laboratories*, 416 F. Supp. 832 (N.D. Ill. 1976). The Commissioner of Food and Drugs has published comprehensive regulations specifying good manufacturing practice, 21 CFR Part 211. These regulations, referenced in paragraph ____ of the Complaint for Injunction, are binding and have the full force and effect of law. *Abbott Laboratories v. Gardner*, 387 U.S. 136 (1967); *National Nutritional Foods Assoc. v. Weinberger*, 512 F.2d 688 (2nd Cir.), cert. denied 423 U.S. 827 (1975).

(Where applicable add) Because the defendants' manufacturing processes are not adequately controlled and are therefore unpredictable, it is not surprising that certain of defendants' drugs have become adulterated by being subpotent (or superpotent, or both). Samples of defendants' drugs analyzed by the Food and Drug Administration establish that such adulteration, within the meaning of 21 U.S.C. 351(b) (or (c)), has in fact occurred.

Exhibit 6-16**DIRTY WAREHOUSE CASE – DESCRIPTION OF CHARGES FROM A COMPLAINT**

The injunction charges defendants with violating the Act, 21 U.S.C. 342(a)(3) and (a)(4). In order to establish adulteration of food within the meaning of 342(a)(4), proof of actual contamination is not required. It is only necessary to prove that the food was held under insanitary conditions whereby it may have become contaminated with filth. *United States v. Wiesenfeld Warehouse Co.*, 376 U.S. 86 (1964); *Berger v. United States*, 200 F.2d 818 (8th Cir. 1952). The test for determining whether the conditions are sufficiently insanitary to cause food to be deemed to be adulterated is whether such conditions could, with reasonable possibility, result in contamination. See *Berger v. United States*, *supra*, at 821; *United States v. H.B. Gregory Co.*, 502 F.2d 700, 704 (7th Cir. 1974). However, proof of actual contamination may be used to establish that the insanitary conditions could (and did) cause actual contamination. *Golden Grain Macaroni Co. v. United States*, 209 F.2d 166, 167-8 (9th Cir. 1953); *Berger v. United States*, *supra*, at 823. The words "insanitary conditions" and "filth" have been given their usual and ordinary meaning by the Courts; restrictive scientific and medical definitions do not apply. *United States v. Cassaro, Inc.*, 443 F.2d 153, 157 (1st Cir. 1971); *United States v. 44 Cases ... Viviano Spaghetti*, 101 F. Supp. 658 (E.D. Ill. 1951).

A violation of 342 (a)(3) requires a showing that a food actually contained filth within the meaning of the Act. However, the Government need only prove the presence of filth. *United States v. 484 Bags ... Coffee Beans*, 423 F.2d 839 (5th Cir. 1970); it need not establish that the food is unfit, deleterious or dangerous to health. Courts have routinely recognized that insect matter and rodent matter is filth within the meaning of the Act. The presence of any amount of filth is forbidden by the Act, even filth which is capable of being discerned only with the aid of a microscope. *United States v. 484 Bags ... Coffee Beans*, *supra*, at 841; *338 Cartons ... Butter v. United States*, 165 F.2d 728, 730 (4th Cir. 1947).

Exhibit 6-17**MISBRANDING (343(A) AND 352(A)) CASE - DESCRIPTION OF CHARGE FROM A COMPLAINT**

Where, as here, labeling is alleged to be false or misleading under 21 U.S.C. 352(a) (or 343(a)) it is not necessary that the Government prove that all representations are false or misleading. Any one false or misleading representation will support a finding that a product is misbranded. See *United States v. Hoxsey Cancer Clinic*, 198 F.2d 273, 281 (5th Cir. 1952), cert. denied 344 U.S. 928 (1953); *United States v. 47 Bottles Jenasol RJ Formula 60*, 320 F.2d 564, 572 (3rd Cir. 1968), cert. denied 375 U.S. 953; *United States v. An Article of Device ... Diapulse*, 389 F.2d 612 (2nd Cir. 1968), cert. denied 392 U.S. 907; *United States v. One Device ... Colonic Irrigator*, 160 F.2d 194, 200 (10th Cir. 1947); *United States v. 2,000 Plastic Tubular Cases ... Toothbrushes*, 352 F.2d 344 (3rd Cir. 1965), cert. denied 383 U.S. 913 (1966); *United States v. An Article of Device ... Ellis Micro-Dynameter*, 224 F. Supp. 265, 268 (E.D. Pa. 1963). A misleading statement need not be false to violate the Act; it is enough that a statement has the capacity or tendency to deceive, by indirection, ambiguity, or by partial or half-truths. A statement can even be technically true in its entirety and still violate the Act. *United States v. 95 Barrels ... Cider Vinegar*, 265 U.S. 438, 442-3 (1924).

Exhibit 6-18**EXAMPLES OF CONSENT DECREE PROVISIONS**

Note: Although we will rely on OCC to draft the consent decrees, there are certain substantive provisions which must be drafted by the centers and by ORA offices and programs, as they describe the particular technical and scientific steps that must be taken to bring an operation into compliance. We are including samples of usual requirements for a variety of FDA's more typical types of cases. Please note that these are examples only, not boilerplate, and are intended to set out the level of detail that the centers and ORA will need to contribute to the scientific/technical aspects of the relief, in lieu of preparing a draft consent decree. The assigned center and ORA personnel must adapt these provisions to the particular circumstances of each case. In reviewing these samples, employees are not limited to linking the specific relief to a particular type of case. For example, in these examples, audit requirements are set out in the CGMP sections, but there may be situations in which a food sanitation case will need that type of relief. Similarly, the examples do not encompass every type of violation seen in FDA's cases, but they should provide sufficient guidance to assist in generating the operative portion of the decree in cases involving other types of violations.

FOOD SANITATION (LISTERIA)

I. Upon entry of this Decree, Defendants and each and all of their directors, officers, agents, employees, representatives, successors, assigns, attorneys, and any and all persons in active concert or participation with any of them each who receive notice of this Decree, are permanently restrained and enjoined under the provisions of 21 U.S.C. § 332(a), and the equitable authority of this Court, from directly or indirectly receiving, preparing, packing, labeling, holding, and distributing at or from their plant located at _____ (the "_____ facility"), and any other locations at which Defendants now or in the future receive, prepare, pack, label, hold, or distribute articles of food, any article of food unless and until the following occur:

A. Defendants retain, at their expense, an independent laboratory (the "laboratory") having no personal or financial ties (other than the retention agreement) to Defendants or their families, which is qualified to collect product and environmental samples from within Defendants' plant and analyze those samples for the presence of *Listeria monocytogenes* ("*L. mono*") in a method that is acceptable to the United States Food and Drug Administration ("FDA"). Defendants shall notify FDA in writing immediately upon retaining such laboratory and shall provide FDA a copy of the service contract. Such service contract shall contain certain provisions, acceptable to FDA, for regular environmental and finished product sample collection and analysis, including how and where to sample, the number and frequency of samples to be collected, and the methods of analysis, in accordance with the Listeria Monitoring Program discussed in paragraph _____ below;

B. Defendants retain, at their expense, an independent expert(s) (the “sanitation expert”) having no personal or financial ties (other than the retention agreement) to Defendants or their families, and who, by reason of background, education, training, and experience, is qualified to inspect Defendants’ plant and to determine whether the methods, facilities, and controls are operated and administered in conformity with the Act and 21 C.F.R. Part 110. Defendants shall notify FDA in writing of the name(s) and qualifications of the sanitation expert(s) as soon as they retain such expert(s);

C. Defendants’ sanitation expert, in consultation with the laboratory, after review of all FDA observations from _____ to present, develop a written *Listeria* Monitoring Program, acceptable to FDA, which shall include, at a minimum, the following:

1. An effective written sanitation control program that establishes adequate methods, facilities, and controls for receiving, processing, preparing, packing, holding, and distributing articles of food to minimize the risk of introduction of *L. mono* into Defendants’ food, and to ensure that foods are not adulterated, within the meaning of 21 U.S.C. § 342(a). Such methods, facilities, and controls shall include, but shall not be limited to, thoroughly cleaning, sanitizing, renovating, and rendering Defendants’ plant and all equipment therein suitable for use in receiving, processing, preparing, packing, holding, and distributing articles of food to prevent the articles of food from becoming adulterated, and instituting procedures to ensure that the plant and equipment therein are continuously maintained in a sanitary condition;
2. A written employee training program (in English and Spanish) that includes, at a minimum, instruction on sanitary food handling techniques and documentation that each employee has received such training;
3. An effective program of environmental monitoring and testing of the plant, conducted by the laboratory, to ensure that *Listeria species* (*L. spp.*) are controlled, and *L. mono* is not present, within the plant. Environmental monitoring shall include, but not be limited to, collecting swab samples from food-contact surfaces, equipment, and other environmental sites throughout the facility (where the raw ingredients, in-process, and finished articles of foods are received, processed, prepared, packed, held, and/or distributed, and common areas that could be reservoirs for cross-contamination), and analysis of collected samples, in a manner acceptable to FDA. Defendants shall ensure that the results of all analyses conducted pursuant to this paragraph are sent to FDA within two (2) calendar days of receipt by Defendants;
4. A plan for remedial action should *L. spp.*, *L. mono*, or any other pathogenic organism be detected; and

5. Assigning continuing responsibility for the operation of the Listeria Monitoring Program to a person or persons who, by reason of background, experience, or education, is competent to maintain the plant in a sanitary condition, coordinate with the laboratory, and implement any necessary remedial action(s), and providing such person with the authority to achieve the necessary corrections;

6. Defendants make English and Spanish versions of the Listeria Monitoring Program available and accessible to all their employees;

D. The sanitation expert conducts a comprehensive inspection of Defendants' plant and the methods and controls used to receive, process, prepare, pack, hold, and distribute foods to determine whether Defendants have effectively implemented all necessary changes and are operating in compliance with this Decree, the Act, and 21 C.F.R. Part 110. The expert shall submit his/her findings to Defendants and FDA concurrently, within ten (10) business days of completion of the inspection;

E. Defendants report to FDA in writing the actions they have taken to bring their operations into compliance with the Act and all applicable regulations, including:

1. Documentation that they have cleaned and sanitized their facility and have received laboratory results showing that *L. mono* is no longer present in the facility;

2. Specific measures that they have taken to address each of the violations documented by FDA since _____; and

3. A copy of the Listeria Monitoring Program;

F. Defendants shall destroy, under FDA supervision, all in-process and finished articles of food currently in their custody, control, or possession. For purposes of this subparagraph, raw ingredients will not be deemed to be in-process if they have remained unopened in their original packaging and if Defendants establish to FDA's satisfaction that they have been held under appropriate temperature controls since receipt.

G. Defendants recall, to the retail level, all foods distributed since _____, at their own expense.

H. FDA, as it deems necessary to evaluate Defendants' compliance with the terms of this Decree, the Act, and all applicable regulations, conducts inspections of Defendants' plant, including the buildings, sanitation-related systems, equipment, utensils, all articles of food, and relevant records contained therein;

I. FDA notifies Defendants in writing that Defendants appear to be in compliance with the requirements set forth in subparagraphs _____ of this Decree, the Act, and 21 C.F.R. Part 110;

J. Defendants have paid all costs of inspection, analysis, review, investigations, examination, and supervision for FDA's oversight with respect to paragraphs_____, at the rates set forth in paragraph _____below.

II. Upon resuming operations after completing the requirements of paragraph____, Defendants shall continuously implement the following steps to prevent further *L. mono* contamination of their food products and facility:

A. Effectively implement, on an ongoing basis, the Listeria Monitoring Program developed pursuant to _____, unless Defendants submit, and FDA approves in writing, an alternative *L. mono* control program, consisting of validated methods and controls that are shown to FDA's satisfaction to eliminate *L. mono* in food. In the event that Defendants, their sanitation expert, or laboratory, determines that the Listeria Monitoring Program needs to be revised, Defendants shall provide suggested changes to FDA in writing at least twenty (20) days prior to their implementation.

B. Conduct finished product testing in the following manner:

1. Immediately upon resumption of operations after the completion of the requirements of paragraph____, Defendants shall test for *L. mono* in all lots of each food product for at least five consecutive production days using a testing method acceptable to FDA;

2. After the completion of testing under paragraph_____, Defendants shall test at least one lot of each food product per day for the next twenty (20) production days;

3. After the completion of testing under paragraph_____, Defendants shall test at least one lot of each food product per every five (5) production days for the next three (3) months; and

4. After the completion of testing under paragraph_____, Defendants shall test at least one lot of each food product per quarter thereafter.

If any laboratory test completed pursuant to paragraphs _____shows the presence of *L. mono* in any article of food, then Defendants must immediately cease production until they have determined and corrected the cause of the microbial contamination. Once the cause of the contamination has been corrected, Defendants shall reinstate the complete sequence of testing under this paragraph anew

III. If, at any time after entry of this Decree, FDA determines, based on the results of an inspection, sample analysis, or other information, that Defendants have failed to comply

with any provision of this Decree, have violated the Act or applicable regulations, or that additional corrective actions are necessary to achieve compliance with this Decree, the Act or applicable regulations, FDA may, as and when it deems necessary, issue a directive notifying Defendants in writing of the noncompliance and ordering Defendants to take appropriate action, including but not limited to ordering them to take one or more of the following actions immediately:

- A. Cease receiving, preparing, packing, labeling, holding, or distributing articles of food until Defendants receive written notification from FDA that they appear to be in compliance with the Decree, the Act, and applicable regulations, and that Defendants may resume operations;
- B. Recall all articles of food that have been distributed or are under the custody and control of Defendants' agents, customers, or consumers;
- C. Submit samples of articles of food to a qualified laboratory to determine whether it is contaminated with chemicals, toxins, microorganisms, or filth;
- D. Take any other corrective actions as FDA deems necessary to protect the public health or bring Defendants into compliance with this Decree, the Act, and applicable regulations, including, but not limited to, requiring that Defendants re-implement or re-institute any of the requirements of this Decree.

FOOD SANITATION

I. Upon entry of this Decree, the defendants and each and all of their officers, agents, employees, successors, assigns, and attorneys, and any persons in active concert or participation with any of them who receive notice of this Decree, are permanently restrained and enjoined under the provisions of 21 U.S.C. § 332(a) from directly or indirectly receiving, manufacturing, preparing, packing, labeling, and distributing at their plant located at _____ (and any new locations at which the defendants receive, manufacture, prepare, pack, label, hold, or distribute articles of food), of any soft-shell flour tortilla unless and until the following occur:

- A. The defendants select an expert or experts (the "sanitation expert") having no personal or financial ties (other than a consulting agreement) to the defendants or the defendants' manufacturing operations and who, by reason of background, education, training, and experience, is qualified to develop, and ensure adequate implementation of, a written sanitation control program, covering the defendants' manufacturing processes, cleaning and sanitizing operations, pest control, employee health and hygiene precautions, and plant construction and maintenance (including the plant's buildings and sanitation-related systems (plumbing, sewage disposal), equipment, and utensils contained therein), to protect against contamination of food, food-contact surfaces, and food-packaging materials with chemicals, toxins, microorganisms, and filth, and:

1. The defendants inform the United States Food and Drug Administration (FDA) in writing of the name and qualifications of the sanitation expert(s) as soon as they retain such expert;

2. The sanitation expert(s) develops a written sanitation control program for preparing, packing, holding, and distributing the defendants' articles of food, as described in subparagraph_____;

3. FDA approves, in writing, the sanitation control program developed by the sanitation expert(s);

4. The defendants make English and Spanish versions of the sanitation control program available and accessible to all their employees;

5. The defendants develop a written employee training program (in English and Spanish) that includes, at a minimum, instruction in sanitation control requirements for food-handling and manufacturing, and the defendants document that each employee has received such training;

6. The defendants assign the responsibility and authority for implementing and monitoring the sanitation control program on a continuing basis to an employee who is trained in sanitation control requirements;

7. The sanitation expert(s) inspects the defendants' plant, including the buildings, sanitation-related systems, equipment, utensils, articles of food, and relevant records contained therein, to determine whether the defendants have adequately established and implemented the FDA-approved sanitation control program, whether the defendants have adequately addressed the FDA investigators' inspectional observations listed on each Form FDA-483 issued to the defendants since_____, and whether the defendants comply with Current Good Manufacturing Practice (CGMP) requirements set forth in 21 C.F.R. Part 110; and

8. The sanitation expert certifies, in writing, to FDA that the defendants: (i) have adequately established and implemented the FDA-approved sanitation control program; (ii) have adequately addressed the Form FDA-483 observations; and (iii) comply with the CGMP requirements in 21 C.F.R. Part 110.

B. The defendants select an expert (the "food processing expert") having no personal or financial ties (other than a consulting agreement) to the defendants or the defendants' manufacturing operations and who, by reason of background, education, training, and experience, is qualified to develop, and ensure adequate implementation of, a food processing quality control program, covering the defendants' processes for preparing, packing, and holding soft-shell flour tortillas, to prevent ingredient mix-ups and ensure that the soft-shell flour tortillas manufactured by the defendants consistently

contain the type and amount of ingredients that they are intended to contain, based on pre-established written batch formulations, and:

1. The defendants inform FDA in writing of the name and qualifications of the food processing expert as soon as they retain such expert;

2. The food processing expert develops a food processing quality control program, as described in subparagraph_____, and such food processing quality control program, at a minimum, requires: (i) applying and maintaining identification of raw ingredients in English and Spanish on raw ingredient containers; (ii) using appropriate proportions of raw ingredients in the soft-shell flour tortillas manufactured by the defendants; (iii) for each size of soft-shell flour tortillas manufactured by the defendants, establishing written batch formulations, which include the name and amount of the raw ingredients and the complete manufacturing instructions; (iv) for each batch of soft-shell flour tortillas manufactured by the defendants, preparing a batch production record, which documents that each step in the established written batch formulation for the product was followed, and lists the lot numbers of each raw ingredient used in the batch production; and (v) for each retail and bulk package of soft-shell flour tortillas manufactured by the defendants, placing an indelible manufacturing date and time code in a conspicuous location on the back panel of the package where it is easily readable;

3. FDA approves, in writing, the food processing quality control program developed by the food processing expert;

4. The defendants make English and Spanish versions of the food processing quality control program – including the established written batch formulation for each size of soft-shell flour tortillas manufactured by the defendants – available and accessible to all their employees;

5. The defendants develop a written employee training program (in English and Spanish) that includes, in addition to the requirements in subparagraph_____, instruction in proper food processing techniques and food processing quality control, and the defendants document that each employee has received such training;

6. The defendants assign the responsibility and authority for implementing and monitoring the food processing quality control program on a continuing basis to an employee who is trained in food processing quality control requirements;

7. The food processing expert inspects the defendants' plant, equipment, utensils, articles of food, and relevant records contained therein, to determine whether the defendants have adequately established and implemented the FDA-approved food processing quality control program; and

8. The food processing expert certifies, in writing, to FDA that the defendants have adequately established and implemented the FDA-approved food processing quality control program;

C. The defendants, under FDA supervision, examine raw ingredients and in-process and finished articles of foods at the defendants' plant, and the conditions under which they have been stored or held, and the defendants destroy, under FDA supervision, all raw ingredients and in-process and finished articles of food as and when FDA deems necessary;

D. FDA, as it deems necessary to evaluate the defendants' compliance with the terms of paragraph____, conducts inspections of the defendants' plant, including the buildings, sanitation-related systems, equipment, utensils, all articles of food, and relevant records contained therein;

E. The defendants pay the costs of any supervision, inspection, analyses, examination, and review that FDA deems necessary to evaluate the defendants' compliance with the terms of paragraph____; and

F. FDA notifies the defendants in writing that the defendants appear to be in compliance with the requirements set forth in subparagraphs_____, 21 C.F.R. Part 110, and the Act.

II. Upon resuming operations after completing the requirements of paragraph____, the defendants shall notify FDA in writing of any change in the type or amount of raw ingredients in any batch formulation for soft-shell flour tortillas (including, but not limited to, switching from an ingredient pre-mix to individually packaged ingredients) or any change in manufacturing instructions for any soft-shell flour tortilla, at least ten (10) calendar days before implementing any such change.

III. The defendants and each and all of their officers, agents, employees, successors, assigns, and attorneys, and any persons in active concert or participation with any of them who receive notice of this Decree, are permanently restrained and enjoined under the provisions of 21 U.S.C. § 332(a) from directly or indirectly doing or causing any act that:

A. violates the Act, 21 U.S.C. § 331(a), by introducing, or delivering for introduction, into interstate commerce articles of food that are adulterated within the meaning of 21 U.S.C. § 342(a)(4);

B. violates the Act, 21 U.S.C. § 331(k), by causing articles of food to be adulterated within the meaning of 21 U.S.C. § 342(a)(4) while such articles are held for sale after shipment of one or more ingredients in interstate commerce; or

C. failing to implement and continuously maintain the requirements of this Decree.

IV. If, at any time after entry of this Decree, FDA determines, based on the results of an inspection, sample analysis, or other information, that the defendants have failed to comply with any provision of this Decree, have violated 21 C.F.R. Part 110 or the Act, or that additional corrective actions are necessary to achieve compliance with this Decree, 21 C.F.R. Part 110 or the Act, FDA may, as and when it deems necessary, issue a directive notifying the defendants in writing of the noncompliance and ordering the defendants to take appropriate action, including but not limited to ordering the defendants immediately to take one or more of the following actions:

A. Cease receiving, manufacturing, preparing, packing, labeling, holding, or distributing articles of food until the defendants receive written notification from FDA that the defendants appear to be in compliance with the Decree, 21 C.F.R. Part 110, and the Act, and that the defendants may resume operations;

B. Recall all articles of food that have been distributed or are under the custody and control of the defendants' agents, customers, or consumers;

C. Submit samples of articles of food to a qualified laboratory to determine whether the food contains the type and amount of ingredients that it is intended to contain and whether it is contaminated with chemicals, toxins, microorganisms, or filth;

D. Take any other corrective actions as FDA deems necessary to protect the public health or bring the defendants into compliance with this Decree, 21 C.F.R. Part 110, and the Act, including but not limited to requiring that the defendants re-implement or re-institute any of the requirements of this Decree.

The provisions of this paragraph shall be apart from, and in addition to, all other remedies available to FDA. The defendants shall pay all costs of recalls and other corrective actions, including the costs of FDA's supervision, inspections, investigations, analyses, examinations, and reviews to implement and monitor recalls and other corrective actions, at the rates specified in paragraph _____ of this Decree.

JUICE HACCP

I. Defendants and each and all of their agents, employees, attorneys, successors, assigns, and any persons in active concert or participation with any of them (including individuals, directors, corporations, subsidiaries, affiliates, and partnerships) who receive actual notice of this Decree, are hereby permanently restrained and enjoined, under the provisions of 21 U.S.C. § 332(a) and the inherent equitable authority of this Court, from receiving, processing, preparing, packing, holding, or distributing juice, at or from Defendants' juice processing plant located at _____ and at or from any other locations at which Defendants may receive, process, prepare, pack, hold, or distribute juice, unless and until:

A. Defendants retain, at Defendants' expense, an independent person or persons ("expert"), who by reason of background, education, training, and experience,

is qualified to develop and implement a Hazard Analysis Critical Control Point (“HACCP”) plan for juice. The expert shall be without personal or financial ties (other than the consulting agreement between the parties) to Defendants or their immediate families. Defendants shall notify the United States Food and Drug Administration (“FDA”) in writing of the identity of the expert as soon as they retain such expert;

B. The expert develops written HACCP plans for each type of juice processed by Defendants, consistent with 21 C.F.R. § 120.8(a) - (c);

C. FDA has approved, in writing, the HACCP plan developed by the expert;

D. Defendants establish and implement to FDA’s satisfaction the written HACCP plan, developed by the expert and approved in writing by FDA, that is adequate to control food safety hazards likely to occur in the processing of juice, as required by 21 C.F.R. §§ 120.7 and 120.8;

E. Defendants have the expert validate and certify in writing to FDA that the control measures in Defendants’ HACCP plan are adequate to consistently produce, at a minimum, a 5-log reduction in the most resistant organism of public health significance that is likely to occur in each juice, as required by 21 C.F.R. § 120.24;

F. To the extent Defendants utilize in their production of citrus juice a surface treatment process to achieve a 5-log reduction of the most resistant organism of public significance, Defendants ensure that their unpasteurized, finished juice products containing citrus juice are analyzed for biotype I *Escherichia coli* (“*E. coli*”) in accordance with the frequency and methods of analysis proscribed in 21 C.F.R. § 120.25;

G. Defendants, under FDA supervision, according to procedures approved by FDA, and as and when directed by FDA, destroy or bring into compliance with the Act all food in the plant at the time this Decree is signed;

H. FDA has inspected the plant, including all records relating to the receipt, processing, preparation, packing, holding, and distribution of juice; and

I. FDA has notified Defendants, in writing, that the processes and controls used for the receipt, processing, preparation, packing, holding, and distribution of juice appear to be in compliance with all of the requirements specified in Paragraph ____ of this Decree, the Act, and 21 C.F.R. Part 120. And, if such notification is based upon one or more FDA inspections, Defendants have paid for such inspection(s) and other work at the rates specified in Paragraph ____.

II. Defendants shall immediately provide any information or records to FDA, upon request, regarding the receipt, processing, preparation, packing, holding, or distribution of juice. Defendants shall maintain a copy of their HACCP plan and all records required by their HACCP plan and 21 C.F.R. Part 120 at the plant in a location where they are readily available

for reference and inspection by FDA representatives. All records required to be kept by the HACCP plan and by regulation shall be retained for at least three (3) years after the date they are prepared and shall be presented immediately to FDA investigators upon request.

III. If, at any time after this Decree has been entered, FDA determines, based on the results of an inspection, the analyses of samples, a report or data submitted by Defendants or the expert, or any other information, that Defendants have failed to comply with any provision of this Decree, or have violated the Act or its implementing regulations, or that additional corrective actions are necessary to achieve compliance with this Decree, the Act, or its implementing regulations, FDA may, as and when it deems necessary, order Defendants in writing to immediately cease receiving, processing, preparing, packing, holding, and distributing juice, and Defendants shall immediately comply with any such written orders. In addition, Defendants shall, as and when FDA deems necessary, recall all articles of food that have been distributed or are under the custody and control of Defendants' agents, distributors, customers, or consumers. All costs of such recall(s) and corrective actions shall be borne by Defendants. The costs of FDA inspections, sampling, testing, travel time, and subsistence expenses to implement the remedies set forth in this paragraph shall be borne by Defendants at the rates specified in Paragraph ____.

IV. After Defendants receive written notification from FDA pursuant to Paragraph ____ that they appear to be in compliance with Paragraphs ____ of this Decree, Defendants and each and all of their agents, employees, attorneys, successors, assigns and any persons in active concert or participation with any of them (including individuals, directors, corporations, subsidiaries, affiliates, and partnerships) who receive actual notice of this Decree, are permanently restrained and enjoined from:

A. directly or indirectly doing or causing any article of food, within the meaning of 21 U.S.C. § 321(f), to become adulterated, within the meaning of 21 U.S.C. § 342(a)(4), while such food is held for sale after shipment in interstate commerce; and

B. failing to implement and continuously maintain the requirements of this Decree.

SEAFOOD HACCP

I. Defendants and each and all of their officers, agents, employees, successors, assigns, attorneys, and those persons in active concert or participation with any of them, are perpetually restrained and enjoined under the provisions of 21 U.S.C. § 332(a) from receiving, processing, preparing, packing, holding, or distributing, at or from their facility located at _____, and any other locations at or from which defendants process, prepare, pack, hold, or distribute food, including any brined, cold-smoked, and hot-smoked fish and fishery products, unless and until:

A. Defendants have thoroughly cleaned and sanitized the facility and equipment therein and made improvements, thereby rendering the facility and equipment suitable for processing, preparing, packing, holding, and distributing articles of food;

B. Defendants have selected a person or persons ("*Listeria* expert"), other than an employee of _____, who by reason of background, experience and education, is qualified to develop a raw ingredient testing program, a Sanitation Standard Operation Procedure ("SSOP"), an employee training program on sanitary food handling techniques and personal hygiene practices, and an environmental microbial monitoring program for the genus *Listeria* ("*L. spp.*") for the processing of brined, cold-smoked, and hot-smoked fish and fishery products;

C. The *Listeria* expert has developed a written raw ingredient testing and treatment program for *Listeria monocytogenes* ("*L. monocytogenes*"), an SSOP, an employee training program, and an environmental microbial monitoring program for *L. spp.* for the processing of brined, cold-smoked, and hot-smoked fish and fishery products;

D. The United States Food and Drug Administration ("FDA") has approved in writing the raw ingredient testing and treatment program, SSOP, training program, and environmental microbial monitoring program developed by the *Listeria* expert;

E. Defendants, under the supervision of and in accordance with methods acceptable to FDA, have examined all lots of brined, cold-smoked, and hot-smoked fish and fishery products on hand at the facility for *L. monocytogenes*, in the following manner:

1. Defendants shall select a competent, independent laboratory to perform the testing;
2. The name of the laboratory shall be submitted to FDA before the testing begins;
3. All written reports of such examinations shall be submitted to FDA within two (2) calendar days after receipt by defendants;
4. FDA is authorized to conduct additional analyses and examine the articles of food, as it deems necessary, to evaluate whether the articles are adulterated; and
5. All brined, cold-smoked, and hot-smoked fish and fishery products that contain *L. monocytogenes* shall be destroyed by defendants under FDA's supervision, or reconditioned under FDA's supervision pursuant to a reconditioning plan approved in writing by FDA prior to its implementation;

F. Defendants have conducted appropriate hazard analyses and have prepared Hazard Analysis Critical Control Point ("HACCP") plans as required by 21 C.F.R. §

123.6(b) for all foods, including all brined, cold-smoked, and hot-smoked fish and fishery products, received, processed, prepared, packed, held, or distributed at the _____ facility and any other facility, at which defendants conduct their food operations. These analyses must be performed, and these plans must be designed to the satisfaction of FDA;

G. Defendants develop and implement an ongoing program of adequate measures to control *L. monocytogenes* ("*Listeria* program"), as described in paragraph__.

H. FDA, as it deems necessary to evaluate defendants' compliance with the terms of paragraph____, conducts inspections of the facility;

I. Defendants pay the costs of inspections, supervision, analyses, and examination by FDA at the rates specified in paragraph__; and

J. FDA has notified defendants in writing that defendants appear to be in compliance with the requirements set forth in paragraphs _____ and with all requirements of 21 C.F.R. Parts 110 and 123.

II. Defendants shall have and implement an ongoing program of adequate measures to control *L. monocytogenes* ("*Listeria* program"). The *Listeria* program shall include the following procedures, unless defendants submit for and receive FDA's written approval for an alternate *L. monocytogenes* control program, consisting of validated methods and controls, that is shown to FDA's satisfaction to eliminate *L. monocytogenes* in both the finished product and in the facility:

A. Treatment or testing of susceptible raw ingredients. Raw material testing for *L. monocytogenes* shall be performed in accordance with timetables and methods submitted to and approved in writing by FDA before testing begins. Defendants shall select a competent, independent laboratory to perform the testing. The name of the laboratory shall be submitted to FDA before testing begins. Defendants shall ensure that the results of all testing conducted pursuant to this paragraph are forwarded to FDA within two (2) calendar days after receipt by defendants. Where a sample analysis shows the presence of *L. monocytogenes* in any raw ingredient, the finished product lot made in whole or in part from that raw ingredient shall be placed on hold or recalled, as FDA deems appropriate, and shall, as FDA deems appropriate, be destroyed by defendants under FDA's supervision, or reconditioned under FDA's supervision pursuant to a reconditioning plan approved by FDA. All expenses of such supervision, analyses, and examination by FDA shall be paid by defendants at the rates specified in paragraph__;

B. Effective and diligent sanitation procedures for cleaning and sanitizing manufacturing equipment and environment to minimize the risk of reintroducing *L. monocytogenes*. These procedures shall consist of the SSOP and the training program

developed by the *Listeria* expert pursuant to the provisions of paragraph ____ and shall be implemented on a continuous basis;

C. An effective program for environmental monitoring and testing of manufacturing and storage environment to ensure that *L. spp.* are controlled within the facility and *L. monocytogenes* does not occur in the finished product. The ongoing environmental microbial monitoring program shall ensure that the SSOP continues to eliminate the *L. monocytogenes* hazard and that the SSOP is consistently being followed. Environmental monitoring shall include collecting swab samples from food-contact surfaces, equipment, and other environmental sites throughout the facility (where the fish or fishery products are received, prepared, packed, and held, up to and including final packaging, and common areas that could be reservoirs for cross-contamination), and analyzing such samples for the presence of *L. spp.* Environmental testing for *L. spp.* shall be performed in accordance with timetables and methods submitted to and approved in writing by FDA before testing begins. Defendants shall select a competent, independent laboratory to perform the testing and submit the name of the laboratory to FDA before testing begins. Defendants shall ensure that the results of all testing conducted pursuant to this paragraph are forwarded to FDA within two (2) calendar days after receipt by defendants;

D. Additional finished product control measures. Defendants shall implement additional control measures to prevent growth of *L. monocytogenes* in finished products. Defendants shall notify FDA regarding the control measures they select. These control measures shall continue until, as in the finished product testing described in paragraph ____, the laboratory test results show no presence of *L. monocytogenes* for a period of six consecutive months. If, after such six month period, a laboratory test result shows the presence of *L. monocytogenes*, defendants shall reinitiate the additional finished product control measures under this paragraph and continue to implement them until the laboratory test results show no presence of *L. monocytogenes* for a period of six consecutive months; and

E. Finished product testing. To demonstrate compliance with the requirements described in ____, finished product testing shall include the following:

1. immediately upon resumption of operations and after completion of the requirements in paragraph ____, defendants shall test for *L. monocytogenes* in each lot of finished product for at least five consecutive production days;
2. immediately after the completion of testing under paragraph ____, defendants shall test at least one lot per day for at least the next 20 production days;
3. immediately after the completion of testing under paragraph ____, defendants shall test at least one lot per every five production days for the next three months; and

4. immediately after the completion of testing under paragraph _____, defendants shall test at least one lot during each three-month period thereafter.

If any laboratory test listed in subparagraphs _____ show the presence of *L. monocytogenes* in any product, defendants must stop production and, before resuming any production, determine and correct the cause of the microbial contamination and start the complete sequence of testing again.

III. If, at any time after entry of this Decree, FDA determines, based on the results of an inspection, analysis of a sample or samples, or other information, that the defendants have failed to comply with any provision of this Decree, have violated the Act or its implementing regulations, or that additional corrective actions are necessary to achieve compliance with this Decree, the regulations, or the Act, FDA may, as and when it deems necessary, notify the defendants in writing of the noncompliance and order the defendants to take appropriate action, including, but not limited to, ordering the defendants to immediately take one or more of the following actions:

- A. Cease receiving, processing, preparing, packing, holding, or distributing any article of food;
- B. Recall all articles of food that have been distributed or are under the custody and control of defendants' agents, distributors, customers, or consumers; or
- C. Take any other corrective actions as FDA deems necessary to bring the defendants into compliance with this Decree, FDA regulations, and the Act.

Defendants shall pay all costs of such recalls and corrective actions, including the costs of FDA supervision, inspections, analyses, examinations, review, travel, and subsistence expenses to implement recalls and other corrective actions, at the rates specified in paragraph ____ of this Decree. This provision shall be separate and apart from, and in addition to, all other remedies available to FDA.

IV. Any cessation of operations as described in paragraph ____ shall continue until defendants receive written notification from FDA that defendants appear to be in compliance with the Decree, the Act, and its implementing regulations. After a cessation of operations, and while determining whether defendants are in compliance with the Decree, the Act, and its regulations, FDA may require that defendants re-institute or re-implement any of the requirements of this Decree.

DIETARY SUPPLEMENT

I. Upon entry of this Decree, Defendants and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, assigns, and any and all persons in active concert or participation with any of them who receive actual notice of this Decree by personal service or otherwise, are permanently restrained and enjoined from

introducing or delivering for introduction, or causing to be introduced or delivered for introduction, into interstate commerce any product unless and until:

- A. An approved new drug application or abbreviated new drug application filed pursuant to 21 U.S.C. § 355(a) or (j) is effective with respect to the product; or
- B. An effective investigational new drug exemption filed pursuant to 21 U.S.C. § 355(i) is in effect for the product; or
- C. The product's claims comport with an authorized health claim set forth in 21 C.F.R. § 101.72-101.83; or
- D. Defendants have received a letter of enforcement discretion for a qualified health claim from FDA for that product; or
- E. Defendants have removed all claims from Defendants' product labels, labeling, promotional materials, websites owned or controlled by or related to Defendants, and in any other media that cause that product to be a drug and/or contain health claims within the meaning of the Act.

II. Within ten (10) calendar days of FDA's request for any labels, labeling, promotional materials, and/or downloaded copies (on CD-Rom) of any internet websites owned and controlled by or related to Defendants, Defendants shall submit a copy of the requested materials to FDA at the address specified in paragraph ____.

III. Within twenty(20) calendar days of entry of this Decree, Defendants shall submit to FDA a certification of compliance, signed by each of the individually-named Defendants in this matter, each Defendant stating that he: (a) has personally reviewed all of Defendants' product labels, labeling, promotional materials, and the internet websites referred to in paragraph __ above; and (b) personally certifies that the product labels, labeling, promotional materials, and internet websites strictly comply with the requirements of the Act and its regulations and do not include claims that the products cure, mitigate, treat, prevent and/or reduce the risk of disease. Thereafter, Defendants shall submit certifications of compliance every three (3) months for a period of two (2) years.

IV. Within fourteen (14) calendar day of entry of this Decree, Defendants shall retain an independent person or persons (the "expert"), without personal, financial (other than the consulting agreement between the parties), or familial ties to Defendants or their immediate families, who by reason of background, experience, education, and training is qualified to assess Defendants' compliance with the Act, to review the claims Defendants make for all of their products on their product labels, labeling, promotional material, and any internet websites owned or controlled by or related to Defendants including, but not limited to, the websites referred to in paragraph __ above. At the conclusion of the expert's review, the expert shall prepare a written report analyzing whether Defendants are operating in compliance with the Act and in particular, certify whether Defendants have omitted all claims from their product

labels, labeling, promotional materials, websites owned or controlled by or related to Defendants and in any other media, that make any of their products drugs and/or constitute health claims within the meaning of the Act. The expert shall submit this report to FDA and Defendants within thirty-five (35) calendar days of the entry of this Decree. If the expert reports any violations of the Act, Defendants shall, within seven (7) calendar days of receipt of the report, correct those deviations, unless FDA notifies Defendants that a shorter time period is necessary.

V. If, at any time after this Decree has been entered, FDA determines, based on the results of an inspection, the analyses of Defendants' product labels, labeling, promotional materials, or websites owned or controlled by or related to Defendants, a report prepared by Defendants' expert, or any other information, that additional corrective actions are necessary to achieve compliance with the Act, applicable regulations, or this Decree, FDA may, as and when it deems necessary, direct Defendants, in writing, to take one or more of the actions:

- A. Cease manufacturing, processing, packing, labeling, holding, and/or distributing any article(s);
- B. Submit additional reports or information to FDA;
- C. Recall any article(s) at Defendants' expense; or
- D. Take any other corrective action(s) as FDA, in its discretion, deems necessary to bring Defendants and their products into compliance with the Act, applicable regulations, and this Decree.

DRUG CGMP

I. Except as provided in this paragraph, within fifteen (15) calendar days of entry of this Decree, Defendants shall, under the United States Food and Drug Administration's ("FDA") supervision destroy: (1) all drugs in Defendants' possession, custody, and/or control that are the subject of recalls announced by _____ from _____ through _____; and (2) in addition to destroying all recalled drugs, all other drugs in Defendant's possession, custody, and/or control, including all in-process drugs and drug components, as well as finished drugs. With respect to any additional recalled drugs that subsequently come into Defendants' possession, custody, and/or control, Defendants shall quarantine any such products, notify FDA in writing of their receipt, and destroy any such products, under FDA's supervision, no later than thirty (30) calendar days after their receipt. Within thirty (30) calendar days of receipt of a reasonable detailed bill of costs, Defendant shall reimburse FDA for the supervision of any destruction under this paragraph, at the rates set forth in paragraph ___ of this Decree. Defendants shall not dispose of any drugs in a manner contrary to any federal, state, or local laws, including but not limited to, the National Environmental Policy Act of 1969.

II. Upon entry of this Decree, Defendants and each and all of their subsidiaries, directors, officers, agents, representatives, employees, attorneys, successors, and assigns, and any and all persons in active concert or participation with any of them who receive actual notice of this Decree by personal service or otherwise, are permanently restrained and enjoined under 21 U.S.C. § 332(a) from directly or indirectly, doing or causing the manufacture, processing, packing, labeling, holding, or distributing, or introducing or delivering for introduction into interstate commerce at or from any of the ____ facilities, any drug, as defined by 21 U.S.C. § 321(g)(1), unless and until:

A. Defendants' methods, facilities, and controls used to manufacture, process, pack, label, hold, and distribute drugs are established, operated, and administered in conformity with CGMP. 21 U.S.C. § 351(a)(2)(B) and 21 C.F.R. Parts 210 and 211;

B. Defendants retain, at Defendant's expense, an independent person or persons (the "CGMP expert"), who is without any personal or financial (other than the consulting agreement between the parties), or familial ties to Defendants or their immediate families, who by reason of background, training, education, or experience, is qualified to inspect Defendants' drug manufacturing facilities to determine whether the methods, facilities, and controls are operated and administered in conformity with CGMP. Defendants shall notify FDA in writing of the identity and qualifications of the CGMP expert as soon as they retain such expert;

C. The CGMP expert shall perform a comprehensive inspection of Defendants' facilities and the methods and controls used to manufacture, process, package, label, hold, and distribute drugs. The CGMP expert shall determine whether Defendants' facilities and the methods and controls used to manufacture, process, package, label, hold, and distribute drugs are in compliance with CGMP.

D. The CGMP expert certifies in writing to FDA that:

1. He or she has inspected Defendants' facilities, methods, processes, and controls;

2. All CGMP deviations brought to Defendants' attention since _____ by FDA, the CGMP expert, or any other source, including but not limited to any experts hired prior to the entry of this Decree, have been corrected; and

3. Such facilities, methods, processes, and controls are in compliance with the requirements of CGMP. As part of this certification, the CGMP expert shall include a full and complete detailed report of the results of his or her inspection;

E. Defendants report to FDA in writing the actions they have taken to:

1. Correct the CGMP deviations brought to Defendants' attention by FDA, the CGMP expert, and any other source, including but not limited to any experts hired prior to the entry of this Decree;
2. Ensure that the methods used in, and the facilities and controls used for, manufacturing, processing, packing, labeling, holding, and distributing drugs are operated and will be continuously administered in conformity with CGMP;
3. Defendants may submit two (2) interim reports under this subparagraph, which shall include the CGMP drug expert certification described in subparagraph_____, in support of the immediate marketing of a priority product(s);

F. FDA representatives inspect Defendants' facilities to determine whether the requirements of this Decree have been met, and whether Defendants' facilities are operating in conformity with CGMP, the Act, and its implementing regulations; and

G. FDA notifies Defendants in writing that Defendants appear to be in compliance with the requirements set forth in subparagraphs_____. In no circumstance will FDA's silence be construed as a substitute for written notification.

III. After Defendants have complied with paragraphs _____ and FDA has notified them pursuant to paragraph ____, Defendants shall retain an independent person or persons (the "auditor") to conduct audit inspections of _____'s drug manufacturing operations not less than once every six (6) months for a period of no less than five (5) years. The auditor shall be qualified by education, training, and experience to conduct such inspections, and shall be without personal or financial ties (other than a consulting agreement entered into by the parties) to any of _____'s officers or employees or their immediate families and may, if _____chooses, be the same person or persons described as the CGMP expert and/or unapproved new drug expert, as set forth in paragraphs ____.

A. At the conclusion of each audit inspection, the auditor shall prepare a detailed written audit report ("audit report") analyzing whether Defendants are in compliance with the Act, its implementing regulations, and this Decree, and identifying in detail any deviations therefrom ("audit report observations"). As a part of every audit report, except the first audit report, the auditor shall assess the adequacy of corrective actions taken by Defendants to correct all previous audit report observations. The audit reports shall be delivered contemporaneously to Defendants and FDA by courier service or overnight delivery service, no later than fifteen (15) calendar days after the date the audit inspection(s) is completed. If audit reports identify deviations from the Act, its implementing regulations, and/or this Decree, FDA may, in its discretion, require that the five (5) year auditing cycle be extended or begin anew. In addition, Defendants

shall maintain the audit reports in separate files at their facility and shall promptly make the audit reports available to FDA upon request.

B. If an audit report contains any adverse observations, Defendants shall, within thirty (30) calendar days of receipt of the audit report, correct those observations, unless FDA notifies Defendants that a shorter time period is necessary. If, after receiving the audit report, Defendants believe that correction of the audit report observations will take longer than thirty (30) calendar days, Defendants shall, within ten (10) business days of receipt of the audit report, submit to FDA in writing a proposed schedule for completing corrections ("correction schedule") and provide justification describing why the additional time is necessary. The correction schedule must be reviewed and approved by FDA in writing prior to implementation by Defendants. In no circumstance will FDA's silence be construed as a substitute for written approval. Defendants shall complete all corrections according to the approved correction schedule. Within thirty (30) calendar days of Defendants' receipt of an audit report, unless FDA notifies Defendants that a shorter time period is necessary, or within the time period provided in a correction schedule approved by FDA, the auditor shall review the actions taken by Defendants to correct the audit report observations. Within five (5) business days of beginning that review, the auditor shall report in writing to FDA whether each of the audit report observations has been corrected and, if not, which audit report observations remain uncorrected.

New Drug

I. Upon entry of this Decree, Defendants and each and all of their directors, officers, agents, employees, representatives, successors, assigns, attorneys, and any and all persons or entities in active concert or participation with any of them (including franchisees, affiliates, and "doing business as" entities), who have received actual notice of this Decree by personal service or otherwise, are permanently restrained and enjoined under 21 U.S.C. § 332(a), from directly or indirectly doing or causing to be done any of the following acts:

A. Introducing or delivering for introduction into interstate commerce, holding for sale after shipment in interstate commerce, manufacturing, processing, packing, labeling, holding, or distributing the drugs identified in Appendix A (attached hereto) (***Appendix A – list to be supplied by Center**) or any drug that is a new drug within the meaning of 21 U.S.C. § 321(p), unless and until:

1. an approved new drug application or abbreviated new drug application filed pursuant to 21 U.S.C. § 355 is in effect for such drug;
2. an investigational new drug application filed pursuant to 21 U.S.C. § 355(i) and 21 C.F.R. Part 312 is in effect for such drug and the drug is distributed and used solely for the purpose of conducting clinical investigations in strict accordance with the investigational new drug application; or

3. Defendants retain, at Defendant's expense, an independent person or persons (the "unapproved new drug expert"), without personal, financial (other than the consulting agreement between the parties), or familial ties to Defendants or their immediate families, who by reason of background, experience, education, and training, is qualified to inspect Defendants' facilities, product labeling, including promotional material and internet site information, adverse event reports, and complaints for all drugs and dietary supplements stored, processed, labeled, packed, or distributed by Defendants. Defendants shall notify FDA in writing of the identity of the unapproved new drug expert as soon as they retain such person.

(a) The unapproved new drug expert shall perform a comprehensive inspection of Defendants' facilities, product labeling, including promotional material and internet site information, adverse event reports, and complaints. The unapproved new drug expert shall determine whether Defendants have eliminated drug claims from their labeling, including promotional materials and internet information, so the products are no longer misbranded or unapproved new drugs;

(b) Defendants' expert shall certify in writing to FDA that he or she has inspected Defendants' facilities, product labeling, including promotional material and internet site information, adverse event reports and complaints, and that Defendants are not making drug claims for their products and that such products constitute dietary supplements, within the meaning of 21 U.S.C. § 321(ff). As a part of this certification, the unapproved new drug expert shall include a full and complete detailed report of the results of his or her inspection;

(c) Defendants shall report to FDA in writing the actions they have taken to eliminate drug claims from their labeling, including any promotional materials and internet site information. Defendants may submit two (2) interim reports under this subparagraph, which shall include the unapproved new drug expert certification described in subparagraph_____, in support of the immediate marketing of a priority product(s);

(d) Within forty-five (45) calendar days after receiving a report under subparagraph_____, FDA shall either notify Defendants in writing that, with respect to the products identified in the report as being reviewed, (1) they appear to be compliance with the requirement of this Decree and the Act, or (2) they do not appear to be in compliance with the requirements of this Decree and the Act, along with the reasons for such appearance of noncompliance.

B. Introducing or delivering for introduction into interstate commerce any drug that is adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B);

C. Causing the adulteration of any drug within the meaning of 21 U.S.C. § 351(a)(2)(B), while such drug is held for sale after shipment of one or more components in interstate commerce; and

D. Introducing or delivering for introduction into interstate commerce any drug that is misbranded within the meaning of 21 U.S.C. § 353(b)(4)(B).

II. After Defendants have complied with paragraphs _____ and FDA has notified them pursuant to paragraph ____, Defendants shall retain an independent person or persons (the "auditor") to conduct audit inspections of ___'s drug manufacturing operations not less than once every six (6) months for a period of no less than five (5) years. The auditor shall be qualified by education, training, and experience to conduct such inspections, and shall be without personal or financial ties (other than a consulting agreement entered into by the parties) to any of ___'s officers or employees or their immediate families and may, if _____ chooses, be the same person or persons described as the CGMP expert and/or unapproved new drug expert, as set forth in paragraphs ____.

A. At the conclusion of each audit inspection, the auditor shall prepare a detailed written audit report ("audit report") analyzing whether Defendants are in compliance with the Act, its implementing regulations, and this Decree, and identifying in detail any deviations therefrom ("audit report observations"). As a part of every audit report, except the first audit report, the auditor shall assess the adequacy of corrective actions taken by Defendants to correct all previous audit report observations. The audit reports shall be delivered contemporaneously to Defendants and FDA by courier service or overnight delivery service, no later than fifteen (15) calendar days after the date the audit inspection(s) is completed. If audit reports identify deviations from the Act, its implementing regulations, and/or this Decree, FDA may, in its discretion, require that the five (5) year auditing cycle be extended or begin anew. In addition, Defendants shall maintain the audit reports in separate files at their facility and shall promptly make the audit reports available to FDA upon request.

B. If an audit report contains any adverse observations, Defendants shall, within thirty (30) calendar days of receipt of the audit report, correct those observations, unless FDA notifies Defendants that a shorter time period is necessary. If, after receiving the audit report, Defendants believe that correction of the audit report observations will take longer than thirty (30) calendar days, Defendants shall, within ten (10) business days of receipt of the audit report, submit to FDA in writing a proposed schedule for completing corrections ("correction schedule") and provide justification describing why the additional time is necessary. The correction schedule must be reviewed and approved by FDA in writing prior to implementation by Defendants. In no circumstance will FDA's silence be construed as a substitute for written approval.

Defendants shall complete all corrections according to the approved correction

schedule. Within thirty (30) calendar days of Defendants' receipt of an audit report, unless FDA notifies Defendants that a shorter time period is necessary, or within the time period provided in a correction schedule approved by FDA, the auditor shall review the actions taken by Defendants to correct the audit report observations. Within five (5) business days of beginning that review, the auditor shall report in writing to FDA whether each of the audit report observations has been corrected and, if not, which audit report observations remain uncorrected.

NEW DRUG/MONOGRAPH

I. Before Defendants may commence manufacturing or distributing any new drug product or continue the manufacture or distribution of any previously distributed drug that is a new drug within the meaning of 21 U.S.C. § 321(p), Defendants shall first notify FDA in writing of their intention to do so, and shall also do the following:

A. For any drug that is an OTC drug and is not manufactured and labeled in strict conformance with an applicable OTC monograph under the terms of subparagraph_____, Defendants shall demonstrate to FDA that the drug is the subject of either (1) an approved application filed under 21 U.S.C. § 355(a) or § 355(j), or (2) an effective investigational new drug application filed under 21 U.S.C. § 355(i). In no event may Defendants distribute a drug product that is not the subject of an approved application under 21 U.S.C. §§ 355(a) or (j), or the subject of an effective investigational new drug application under 21 U.S.C. § 355(i), which must explicitly authorize manufacture of the drug at Defendants' facility;

B. If the product purports to be an OTC monograph drug as described in paragraph _____, Defendants may not distribute such drug unless and until:

1. Defendants retain, at Defendants' expense, an independent person or persons (the "drug monograph expert"), who is without any personal or financial ties (other than the agreement) to Defendants and their families, and who, by reason of background, training, education, or experience, is qualified to review the labeling of Defendants' OTC drug(s) to determine whether such product complies with the applicable OTC drug monograph and other labeling requirements of the Act and FDA regulations. Defendants shall notify FDA in writing of the identity and qualifications of the drug monograph expert as soon as they obtain such expert;

2. The drug monograph expert performs a comprehensive review of the OTC drug and the drug's proposed labeling to determine whether the product strictly conforms to an applicable FDA OTC monograph and all labeling requirements, including 21 C.F.R. Part 201, and that the OTC drug is not otherwise misbranded;

3. The drug monograph expert certifies in writing to FDA that: (a) he or she has reviewed the OTC drug and its labeling; (b) the OTC drug and its labeling conform to the requirements of an OTC drug monograph and all applicable labeling requirements, including 21 C.F.R. Part 201; and (c) the OTC drug is not otherwise adulterated or misbranded. As part of this certification, the drug monograph expert shall attach the labeling he or she has received to a full and complete detailed report of the results of his or her review, including, but not limited to, identifying the labeling he or she reviewed and references to the OTC monograph and labeling regulations addressed in the process of conducting the labeling review;

4. Defendants have provided to FDA any additional information requested by FDA after FDA's review of the drug monograph expert's certification pursuant to subparagraph _____; and

5. FDA notifies Defendants in writing that Defendants appear to be in compliance with the requirements set forth in subparagraphs _____, the Act, and the applicable regulations related to OTC drug products. In no circumstance may FDA's silence be construed as a substitute for written notification. If FDA finds, after issuance of this notification, that Defendants are not in compliance with subparagraphs _____, the Act, or applicable regulations related to OTC drug products, Defendants, upon notification from FDA, shall immediately take whatever action that FDA specifies.

II. If, at any time after this Decree has been entered, FDA determines, based on the results of an inspection, the analyses of samples, a report or data prepared or submitted by defendants, the expert, the auditor, or any other information, that defendants have failed to comply with any provision of this Decree, or have violated the Act, its implementing regulations, or that additional corrective actions are necessary to achieve compliance with this Decree or the Act, FDA may, as and when it deems necessary, order defendants in writing to take appropriate action, including, but not limited to, one or more of the following actions:

A. Cease manufacturing, processing, packing, labeling, holding, and distributing any or all drug(s);

B. Revise, modify, or expand any report(s) or plan(s) prepared pursuant to this Decree;

C. Submit additional reports or information to FDA;

D. Recall specified drug products released or distributed by defendants or that are under the custody and control of defendants' agents, distributors, customers, or consumers. Defendants shall bear the costs of such recall(s); and/or

E. Take any other corrective action(s) as FDA, in its discretion, deems necessary to protect the public health or bring defendants into compliance with the Act, its implementing regulations or this Decree.

DEVICE APPROVAL/CLASSIFICATION/CGMP

I. Upon entry of this Decree, Defendants, and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, and assigns, and any and all persons in active concert or participation with any of them (including franchisees, affiliates, and "doing business as" entities), who have received actual notice of the contents of this Decree by personal service or otherwise, are permanently restrained and enjoined, pursuant to 21 U.S.C. § 332(a), from directly or indirectly designing, manufacturing, processing, packing, repacking, labeling, holding, distributing, importing into or exporting from the United States of America, any device, unless and until:

A. Defendants' methods, facilities, and controls used to manufacture, process, pack, label, hold, and distribute devices are established, operated, and administered in compliance with 21 U.S.C. § 360j(f)(1) and the Quality System regulation prescribed in 21 C.F.R. Part 820.

B. Defendants select and retain at their expense an independent person or persons (the "Expert"), to conduct inspections of Defendants' operations and to review Defendants' procedures and methods for designing, manufacturing, processing, packing, repacking, labeling, holding, and distributing devices, to determine whether their methods, facilities, and controls are operated and administered in conformity with the Act, its implementing regulations, and this Decree. The Expert shall be qualified by education, training, and experience to conduct such inspections, and shall be without personal or financial ties (other than a consulting agreement between the parties) to Defendants' officers or employees or their immediate families. Defendants shall notify FDA in writing of the identity of the Expert within ten (10) calendar days of retaining such Expert.

C. The Expert shall perform a comprehensive inspection of Defendants' operations and certify in writing to FDA: (1) that he or she has inspected Defendants' facilities, processes, and controls; (2) whether Defendants have corrected all violations set forth in FDA's Inspectional Observations (Forms FDA 483) from all prior FDA inspections since _____; and (3) based upon this comprehensive inspection, whether Defendants' operations are operated in conformity with the Act, its implementing regulations, and this Decree. The Expert's certification report shall encompass, but not be limited to, an evaluation of the following:

1. Defendants' compliance with 21 U.S.C. §§ 351(h), 360j(f)(1), 352(t)(2), and 352(o), and 21 C.F.R. Parts 803 and 820;

2. Defendants' procedures for its Corrective and Preventive Action ("CAPA") system including, but not limited to: analyzing quality data to identify existing and potential causes of nonconforming product and other quality problems; investigating the causes of nonconformities relating to product, processes, and the quality system; identifying the action(s) needed to correct and prevent recurrence of nonconforming product and other quality problems; verifying or validating corrective and preventative actions to ensure such actions are effective and do not adversely affect the finished device; implementing and recording changes in methods and procedures as needed to correct and prevent quality problems; conducting and documenting adequate failure investigations; and implementing an effective complaint handling system;

3. Defendants' design control system, including the design change control process; and

4. Defendants procedures to adequately control received or purchased products to verify conformance to product specifications.

D. Defendants report to FDA in writing the actions that they have taken to: (1) correct all violations brought to Defendants' attention by the Expert and/or set forth in FDA's Inspectional Observations from all prior FDA inspections since _____; and (2) ensure that the methods used in, and the facilities and controls used for designing, manufacturing, processing, packing, repacking, labeling, holding, and distributing devices are operated and administered and will be continuously operated and administered in conformity with the Act, its implementing regulations, and this Decree.

E. FDA representatives inspect Defendants' operations to determine whether the requirements of this Decree have been met, and whether Defendants' operations are otherwise operated in conformity with current good manufacturing practice, the Act, and its implementing regulations.

F. FDA notifies Defendants in writing that Defendants appear to be in compliance with the requirements set forth in paragraphs _____ of this Decree.

II. Before Defendants may commence designing, manufacturing, or distributing any device, they shall first notify FDA in writing of their intent to do so, and shall demonstrate to FDA that the device is either (a) the subject an approved application for premarket approval pursuant to 21 U.S.C. § 360e(a); (b) the subject of a cleared premarket notification pursuant to 21 U.S.C. § 360(k); or (c) is exempt from the premarket approval/clearance requirements. Defendants shall not commence distributing any device prior to receiving written notification from FDA that the device appears to be in compliance with this paragraph. In no circumstances may FDA's silence be construed as a substitute for written notification.

III. After Defendants have complied with paragraphs _____ and FDA has notified Defendants in writing pursuant to paragraph _____, Defendants shall retain an independent person or persons (the "Auditor") at Defendants' expense to conduct audit inspections of Defendants' operations not less than once every six (6) months for a period of one (1) year and not less than once every twelve (12) months for a period of four (4) years thereafter, for a total of five (5) years. The Auditor shall be qualified by education, training, and experience to conduct such inspections, and shall be without personal or financial ties (other than a consulting agreement entered into by the parties) to Defendants' officers or employees or their immediate families. The Auditor may be the same person or persons described as the Expert in paragraph _____.

A. At the conclusion of each audit inspection, the Auditor shall prepare a written audit report (the "Audit Report") analyzing whether Defendants' operations are conducted and administered in compliance with the Act, its implementing regulations, and this Decree, and identifying in detail any deviations from the foregoing ("Audit Report Observations"). As part of every Audit Report, except the first, the Auditor shall assess the adequacy of corrective actions taken by Defendants to correct all previous Audit Report Observations. The Audit Reports shall be delivered contemporaneously to Defendants and FDA by courier service or overnight delivery service, no later than twenty (20) calendar days after the date the audit inspections are completed. If any Audit Reports identify any deviations from the Act, its implementing regulations, and/or this Decree, FDA may, in its discretion, require that the five (5) year auditing cycle be extended or begin anew. In addition, Defendants shall maintain complete Audit Reports and all of their underlying data in separate files at their facilities and shall promptly make the Audit Reports and underlying data available to FDA upon request.

B. If an Audit Report contains any adverse Audit Report Observations, Defendants shall, within thirty (30) calendar days of receipt of the Audit Report, correct those observations, unless FDA notifies Defendants that a shorter time period is necessary. If, after receiving the Audit Report, Defendants believe that correction of any adverse Audit Report Observation will take longer than thirty (30) calendar days, Defendants shall, within ten (10) calendar days of receipt of the Audit Report, propose a schedule for completing corrections ("Correction Schedule") and provide justification for the additional time. That Correction Schedule must be reviewed and approved by FDA in writing prior to implementation. Defendants shall complete all corrections according to the approved Correction Schedule. Within thirty (30) calendar days of Defendants' receipt of an Audit Report, or within the time period provided in a Correction Schedule approved by FDA, the Auditor shall review the actions taken by Defendants to correct the adverse Audit Report Observation(s). Within five (5) calendar days of the beginning of that review, the Auditor shall report in writing to FDA whether each of the adverse Audit Report Observations has been corrected and, if not, which adverse Audit Report Observations remain uncorrected.

IV. If, at any time after this Decree has been entered, FDA determines, based on the results of an inspection, the analysis of samples, a report or data prepared or submitted by Defendants, the Expert, or the Auditor pursuant to this Decree, or any other information, that Defendants have failed to comply with any provision of this Decree, or have violated the Act or its implementing regulations, or that additional corrective actions are necessary to achieve compliance with this Decree, the Act, or its implementing regulations, FDA may, as and when it deems necessary, order Defendants in writing to take appropriate actions. Such actions may include, but are not limited to, the following:

- A. Cease designing, manufacturing, processing, packing, repacking, labeling, holding, storing, distributing, installing, servicing, importing, and/or exporting devices;
- B. Revise, modify, or expand any report(s) prepared pursuant to the Decree;
- C. Submit additional notifications, reports, or any other materials or information to FDA;
- D. Recall, at Defendants' sole expense, adulterated or misbranded devices or components therein manufactured, distributed, and/or sold by Defendants or that are under the custody and control of Defendants' agents, distributors, customers, or consumers;
- E. Issue a safety alert, public health advisory and/or press release; and/or
- F. Take any other corrective action(s) as FDA, in its discretion, deems necessary to protect the public health or to bring Defendants into compliance with Act, its implementing regulations, and this Decree.

NO PMA/NO 510K

I. Defendants and each of their directors, officers, agents, representatives, employees, attorneys, successors, and assigns, and any and all persons in active concert or participation with any of them who have received actual notice of this Decree by personal service or otherwise, are enjoined under 21 U.S.C. § 332(a) from directly or indirectly manufacturing, processing, packing, labeling, holding, introducing or delivering for introduction into interstate commerce (including foreign commerce) the ____ or any other device that is adulterated within the meaning of 21 U.S.C. § 351(f)(1)(B), unless and until:

- A. An approved investigational device exemption ("IDE") by FDA, filed under 21 U.S.C. § 360j(g) and 21 C.F.R. § 812, for such device is in effect, and the use and distribution of the device conforms strictly to those requirements; or

B. There is an FDA approved application for premarket approval (PMA) filed under 21 U.S.C. § 360e; or

C. FDA has received a premarket notification as required by 21 U.S.C. § 360(k) (also referred to as 510(k) submission) for the device and has advised Defendants in writing pursuant to 21 U.S.C. § 360c(i)(1)(A) that the device is substantially equivalent to a predicate device.

II. If, at any time after entry of this Decree, FDA determines, based on the results of an inspection, the analysis of a sample, a report or data prepared or submitted by Defendants, or any other information, that Defendants have failed to comply with any provision of this Decree, have violated the Act or its implementing regulations, or that additional corrective actions are necessary to achieve compliance with this Decree, the Act, or its implementing regulations, FDA may, as and when it deems necessary, order Defendants in writing to take appropriate corrective actions, including, but not limited to, the following:

A. Cease all manufacturing, processing, packing, repacking, labeling, holding, and/or distributing any or all device(s);

B. Recall, at Defendant's expense, any device that is adulterated, misbranded, or otherwise in violation of this Decree, the Act, or its implementing regulations;

C. Revise, modify, or expand any report(s) or plan(s) prepared pursuant to this Decree;

D. Submit additional reports or information to FDA;

E. Submit any application or any supplement to an existing device application to FDA;

F. Issue a safety alert; and/or

G. Take any other corrective actions as FDA, in its discretion, deems necessary to bring Defendants into compliance with this Decree, the Act, or its implementing regulations.

DEVICE CGMP

I. Upon entry of this Decree, Defendants and each of their officers, directors, agents, employees, representatives, attorneys, successors, and assigns, and any and all persons in active concert or participation with any of them who have received actual notice of this Decree by personal service or otherwise, are enjoined from manufacturing, processing, packing, labeling, and distributing any device (including components) unless and until Defendants:

A. Defendants' methods, facilities, and controls used to manufacture, process, pack, label, and distribute devices are established, operated, and administered in

compliance with the requirements of CGMP and the QS regulation, 21 C.F.R. Part 820, including but not limited to the following:

- 1) Establishing and implementing adequate written procedures for finished device acceptance to ensure that each production run, lot, or batch of finished devices meets acceptance criteria;
- 2) Establishing and implementing adequate written procedures to control product that does not conform to specified requirements;
- 3) Establishing and implementing adequate quality requirements that must be met by suppliers, contractors, and suppliers, and adequate written procedures to ensure that all purchased or otherwise received products and services conform to specified requirements;
- 4) Developing, conducting, controlling, and monitoring production processes to ensure that device conform to their specifications;
- 5) Adequately validating processes whose results cannot be fully verified by subsequent inspection and testing, and establishing and implementing adequate written procedures for monitoring and controlling process parameters for validated processes to ensure that specified requirements continue to be met;
- 6) Establishing and implementing adequate written procedures to prevent contamination of equipment or product by substances that could reasonably be expected to have an adverse effect on product quality;
- 7) Establishing and implementing adequate written procedures to control environmental conditions that could reasonably be expected to have an adverse effect on product quality;
- 8) Establishing and implementing adequate requirements for the health, cleanliness, personal practices, and clothing of personnel;
- 9) Establishing and implementing adequate written procedures for identifying, documenting, validating or verifying, reviewing, and approving design changes prior to their implementation;
- 10) Establishing and implementing adequate design validation requirements to ensure that devices conform to defined user needs and intended uses; and
- 11) Establishing and implementing adequate written procedures for identifying employee training needs and for ensuring that all personnel are trained to adequately perform their assigned responsibilities.

B. Defendants develop and implement adequate written Medical Device Reporting (MDR) procedures in compliance with 21 C.F.R. Part 803.

C. Defendants recall at their own expense _____ [which devices from which time frame?]

D. Defendants select and retain, at Defendants' expense, an independent person or persons (the "expert(s)"), who is qualified by education, training, and experience to evaluate whether Defendants are in compliance with CGMP/QS regulation requirements as set forth at 21 C.F.R. Part 820 and the MDR reporting requirements set forth at 21 C.F.R. Part 803. The expert(s) shall be without personal or financial ties (other than the consulting agreement between the parties) to any officer or employee of Defendants or their immediate families. Defendants shall notify FDA in writing of the identity of the expert(s) as soon as they retain such expert(s), and the expert(s) shall:

1) Determine whether Defendants are in compliance with the CGMP/QS regulation requirements as set forth at 21 C.F.R. Part 820 and the MDR requirements set forth at 21 C.F.R. Part 803; and

2) Provide FDA with a complete and adequate written evaluation of Defendants' compliance with CGMP and 21 C.F.R. Parts 820 and 803.

E. Defendants submit an adequate written report of all corrections Defendants have made to come in to compliance with the requirements of the Act and 21 C.F.R. Parts 820 and 803.

F. Defendants submit a written report to FDA documenting what steps have been taken to ensure that Defendants' employees and managers are adequately trained in the CGMP/QS regulation and MDR requirements applicable to their assigned responsibilities and positions.

G. The expert(s) has certified to FDA in writing that Defendants are in compliance with the Act, CGMP, and 21 C.F.R. Parts 820 and 803.

H. Duly authorized FDA representatives have made inspections, as and when FDA deems necessary and without prior notice, of Defendants' facilities, including buildings, equipment, personnel, finished and unfinished materials, containers and labeling, and all records relating to the manufacturing, packing, labeling and distributing of devices to determine whether the requirements of paragraph _____ of this Decree have been met. Such inspection shall commence no later than _____ days after receipt of the reports and certifications pursuant to paragraph _____ above; and

I. FDA notifies Defendants in writing that they may commence manufacturing, packing, labeling, and distributing medical devices.

DRUG (OR DEVICE) CGMP

I. Upon entry of this Decree, Defendants and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, and assigns, and any and all persons in active concert or participation with any of them who receive actual notice of this Decree by personal service or otherwise, are permanently restrained and enjoined under 21 U.S.C. § 332(a) from directly or indirectly manufacturing, processing, packing, labeling, holding, or distributing any articles of drug unless and until:

A. Defendants' methods, facilities, and controls used to manufacture, process, pack, label, hold, and distribute drugs are established, operated, and administered in compliance with CGMP. 21 U.S.C. § 351(a)(2)(B) and 21 C.F.R. Parts 210 and 211;

B. Defendants retain, at Defendants' expense, an independent person or persons (the "CGMP expert"), who is without any personal or financial ties (other than the retention agreement) to Defendants and their families, and who, by reason of background, training, education, or experience, is qualified to inspect Defendants' drug manufacturing facilities to determine whether the methods, facilities, and controls are operated and administered in conformity with CGMP. Defendants shall notify the United States Food and Drug Administration ("FDA") in writing of the identity and qualifications of the CGMP expert as soon as they retain such expert;

C. The CGMP expert performs a comprehensive inspection of Defendants' facilities and the methods and controls used to manufacture, process, pack, label, hold, and distribute drugs to determine whether they are in compliance with CGMP. This inspection shall include, at a minimum, the following:

(1) An evaluation as to whether the Defendants have established a comprehensive written quality assurance (QA) and quality control (QC) program (QA/QC program) that is adequate to ensure continuous compliance with applicable laws and regulations.

(2) The CGMP expert shall determine whether the QA/QC program, at a minimum:

a. Addresses all facets of compliance monitoring and trend analyses, and internal audit procedures, and confirms that Defendants' Quality Unit is adequately trained and staffed to evaluate CGMP compliance and prevent and correct future deviations from CGMP;

b. Includes procedures to ensure that the Defendants, in a timely manner, thoroughly investigate any unexplained discrepancy or the failure of a batch of drug or its components to meet any of the product's or component's specifications, including the extension of such investigation to other batches of the same drug product and other drug

products that may have been associated with the specific failure or discrepancy, and to take required and timely corrective actions for all products that fail to meet their specifications;

c. Establishes mechanisms to ensure that written standard operating procedures (SOPs) specifying the responsibilities and procedures applicable to QA or QC personnel are updated, followed, and periodically reviewed by the Quality Unit to ensure that they reflect current and CGMP compliant-practices;

d. Includes written SOPs necessary to ensure that all facets of compliance monitoring are reviewed and controlled by QA personnel; and

e. Includes written SOPs to ensure that the Defendants' QA personnel participate in or monitor the implementation and verification of corrective actions to prevent future occurrences of such deviations and/or problems and there are systems to ensure that such written SOPs are continuously followed;

D. The CGMP expert certifies in writing to FDA that:

(1) He or she has inspected Defendants' facilities, methods, processes, and controls;

(2) All CGMP deviations brought to Defendants' attention since _____ by FDA, the CGMP expert, or any other source, including but not limited to any experts hired prior to the entry of this Decree, have been corrected; and

(3) Such facilities, methods, processes, and controls are in compliance with the requirements of CGMP. As part of this certification, the CGMP expert shall include a full and complete detailed report of the results of his or her inspection;

E. Defendants report to FDA in writing the actions they have taken to:

(1) Correct the CGMP deviations brought to Defendants' attention by FDA, the CGMP expert, and any other source, including but not limited to any experts hired prior to the entry of this Decree; and

(2) Ensure that the methods used in, and the facilities and controls used for, manufacturing, processing, packing, labeling, holding, and distributing drugs are operated and will be continuously administered in conformity with CGMP.

F. Defendants recall and destroy in accordance with the procedures provided in paragraph ____ all drugs that they manufactured, processed, packed, labeled, held, or distributed prior to _____;

G. FDA representatives inspect Defendants' facilities to determine whether the requirements of this Decree have been met, and whether Defendants' facilities are operating in conformity with CGMP, the Act, and its implementing regulations; and

H. FDA notifies Defendants in writing that Defendants appear to be in compliance with the requirements set forth in subparagraphs _____. In no circumstance will FDA's silence be construed as a substitute for written notification.

II. Within fifteen (15) calendar days of entry of this Decree, Defendants shall, under FDA supervision, destroy all drugs in Defendants' possession, custody, and/or control that are adulterated because they were not manufactured, processed, packed, labeled, held, and/or distributed in accordance with CGMP. Defendants shall reimburse FDA for the supervision of the destruction, including Defendants' destruction of products since _____, and prior to entry of this Decree, at the rates set forth in paragraph ____ of this Decree. Defendants shall not dispose of any drugs in a manner contrary to any federal, state, or local laws, including but not limited to, the National Environmental Policy Act of 1969.

III. After Defendants have complied with paragraphs _____ and FDA has notified them pursuant to paragraph _____, Defendants shall retain an independent person or persons who shall meet the criteria described in paragraph _____ to conduct audit inspections of their drug manufacturing operations no less frequently than once every six (6) months for a period of no less than five (5) years (hereinafter, "auditor"). If Defendants choose, the auditor may be the same person or persons retained as the CGMP expert in paragraph _____.

A. At the conclusion of each audit inspection, the auditor shall prepare a detailed written audit report ("audit report") analyzing whether Defendants are in compliance with CGMP and identifying any deviations from CGMP ("audit report observations"). As a part of every audit report, except the first audit report, the auditor shall assess the adequacy of corrective actions taken by Defendants to correct all previous audit report observations. The audit reports shall be delivered contemporaneously to Defendants and FDA by courier service or overnight delivery service, no later than fifteen (15) business days after the date the audit inspection(s) is completed. In addition, Defendants shall maintain the audit reports in separate files at their facility and shall promptly make the audit reports available to FDA upon request.

B. If an audit report contains any observations indicating that Defendants are not in compliance with CGMP, Defendants shall, within thirty (30) calendar days of receipt of the audit report, correct those observations, unless FDA notifies Defendants that a shorter time period is necessary. If, after receiving the audit report, Defendants believe that correction of the deviations will take longer than thirty

(30) calendar days, Defendants shall, within ten (10) calendar days of receipt of the audit report, submit to FDA in writing a proposed schedule for completing corrections ("correction schedule"). The correction schedule must be reviewed and approved by FDA in writing prior to implementation by Defendants. In no circumstance will FDA's silence be construed as a substitute for written approval. Defendants shall complete all corrections according to the approved correction schedule. Within thirty (30) calendar days of Defendants' receipt of an audit report, unless FDA notifies Defendants that a shorter time period is necessary, or within the time period provided in a correction schedule approved by FDA, the auditor shall review the actions taken by Defendants to correct the audit report observations. Within five (5) business days of beginning that review, the auditor shall report in writing to FDA whether each of the audit report observations has been corrected and, if not, which audit report observations remain uncorrected.

IV. If, at any time after entry of this Decree, FDA determines, based on the results of an inspection, the analysis of a sample, a report or data prepared or submitted by Defendants, the CGMP expert, the auditor, or any other information, that Defendants have failed to comply with any provision of this Decree, have violated CGMP, the Act, or its implementing regulations, or that additional corrective actions are necessary to achieve compliance with this Decree, CGMP, the Act, or its implementing regulations, FDA may, as and when it deems necessary, notify Defendants in writing of the noncompliance and order Defendants to take appropriate corrective action, including, but not limited to, ordering Defendants to immediately take one or more of the following actions:

- A. Cease all manufacturing, processing, packing, labeling, holding, and/or distributing any or all drug(s);
- B. Recall, at Defendants' own expense, any drug that is adulterated or otherwise in violation of this Decree, CGMP, the Act, or its implementing regulations;
- C. Revise, modify, or expand any report(s) or plan(s) prepared pursuant to this Decree;
- D. Submit additional reports or information to FDA;
- E. Issue a safety alert; and/or
- F. Take any other corrective actions as FDA, in its discretion, deems necessary to protect the public health or to bring Defendants into compliance with this Decree, CGMP, the Act, or its implementing regulations.

TISSUE RESIDUE

I. Defendants and each and all of their officers, agents, representatives, employees, attorneys, successors, assigns, and any and all persons in active concert or participation with any of them who have received notice of this Decree, are hereby permanently restrained and

enjoined under the provisions of 21 U.S.C. § 332(a) from directly or indirectly: introducing and causing to be introduced into interstate commerce, and delivering and causing to be delivered for introduction into interstate commerce, any article of food, within the meaning of 21 U.S.C. § 321(f), consisting of animals and their edible tissues; and, subject to paragraph____, administering any new animal drug, within the meaning of 21 U.S.C. § 321(v), to any animal while such drug is held for sale after shipment in interstate commerce, unless and until the following occur:

A. Defendants have established and implemented a system that ensures that each of the animals that they acquire, purchase, hold, transport, sell, consign, or distribute is individually and permanently identified by tag number;

B. Defendants have established and implemented a written record-keeping system that prevents them from selling, consigning, or distributing animals whose edible tissue contains new animal drugs in amounts above the levels permitted by law. This system shall include, but not be limited to, keeping written records on every animal to which Defendants administer drugs. These records shall include, at a minimum: (1) the identity of each animal that Defendants medicate; (2) the date of each administration of each drug to each animal; (3) the name of each drug administered; (4) the dosage of each drug administered; (5) the route of administration of each drug; (6) the written order of a licensed veterinarian for each drug used, if applicable; (7) the name of the person administering each drug; (8) the established withdrawal period for each drug administered; (9) the date the withdrawal period will terminate for each drug; (10) the date each medicated animal is shipped for slaughter or leaves Defendants' control; and (11) the name and address of the purchaser, consignee, or recipient of each medicated animal that is shipped for slaughter or leaves Defendants' control;

C. Defendants have established and implemented a system that ensures that their use of new animal drugs conforms to the uses approved by the United States Food and Drug Administration ("FDA") as set forth in the drugs' approved labeling or, for new animal drugs used in an extra-label manner, to the lawful written orders of a licensed veterinarian and in compliance with 21 U.S.C. § 360b(a)(4)(A) and 21 C.F.R. Part 530. This system shall include, at a minimum, measures to prevent: (1) the use of drugs in Defendants' animals that are not approved for use in that species or not approved for the disease or other condition for which the animal is being medicated, unless such use is in accordance with the lawful written order of a licensed veterinarian within the context of a valid veterinarian-client-patient relationship and is in compliance with 21 C.F.R. Part 530; (2) the administration of drugs in excess of the approved dosage, unless such administration is in accordance with the lawful written order of a licensed veterinarian within the context of a valid veterinarian-client-patient relationship and is in compliance with 21 C.F.R. Part 530; (3) the administration of drugs by a non-approved route unless such administration is in accordance with the lawful written order of a licensed veterinarian within the context of a valid veterinarian-client-patient relationship and is in compliance with 21 C.F.R. Part 530; and (4) the sale and delivery for slaughter

of medicated animals before the expiration of the withdrawal period, as specified in the approved labeling or, for new animal drugs used in an extra-label manner, in the lawful written order of a licensed veterinarian within the context of a valid veterinarian-client-patient relationship and in compliance with 21 C.F.R. Part 530);

D. Defendants have established and implemented a drug inventory and accountability system that prevents them from selling, consigning, or distributing animals with illegal new animal drug residues. This system shall include a written record for each drug that Defendants purchase or receive for medicating their animals, which record shall include, at a minimum: (1) the name of the drug; (2) the date of purchase or receipt of the drug; (3) the quantity, strength, and form of the drug; (4) the expiration date of the drug; (5) the name and address of the seller or supplier of the drug; (6) the date each drug is administered; and (7) the amount and method of each administration of each drug. In addition, the inventory and accountability system shall include periodic checks of inventory and records, no less frequently than once every fourteen (14) calendar days, to ensure that records accurately document the drugs currently on hand and the disposition of all drugs purchased or received;

E. Defendants have established and implemented a quarantine or segregation system that ensures ready distinction between medicated and unmedicated animals and that prevents Defendants from selling, consigning, or delivering for slaughter for use as food any animal with illegal new animal drug residues;

F. Defendants have established and implemented a system that ensures that each animal that has been medicated is not directly or indirectly sold, consigned, or delivered for immediate or ultimate slaughter before expiration of the withdrawal period (specified in the approved labeling or, for new animal drugs used in an extra-label manner, in the lawful written order of a licensed veterinarian and in compliance with 21 U.S.C. § 360b(a)(4)(A) and 21 C.F.R. Part 530). This system shall also ensure that each purchaser, consignee, or recipient receives, prior to accepting any animal, a written statement from Defendants certifying either that any animal that has been medicated has also been withdrawn for the appropriate time period or that the animal has not been medicated. This written statement shall also include the date(s) on which the animal was medicated, each drug with which the animal was medicated, the required withdrawal period for each drug, and the date(s) on which the withdrawal period(s) expired. Defendants shall, prior to selling any animal, obtain the signature of the purchaser, consignee, or recipient documenting date of receipt of the statement from Defendants. Defendants shall keep, as part of their records, a copy of the signed written statement described in this paragraph;

G. Defendants have established and implemented a system to identify the source of each animal that they purchase or transport and to document whether the animal has been medicated, the date of medication, the drug used, and the withdrawal period for the drug;

H. Defendants have reported to FDA in writing the steps they have taken to comply with paragraphs _____;

I. FDA has inspected Defendants' operations, including all records relating to the medication, purchase, sale, consignment, and distribution of food-producing animals;

J. Defendants have paid for the costs of the inspections, as described in paragraph _____; and

K. FDA has notified Defendants in writing that they appear to be in compliance with the requirements of paragraphs _____ of this Decree

II. Prior to obtaining written notification from FDA as specified in paragraph _____, Defendants may administer drugs to an ill food-producing animal that they own, but only after the animal has been examined by a licensed veterinarian and the veterinarian has diagnosed the animal and prescribed that drug for that animal. Within ten (10) calendar days after the drug is administered to Defendants' animals pursuant to this paragraph, Defendants shall provide FDA with copies of the veterinarian's diagnosis, prescription, and receipts for treatment (or the equivalent)

III. Defendants shall maintain all records described in paragraph _____ for each animal for a period of at least two (2) years after the date that the animal is sold, consigned, or delivered for slaughter. These records shall be made available immediately to FDA upon request for purposes of inspection and copying.

IV. After Defendants receive written notification from FDA as specified in paragraph _____, Defendants and each and all of their officers, agents, representatives, employees, attorneys, successors, assigns, and any and all persons in active concert or participation with any of them, are permanently restrained and enjoined from directly or indirectly doing and causing to be done any of the following acts:

A. Introducing and delivering for introduction into interstate commerce any article of food, within the meaning of 21 U.S.C. § 321(f), that is adulterated within the meaning of 21 U.S.C. §§ 342(a)(2)(C)(ii) or 342(a)(4);

B. Administering any article of drug, within the meaning of 21 U.S.C. 321(g), to any food-producing animal unless the administration conforms to the drug's labeled conditions for use or to the lawful written order of a licensed veterinarian within the context of a valid veterinarian-client-patient relationship and in compliance with 21 C.F.R. Part 530;

C. Doing any act with respect to any article of drug, within the meaning of 21 U.S.C. § 321(g), if the act is done while such drug is held for sale after shipment in interstate commerce and results in the drug being adulterated within the meaning of 21 U.S.C. § 351(a)(5); and

D. Failing to implement and continuously maintain the requirements of this Decree.

V. Upon request, Defendants shall promptly provide any information and records to FDA regarding the sale, consignment, distribution, or medication of any animal.

VI. If, based on the results of any inspection or analysis conducted after the inspection described in paragraph _____ or any other information, FDA finds that any Defendant is not in compliance with the requirements of this Decree, the Act, and FDA regulations, FDA may, as and when it deems necessary, notify Defendants in writing of the non-compliance and may require that Defendants immediately take one or more of the following actions:

A. Cease selling and delivering, and causing to be sold and delivered, any article of food within the meaning of 21 U.S.C. § 321(f);

B. Cease administering to animals any new animal drug, within the meaning of 21 U.S.C. § 321(v), except under the terms specified in paragraph ____; and

C. Take any other corrective actions as FDA deems necessary to bring Defendants into compliance with this Decree, the Act, and FDA regulations, including, but not limited to, requiring that Defendants re-institute or re-implement any of the requirements in paragraph ____ of this Decree.

Upon receipt of such notification, Defendants shall immediately and fully comply with the terms of the notice. Any cessation of operations or other action ordered by FDA as described above shall continue until Defendants receive written notification from FDA that Defendants appear to be in compliance with the terms of this Decree and that they may resume operations.

Animal Drug CGMP

I. Upon entry of this Decree, the defendants and each and all of their officers, agents, employees, successors, assigns, and attorneys, and all persons in active concert or participation with any of them who receive notice of this Decree, are permanently restrained and enjoined under the provisions of 21 U.S.C. § 332(a) from directly and indirectly manufacturing, processing, packing, labeling, holding, and distributing any animal drug at their facilities located at _____ (and any other location or any new location at which the defendants manufacture, process, pack, label, hold, or distribute animal drugs), unless and until all the following occur:

A. The defendants' methods, facilities, and controls used to manufacture, process, pack, label, hold, and distribute animal drugs are established, operated, and administered in compliance with CGMP requirements within the meaning of 21 U.S.C. § 351(a)(2)(B) and 21 C.F.R. Parts 210 and 211;

B. The defendants establish and implement a quality assurance and quality control program to ensure that the methods, facilities, and controls used to

manufacture, process, pack, label, hold, and distribute animal drugs are established, operated, and administered in continuous compliance with CGMP. The defendants shall assign responsibility and authority for monitoring quality assurance and quality control at the defendants' facilities on a continuous basis to an individual who is appropriately qualified;

C. The defendants retain, at their expense, an independent person or persons (the "expert"), to make inspections of their animal drug manufacturing operations to determine whether their methods, facilities, and controls are operated and administered in conformity with CGMP. The expert shall be qualified by education, training, and experience to conduct the inspections, and shall be without personal or financial ties (other than a consulting agreement) to the defendants or their immediate families. The defendants shall notify the United States Food and Drug Administration (FDA) in writing of the identity and qualifications of the expert as soon as the defendants retain the expert;

D. The expert performs a comprehensive inspection of the defendants' animal drug manufacturing operations. The expert shall determine whether the defendants' facilities and the methods and controls used to manufacture, process, pack, label, hold, and distribute animal drugs are in compliance with CGMP. The expert shall also evaluate whether the defendants have established and implemented adequate quality assurance and quality control measures to ensure continuous compliance with CGMP;

E. The expert certifies in writing to FDA that: (1) he or she has inspected the defendants' animal drug manufacturing operations; (2) all CGMP deviations brought to the defendants' attention by FDA since _____, or by the expert, or through any other source have been corrected; and (3) the defendants' facilities, methods, and controls are in compliance with CGMP. Among others, the CGMP deviations previously brought to the defendants' attention by FDA relate to the requirements in: 21 C.F.R. §§ 211.22, 211.25(a), 211.42(c)(10)(v), 211.67(a), 211.67(b), 211.100(a), 211.100(b), 211.110(a), 211.113(b), 211.160(b), 211.160(b)(4), 211.165(d), 211.165(e), 211.165(f), 211.166(a)(3), 211.170(b), and 211.192. As part of the expert's certification, the expert shall include a complete and detailed written report with the results of his or her inspection;

F. The defendants report to FDA in writing the actions they have taken to (1) correct the CGMP deviations brought to their attention by FDA, the expert, and any other source, and (2) ensure that the methods used in, and the facilities and controls used for, manufacturing, processing, packing, labeling, holding, and distributing animal drugs at their facilities will remain in continuous compliance with CGMP;

G. The defendants recall, as FDA deems necessary, all animal drugs that are within the possession, custody, or control of the defendants and their distributors;

H. The defendants destroy, under FDA supervision, such in-process materials and finished animal drug products as FDA shall designate that were manufactured, processed, packed, held, labeled, or distributed at the defendants' facilities, and are within the defendants' possession, custody, or control, including all animal drugs to be recalled pursuant to Paragraph _____. The defendants shall not dispose of animal drugs in a manner contrary to any federal, state, or local laws, including the National Environmental Protection Act of 1969;

I. FDA, in its discretion and without prior notice, inspects the defendants' facilities to determine whether the defendants are operating their facilities in conformity with the Act, CGMP, and this Decree;

J. The defendants pay the costs of any supervision, inspections, analyses, examinations, and reviews that FDA deems necessary to evaluate the defendants' compliance with the terms of Paragraph ____; and

K. FDA notifies the defendants in writing that they appear to be in compliance with the requirements set forth in Paragraphs _____ and that they are authorized to resume manufacturing, processing, packing, labeling, holding, and distributing animal drugs

II. Upon resuming operations after completing the requirements in Paragraph ____, the defendants shall meet the following requirements:

A. The defendants shall retain an independent person or persons (the "auditor") to conduct audit inspections of their animal drug manufacturing operations not less than once every six (6) months for a period of five (5) years. The auditor shall be qualified by education, training, and experience to conduct such inspections, and shall be without personal or financial ties (other than the consulting agreement) to the defendants or their immediate families. If the defendants choose, the auditor may be the same person or persons retained as the expert in Paragraph _____.

B. At the conclusion of each audit inspection, the auditor shall prepare a written audit report (the "audit report") analyzing whether the defendants are in compliance with the Act, CGMP, and this Decree, and identifying any deviations from CGMP ("audit report observations"). As a part of every audit report, except the first audit report, the auditor shall assess the adequacy of corrective actions taken by the defendants to correct all previous audit report observations. The audit reports shall be delivered contemporaneously to the defendants and FDA by courier service or overnight delivery service, no later than ten (10) business days after the date the audit inspections are completed. If any audit report identifies CGMP deviations, FDA may, in its discretion, require that the five (5)-year auditing cycle be extended or begin anew. In addition, the defendants shall maintain the audit reports in separate files at their facility and shall promptly make the audit reports available to FDA upon request.

C. If an audit report contains any audit report observations indicating that the defendants are not in compliance with the Act, CGMP, and this Decree, the defendants shall, within thirty (30) calendar days of receipt of the audit report, correct those observations, unless FDA notifies the defendants that a shorter time period is necessary. If, after receiving the audit report, the defendants believe that correction of the deviations will take longer than thirty (30) calendar days, the defendants shall, within five (5) business days of receipt of the audit report, submit to FDA in writing a proposed schedule for completing corrections ("correction schedule") and provide justification describing why the additional time is needed. The correction schedule must be reviewed and approved by FDA in writing prior to implementation by the defendants. The defendants shall complete all corrections according to the approved correction schedule. Within thirty (30) calendar days of the defendants' receipt of an audit report, unless FDA notifies the defendants that a shorter time period is necessary, or within the time period provided in a correction schedule approved by FDA, the auditor shall review the actions taken by the defendants to correct the audit report observations. Within ten (10) business days of beginning that review, the auditor shall report in writing to FDA whether each of the audit report observations has been corrected and, if not, which audit report observations remain uncorrected.

III. If, at any time after entry of this Decree, FDA determines, based on the results of an inspection, sample analysis, report, or other information, that the defendants have failed to comply with any provision of this Decree, have violated CGMP or the Act, or that additional corrective actions are necessary to achieve compliance with this Decree, CGMP, or the Act, FDA may, as and when it deems necessary, issue a directive notifying the defendants in writing of the noncompliance and ordering the defendants to take appropriate action, including but not limited to ordering the defendants immediately to take one or more of the following actions:

- A. Cease manufacturing, processing, packing, labeling, holding, and distributing animal drugs unless and until the defendants receive written notification from FDA that the defendants appear to be in compliance with the Decree, CGMP, and the Act, and that the defendants may resume operations;
- B. Recall any and all animal drugs;
- C. Submit additional reports or information to FDA; and
- D. Take any other corrective actions as FDA deems necessary to bring the defendants into compliance with this Decree, CGMP, and the Act, including but not limited to requiring that the defendants re-implement or re-institute any of the requirements of this Decree. The provisions of this paragraph shall be apart from, and in addition to, all other remedies available to FDA. The defendants shall pay all costs of recalls and other corrective actions, including the costs of FDA's supervision, inspections, investigations, analyses, examinations, and reviews to implement and

monitor recalls and other corrective actions, at the rates specified in Paragraph _____ of this Decree.

MEDICATED FEEDS

I. The defendants and each and all of their officers, agents, employees, successors, assigns, and attorneys, and any persons in active concert or participation with any of them (including individuals, directors, partnerships, corporations, subsidiaries, and affiliates) who receive actual notice of this Decree, are permanently restrained and enjoined under the provisions of 21 U.S.C. § 332(a) from directly or indirectly doing or causing the manufacture, processing, packing, labeling, holding, and distribution at their facilities located at _____ (and any new locations at which the defendants manufacture, process, pack, label, hold, or distribute medicated feeds), of any article of medicated feed unless and until:

A. The defendants establish, operate, and administer their feed manufacturing methods, facilities, and controls in conformity with the current good manufacturing practice ("CGMP") regulations for medicated feeds, 21 C.F.R. Part 225, and in a manner that ensures that all medicated feeds manufactured by the defendants are in accord with their label specifications and meet the assay limits set forth at 21 C.F.R. § 558.4(d);

B. The defendants retain a person ("qualified person") who is without any personal or financial ties other than the consulting agreement to the defendants and their families and who, by reason of background, training, and experience, is qualified to make inspections of medicated feed manufacturing mills to determine whether the established methods, facilities, and controls are operated and administered in conformity with CGMP requirements, as specified in 21 C.F.R. Part 225; the defendants notify the United States Food and Drug Administration ("FDA") in writing of the person's identity and qualifications as soon as they retain the person; the qualified person inspects _____ and the manner of operating _____, and any new locations at which the defendants manufacture medicated feeds; and the qualified person certifies in writing to FDA that the requirements set forth in paragraph ____ of this Decree have been met;

C. The defendants retain a laboratory other than one affiliated with _____ that, by reason of background, staff training, and experience, is qualified to analyze medicated feeds to determine whether the medicated feeds contain each drug that they purport or are represented to contain and said drug(s) meet(s) the assay limits set forth at 21 C.F.R. § 558.4(d); the defendants notify FDA in writing of the laboratory's identity as soon as they retain the laboratory; the defendants provide the laboratory with samples of each medicated feed, and the corresponding labels, manufactured at _____ that is still in the possession or under the custody or control of the defendants at the time this Decree is filed; and the laboratory analyzes all samples and simultaneously provides FDA and the defendants the results of all tests performed on

the samples, along with the labels, and certifies in writing whether the samples contain each drug that they purport or are represented to contain and whether such drug(s) meet(s) the assay limits set forth at 21 C.F.R. § 558.4(d);

D. The defendants, under the supervision of and in accordance with methods acceptable to FDA, recall, destroy, or otherwise bring into compliance with FDA regulations and the Act all adulterated lots of medicated feed identified by the laboratory analyses described in the preceding paragraph, including, when FDA deems necessary, medicated feed distributed to the defendants' agents, distributors, customers, or consumers;

E. The defendants report in writing to FDA all actions they have taken to ensure that the requirements in paragraph _____ of this Decree have been met;

F. FDA, as it deems necessary to evaluate the defendants' compliance with the terms of this Decree, conducts inspections of the defendants' facilities;

G. The defendants pay the costs of any supervision, inspection, analyses, examination, and review that FDA deems necessary to evaluate the defendants' compliance with the terms of this Decree; and

H. FDA notifies the defendants in writing that the defendants appear to be in compliance with the requirements in paragraphs_____, FDA regulations, and the Act.

II. Upon resuming operations after completing the requirements of paragraph_____, the defendants shall have the laboratory retained pursuant to paragraph _____ (or a similarly qualified laboratory) conduct the following analyses:

A. During the first six months of such operation, the defendants shall – for each drug and drug combination the defendants use to manufacture medicated feeds – collect and have tested at least three representative samples of medicated feed to determine whether the drug(s) meet(s) the assay limits set forth at 21 C.F.R. § 558.4(d). The sample collection and testing for each drug and drug combination the defendants use to manufacture medicated feeds shall be conducted under the following conditions:

1. The representative samples of medicated feed shall be collected and tested at periodic intervals throughout the six-month period;
2. One of the representative samples of medicated feed shall be collected from the batch that contains the first use of the drug or drug combination during the six-month period;

3. The defendants shall have the laboratory simultaneously provide FDA and the defendants all results of the analyses; and

4. The defendants shall investigate and take corrective action for all medicated feeds determined by laboratory analyses to be outside the assay limits set forth at 21 C.F.R. § 558.4(d). All investigation and corrective action regarding medicated feeds found to be outside the assay limits set forth at 21 C.F.R. § 558.4(d) shall be conducted pursuant to 21 C.F.R. § 225.58(d) and (e);

B. During the subsequent six-month period, the defendants shall repeat all of the requirements set forth at paragraph _____; and

C. After the first year, the defendants shall follow the medicated feed sampling and testing requirements set forth at 21 C.F.R. § 225.58

III. If, at any time after entry of this Decree, FDA determines, based on the results of an inspection, analysis of a sample or samples, or other information, that the defendants have failed to comply with any provision of this Decree, have violated FDA regulations or the Act, or that additional corrective actions are necessary to achieve compliance with this Decree, FDA regulations, or the Act, FDA may, as and when it deems necessary, notify the defendants in writing of the noncompliance and order the defendants to take appropriate action, including, but not limited to, ordering the defendants to immediately take one or more of the following actions:

A. Cease manufacturing, processing, packing, labeling, holding, or distributing any medicated feeds;

B. Recall all articles of medicated feed distributed at _____ (or any new location), including feed distributed to the defendants' agents, distributors, customers, or consumers; or

C. Take any other corrective actions as FDA deems necessary to bring the defendants into compliance with this Decree, FDA regulations, and the Act, including, but not limited to, requiring that the defendants re-institute or re-implement any of the requirements in paragraphs _____ of this Decree. Upon receipt of such notification, the defendants shall immediately and fully comply with the terms of the notice. In the event that the defendants disagree with the terms of the notice, the defendants may appeal to this Court but shall continue to immediately and fully comply with the terms of the notice unless and until the Court modifies or overturns the notice. The defendants shall pay all costs of such recalls and corrective actions, including the costs of FDA supervision, inspections, analyses, examinations, review, travel, and subsistence expenses to implement recalls and other corrective actions, at the rates specified in paragraph _____ of this Decree. This provision shall be separate and apart from, and in addition to, all other remedies available to FDA.

Exhibit 6-19**EXAMPLES OF COMPLAINT PROVISIONS****A. (Jurisdiction Model)**

In this action, plaintiff, the United States of America, seeks a statutory injunction to restrain defendants, (Firm Name), and (Individual) , from manufacturing and distributing in interstate commerce an adulterated drug in violation of the Federal Food, Drug, and Cosmetic Act (Act), 21 U.S.C. 301 et seq. Jurisdiction to restrain such violations is granted to the district courts of the United States pursuant to 21 U.S.C. 332(a). This Court also has jurisdiction over this action pursuant to 28 U.S.C. 1331, 1337, and 1345. Venue is proper in this District pursuant to 28 U.S.C. 1391(b) and 1391(c).

B. (Models of Defendants' Responsibility/Authority--Drug Manufacturer)

Defendant (Firm) is a corporation incorporated under the laws of the Commonwealth of Pennsylvania with its principal place of business at (street address, City, State), within the jurisdiction of this Court

Defendant (Individual), an individual, is the president of (firm), and has overall responsibility for, and authority over, all operations of the corporation, including the manufacture and distribution of drug products

(Individual) performs his duties as president of (firm) at (street address, city, State).

The defendant, _____, an individual, is the Chief Executive Officer of _____. He is responsible for personnel and pharmaceutical operations of the firm. He performs those duties at _____.

The defendant, _____, an individual, is the Treasurer of _____. He is also a principal stockholder in _____. _____ is responsible for deciding whether the firm will market particular drugs. He shares final responsibility with _____ for authorizing financial expenditures. He performs those duties at _____.

C. (Model of Defendant Responsibility/Authority--Food Warehouse)

The defendant, _____, an individual, is secretary, treasurer, and manager of the corporation, performing his duties at _____. He has responsibility for and authority over the day-to-day operations at the warehouse, including the expenditure of funds for the proper operation and maintenance of the facility.

D. (Model of Defendants' Business Activities and Related Violations--Unapproved New Drug)

The defendants have been and are now engaged, at the _____ facility at (Street address, City, State), in repacking, labeling, storing, promoting, and distributing in interstate commerce, the drug "_____", " which defendants promote through the use of literature accompanying (the drug) shipments to be used in the treatment, mitigation, cure, and prevention of various human diseases, including AIDS, lupus, and Parkinson's disease.

(Drug name) is a drug within the meaning of the FD&C Act, 21 U.S.C. 321(g)(1)(B), because, based on the therapeutic claims made by the defendant, it is intended for use in the cure, mitigation, treatment, or prevention of disease in humans.

_____ is a new drug within the meaning of the FD&C Act, 21 U.S.C. 321(p), because it is not generally recognized by qualified experts as safe and effective for use under the conditions prescribed, recommended, or suggested in its labeling. There is not now nor has there ever been in effect an approval by the United States Food and Drug Administration (FDA) of an application, filed pursuant to 21 U.S.C. 355(i). _____ is, therefore, an unapproved new drug pursuant to 21 U.S.C. 355(a).

E. (Model of Defendant's Business Activities and Related Adulterations-Medicated Feeds)

The defendants have been and are now engaged at their plant at Street address, City, State, in manufacturing, processing, packing, labeling, storing, and holding for sale various articles of medicated feed, which articles of medicated feed are drugs within the meaning of 21 U.S.C. 321(g)(1) and new animal drugs within the meaning of 21 U.S.C. 321(w) after shipment of one or more of the components of the feeds have moved in interstate commerce, and in distributing said articles of medicated feed in interstate and intrastate commerce.

Medicated feeds manufactured by defendants are adulterated while held for sale after shipment of one or more of their components in interstate commerce, within the meaning of 21 U.S.C. 351(a)(2)(B) in that the methods used in, and the facilities and controls used for, their manufacture, processing, packing, and holding do not conform to and are not operated and administered in conformity with current good manufacturing practice, 21 CFR 225, to assure that such drugs meet the safety requirements of the Act and have the identity and strength, and meet the quality and purity characteristics, which they purport or are represented to possess.

Certain medicated feeds manufactured by defendants, including those containing amprolium, lincomycin, and monensin in combination, and monensin, chlortetracycline, and sulfamethazine in combination, are also adulterated within the meaning of 21 U.S.C. 351(a)(6) while held for sale after shipment of one or more of their components in interstate commerce, in that such feeds bear or contain new animal drugs, 21 U.S.C. 321(w), which are unsafe within the meaning of 21 U.S.C. 360b(a)(2) since no approvals of applications filed pursuant to 21 U.S.C. 360b(b) and 21 U.S.C. 360b(m) are in effect with respect to the use and intended use of such drugs.

Certain medicated feeds manufactured by defendants, including _____ and _____, are also adulterated within the meaning of 21 U.S.C. 351(c) while held for sale after shipment of one or more of their components in interstate commerce, in that their quality and purity fall below or their strength differs from that which they purport and are represented to possess because they do not contain the amount of drug declared on their label.

**F. (Model of Defendants' Business Activities & Related Adulteration
1. Model-Food Processor)**

The defendants have been and are now engaged in processing in-shell pecans into shelled pecan nut meats, a food within the meaning of 21 U.S.C. 321(f). The defendants routinely ship finished shelled nut meats to customers outside the State of _____.

The shelled pecan nut meats being produced by defendants are adulterated within the meaning of 21 U.S.C. 342(a)(4) in that they have been prepared and packed under insanitary conditions whereby they may have become contaminated with filth.

2. (Another Model; Food Adulteration)

The wheat, when introduced or delivered for introduction into interstate commerce, is adulterated within the meaning of 21 U.S.C. 342(a)(2)(B), in that it bears and contains a pesticide chemical, malathion, which is unsafe within the meaning of 21 U.S.C. 346a in that the malathion is present in excess of the tolerance prescribed for the pesticide chemical on the raw agricultural commodity under 21 U.S.C. 346a(a).

3. (Another Model; Device Adulteration/Misbranding)

All of the defendants' devices are adulterated within the meaning of 21 U.S.C. 351(h) because the methods used in, and the facilities and controls used for, their manufacture, packing, and storage do not conform to FDA regulations establishing good manufacturing practice requirements, 21 CFR Part 820, promulgated under authority of 21 U.S.C. 360j(f)(1).

Certain of the defendants' in vitro diagnostic devices are misbranded within the meaning of 21 U.S.C. 352(f)(1) in that their labeling lacks adequate directions for use because the data required by regulation, 21 CFR 809.10(a)(5), to support the expiration dates appearing on the labeling of the devices either does not exist or has not been analyzed to verify the expiration period represented.

G. (Model for Inspectional Evidence--Food Processor)

Two recent inspections of _____ facility by FDA found insect infestation and other insanitary conditions that could cause the flour produced there to become contaminated with filth. During an inspection on April 23 and 24, 2003, moth cocoons and insect webbing were observed on each of the firm's three milling machines, and live insects were seen on walls in the milling room and on floors and walls of the packaging room. Similar insanitary conditions had been observed at a previous inspection on February 9, 2002.

Inspections by the State of _____ have also found continuing insect and rodent activity within _____'s facility. The _____ State Department of Agriculture ("_SDA") has inspected _____ at least five times since 2001 under a federal/state contract with FDA. _SDA investigators observed evidence of insect and/or rodent activity on three of these inspections.

Inspections conducted by FDA on _____, and _____, 20__, at the defendants' facility revealed insanitary conditions substantially similar to those found during the most recent inspection.

H. (Model for Previous Inspectional Evidence--Drug GMP)

Previous inspections of _____ establish that it has a consistent history of failure to comply with GMP. Inspections conducted by FDA from _____ to _____, 20__, and from _____ to _____, 20__, at the defendants' plant revealed substantially similar, and equally serious, deviations from the GMP regulations as revealed during the _____, 20__,

inspection. (Also identify other written notifications given by FDA to the defendants about their violative conduct.)

I. (Model for Inspectional Evidence--Illegal Sale of Animal Drugs)

On _____, 20__, an FDA investigator inspected the defendants' facility to determine their activities with respect to the sale of prescription veterinary drugs and new animal drugs. A review of sales invoices and other records revealed that the defendants routinely sold prescription veterinary drugs without valid prescriptions, and sold new animal drug Type A medicated articles without having an unrevoked written statement that the purchasers held approved medicated feed applications for the use of such Type A medicated articles in animal feed. The inspection disclosed that the defendants had made numerous sales of prescription veterinary drugs, including oxytocin, dexamethasone, and Liqueamycin, without a valid prescription or an order from a licensed veterinarian reduced to writing. The defendants had also made four sales of the new animal drug Type A medicated article Mecadox (carbadox) to three consignees for use in animal feed. At the time of these sales, the defendants did not have valid written statements from the purchasers that they were holders of approved medicated feed applications.

J. (Model for Charging 301(k))

Defendants violate 21 U.S.C. 331(k) by their acts of manufacturing, processing, packing, and holding, and by their acts of causing to be manufactured, processed, packed, and held, articles of food and drug, after one or more of the components of such foods and drugs have been shipped in interstate commerce, all of which acts result in the articles being adulterated as set out in paragraph _____ above, and being misbranded as set out in paragraph _____ above.

K. (Model for Charging 301(a))

Defendants violate 21 U.S.C. 331(a) by introducing and causing the introduction in interstate commerce of articles of device that are adulterated and misbranded as set forth in paragraph _____.

L. (Model for Charging 301(d))

The defendant, by introducing or delivering for introduction into interstate commerce _____, an unapproved new drug, has been and is in violation of 21 U.S.C. 331(d).

M. (Affirming Need for Injunction)

1. Model

Despite having been warned by FDA that the distribution of _____ violates the Act, the defendants continue to repackage, label, store, distribute, and promote this product in the manner described (in the complaint) above.

2. (Another Model)

The defendants' history of sanitation control problems demonstrates their unwillingness and/or inability to maintain a sanitary food manufacturing facility. Both FDA and _SDA have warned defendants that the insanitary conditions at their facility might subject them to regulatory action. Notwithstanding these warnings, and

notwithstanding assurances from defendants that the sanitation problems would be remedied, the problems persist.

Based on the defendants' repeated course of conduct, it is evident that unless restrained by order of this Court, defendants may well continue to manufacture and distribute _____ in violation of the Act, 21 U.S.C. 331(a) and 331(k).

N. (Model Prayers)

WHEREFORE, PLAINTIFF PRAYS:

I. That the defendants, _____, a corporation, and _____, and _____, individuals, and each and all of their officers, agents, representatives, employees, successors or assigns, attorneys, and those persons in active concert or participation with them or any of them, be perpetually restrained and enjoined pursuant to 21 U.S.C. 332(a) from directly or indirectly doing or causing the introduction or delivery for introduction into interstate commerce of any drug that is a new drug within the meaning of 21 U.S.C. 321(p); and from directly or indirectly manufacturing, processing, packing, labeling, or holding for sale, after shipment of one or more of its components in interstate commerce, any drug that is a new drug within the meaning of 21 U.S.C. 321(p), unless and until:

A. An approved application filed pursuant to 21 U.S.C. 355(b) is effective with respect to said drug;

B. An acceptable notice of claimed investigational exemption filed pursuant to 21 U.S.C. 355(i) and regulation 21 CFR 312.1 is on file for such drug; or

C. FDA has advised defendants that the drug is not a "new drug."

II. That the plaintiff be granted judgment for its costs herein, and that the Court grant such other and further relief as the Court deems just and proper.

1. (Another Model)

WHEREFORE PLAINTIFF PRAYS:

I. That the defendants _____, a corporation, _____, and _____, individuals, and all of their officers, agents, representatives, employees, successors or assigns, attorneys, and all persons in active concert or participation with them or any of them, be preliminarily and perpetually restrained and enjoined from directly or indirectly introducing or causing the introduction into interstate commerce of any device, or holding for sale any device after shipment of one or more of its components in interstate commerce, unless and until defendants satisfy FDA that:

A. The labeling for the devices is not false or misleading; and

B. The methods, facilities, and controls for manufacturing, processing, packing, and labeling the devices are established, operated, and administered in conformity with FDA's GMP regulations for devices, 21 CFR Part 820.

II. That recalls of devices manufactured by the defendants shall be made as the FDA deems necessary.

III. That the Court award plaintiff its costs herein, and such other and further relief as the Court deems just and proper.

(Another Model)

WHEREFORE PLAINTIFF respectfully requests that this Court:

I. Preliminarily and permanently enjoin the defendants, _____, a corporation, and _____, an individual, and each and all of their directors, officers, agents, representatives, employees, successors or assigns, attorneys, and any and all persons in active concert or participation with them or any of them, from directly or indirectly doing or causing the introduction or delivery for introduction into interstate commerce of any adulterated food which has been received, prepared, packed, or held at the defendants' facility.

II. Order the defendants to recondition or destroy all food under their control, and render their warehouse facility suitable for handling foods, in the manner and to the extent FDA deems necessary.

III. Grant plaintiff its costs and such other further relief as the Court deems just and proper.

Respectfully submitted,

NAME IN CAPS
Assistant Attorney General
Civil Division

NAME IN CAPS
United States Attorney

NAME IN CAPS
Assistant U.S. Attorney
Mail Address
City, State Zip

OF COUNSEL:

NAME IN CAPS
Chief Counsel
Food and Drug Administration

NAME IN CAPS
Trial Attorney
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

NAME IN CAPS
Attorney
Office of Consumer Litigation
Civil Division
U.S. Department of Justice
P.O. Box 386
Washington, D.C. 20044
(202) 307-0047

Exhibit 6-20**AFFIDAVIT/DECLARATION**

(NOTE: FOR AFFIDAVIT FORM, SEE END OF THIS MODEL)

IN THE UNITED STATES DISTRICT COURT

FOR THE _____ DISTRICT OF _____

UNITED STATES OF AMERICA)

) Civil Action No.

)

Plaintiff,

)

)

v.

)

)

_____, INC., a corporation,

)

NAME IN CAPS, and

)

NAME IN CAPS, individuals

)

)

)

Defendants.

)

State of _____

)

County of _____

)

STATEMENT OF
NAME IN CAPS

1. I am District/Division/Program Director, _____ Division, _____ Program, Food and Drug Administration, Department of Health and Human Services, Street Address, City, State.

2. I direct and supervise the day-to-day enforcement of the Federal Food, Drug, and Cosmetic Act for the United States Food and Drug Administration, _____ Division/Program, _____ Program which includes the States/Program of _____, _____, _____ and _____.

3. I am familiar with the investigation of Firm, Inc. performed by the _____ Division/Program, and the laboratory at the _____ Office, Food and Drug Administration. The official records of the Food and Drug Administration, contained in the files located in the _____ Division/Program, establish the facts in this statement.

4. Firm, Inc. was incorporated in 1954 under the laws of the State of _____ and is now engaged in the manufacture of prescription and non-prescription drug products (tablets) primarily on the special order of customers who specify the formulation.

5. Firm, Inc., is presently doing business at street address, City, State Zip.

6. Individual A, President of Firm, Inc., presently resides at Street address, City, State.

7. Individual B, Production Manager for Firm, Inc. presently resides at Street address, City, State.

8. Inspection of Firm, Inc. during July 1999 revealed deviations from good manufacturing practices, including improper batch production records. A list of Observations was presented to and discussed with Individual A, who promised that corrections would be made.

9. Inspection of Firm, Inc. during March-April 2000, revealed a continuation of the deviations previously brought to the attention of Individual A. A written List of Observations was presented to Mr. _____, Production Manager, who promised corrections on most of the observations.
10. On July 14, 2000, an Untitled Letter was issued to Individual A informing him that two lots of ascorbic acid tablets, 20214-4 and 20214-5, manufactured by Firm for private label distribution by a consignee in City, State, failed content uniformity testing. Lot 20214-4 contained only 92.2% of the declared ascorbic acid and was therefore also subpotent.
11. Inspection of Firm, Inc. on November 2 through 11, 2001, revealed serious deviations from current good manufacturing practice regulations as they appear in Title 21, Code of Federal Regulations, Parts 210 and 211. At the conclusion of that inspection, a List of Observations, consisting of 54 deviations from good manufacturing practice regulations, a copy of which is appended as Exhibit A, was issued to Individual A and discussed with him and Individual B, Assistant Production Manager. Individual A stated during the discussion that Individual B was hired to assist the firm in complying with current good manufacturing practice regulations. The investigator informed Individual A and Individual B of their responsibilities under the Federal Food, Drug, and Cosmetic Act when manufacturing drug products and the penalties that can be invoked for violating said Act. Individual A stated that he intended to bring Firm, Inc. into compliance with current good manufacturing practice regulations.
12. A sample of sugar coated yellow oval tablets of conjugated estrogen 1.25 mg manufactured by Firm was collected by _____ ORA investigator _____ on November 3, 2001, during the course of his inspection of the firm. Analyses of the drug at the FDA _____ Laboratory and a headquarters laboratory revealed that the product was not only subpotent with respect to total conjugated estrogens (51.7% and 46.6%) but also failed to meet compendial standards for the relative amounts of two constituent estrogens.
13. As a result of the violative inspection November 2 through 11, 2001, a sample of Nitroglycerin tablets, among others, was collected at a consignee in City, State, by the Food and Drug Administration. Analysis of the sample revealed that seven of thirty tablets failed to meet prescribed potency requirements and on a check analysis three of thirty tablets were not within compendial limits. The article therefore did not conform to United States Pharmacopeia requirements for content uniformity. Furthermore, seventeen of eighteen tablets on original analysis and eighteen tablets on check analysis failed to comply with compendial disintegration requirements. Firm, Inc. was advised of these results and recalled and destroyed the lot.
14. A sample of lot 21244-1 of Potassium Sulfate tablets manufactured by Firm was collected by FDA in November 2001. Analysis revealed that this drug did not meet the requirements for disintegration of an enteric coated tablet as prescribed in the United States Pharmacopeia. Upon the firm's failure to recall this drug, seizure was accomplished on January 27, 2002, in the United States District Court for the _____ District of _____ (Docket #CA _____; FDC _____).
15. On December 23, 2001, a Warning Letter, a copy of which is appended as Exhibit B, was issued to Individual A. This letter outlined deviations from current good manufacturing practice regulations observed during the November 1998 inspection.
16. Inspection of February 1 through 9, 2002, made as a follow-up to the November 1998 inspection, revealed a continued lack of compliance with good manufacturing practice regulations. Numerous deviations from current good manufacturing practice regulations were observed. A List of Observations, a copy of which is appended as Exhibit C, consisting of 79

items was presented to Individual A and discussed with him and Individual B, who was now Production Manager, and four other Firm, Inc. personnel. Individual A stated that he was aware of the seriousness of the situation. Individual A and Individual B agreed to make some corrections, many of them deviations previously called to their attention which they had failed to correct.

17. As a result of the violative inspection of February 1 - 9, 2002, a sample of _____ tablets manufactured by Firm was collected at a consignee in City, State, by FDA. Analysis revealed that the drug was subpotent in declared opium (67.2% original analysis and 64.8% by check analysis) and atropine sulfate (58% original analysis and 69.4% by check analysis). When notified of these results, Individual A stated he would not remove this lot from sale. Upon the firm's failure to recall this drug, seizure was recommended to the United States Attorney for the _____ District of _____.

18. A limited inspection was instituted March 11, 2002, to determine what corrections had been made in the firm's operation based upon the observations called to management's attention in February. Inspection revealed that while a few improvements had been made, there was a continuing lack of compliance with current good manufacturing practice regulations. A List of Observations consisting of 47 items, attached as Exhibit D, was presented to Individual A and discussed with him, with Individual B, and with Dr. _____, President of _____ Associates, Inc., a consultant to Firm, Inc.

19. During the course of the inspection instituted March 11, 2002, the investigators noted that two lots of _____ tablets had been returned by the consignee in City, State, because of visible deterioration.

I declare under penalty of perjury that the forgoing is true and correct.

Executed on _____.

NAME IN CAPS

District/Division/Program Director

If an affidavit, rather than a statement, is to be used, make the following changes:

1. Change the word STATEMENT to AFFIDAVIT.
2. Before item 1. add: " Before me, _____, a Notary Public, personally appeared _____, who, first being duly sworn, deposes and says:"
3. At the end, delete the last sentence and, under the signature add: "Subscribed and sworn to before me in the City and District aforesaid this day of _____ 20__.

Notary Public

The end of the affidavit will then appear as follows:

19. During the course of the inspection instituted March 11, 2002, the investigators noted that two lots of _____ tablets had been returned by the consignee in City, State, because of visible deterioration.

NAME IN CAPS

District/Division/Program Director

Subscribed and sworn to before me in the City and District aforesaid this ____ day of _____ 20__.

Notary Public

Exhibit 6-21**MODEL LETTER BILLING CHARGES**

Sample Number
INJ ____, FDC _____

Date

Firm
Street Address
City, State, Zip Code

Sir/Madam:

The following costs have been incurred by your firm as a result of the Decree of Preliminary Injunction entered by the Court on _____.

Under the terms of that Decree, your firm is required to pay the costs of inspection and analytical work performed by FDA to insure compliance with the terms of the injunction.

Investigator's time	6 hrs. at \$**. ** per hr	\$XXX.XX
Mileage-Gov't car	18 miles at \$0.*** per mile	\$ X.XX
Analyst's time	5 hrs. at \$**. ** per hr	<u>\$XXX.XX</u>
	Total Charges	\$XXX.XX

(* Note: Use rates of reimbursement specified in Consent Decree)

Please remit promptly a money order, bank draft, or certified check for \$XXX.XX, made payable to the United States Treasury, attach to the enclosed copy of this letter, and return to this office.

Sincerely yours,

Director, Compliance Branch District/Division

Enc: cc this letter

Exhibit 6-22**PETITION FOR ORDER TO SHOW CAUSE**

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF _____

UNITED STATES OF AMERICA,	)	
Plaintiff,	)	
	)	
v.	)	Criminal Action No. _____
	)	
NAME IN CAPS,	)	
and	)	
NAME IN CAPS,	)	
Corporations,	)	
	)	
and	)	
	)	
NAME IN CAPS,	)	
NAME IN CAPS,	)	
NAME IN CAPS,	)	
NAME IN CAPS, and	)	
NAME IN CAPS,	)	
Individuals,	)	
Defendants	)	

PETITION FOR ORDER TO SHOW CAUSE WHY DEFENDANTS
SHOULD NOT BE HELD IN CRIMINAL CONTEMPT

Plaintiff, United States of America, hereby moves this Court for an Order to Show Cause why Firm A, Inc. (Firm A), and Firm B, Inc. (Firm B), corporations, and Individual A, Individual B, Individual C, Individual D, and Individual E, individuals (hereafter, collectively, the defendants) should not be adjudged in criminal contempt of a Consent Decree of Permanent Injunction (Decree) entered by this Court on April 25, 1999. In support of this Petition, the United States of America states as follows.

BACKGROUND

1. On April 7, 1999, the United States filed a Complaint for Injunction (1999 Complaint) against named defendants Firm A, Individual A, and another individual not named in this action, Ex. 1, along with a signed Consent Decree of Permanent Injunction (Decree). Ex. 2. Judge _____ entered the Consent Decree on April 25, 1999. Id. Firm A was and is a manufacturer of devices within the meaning of the Federal Food, Drug, and Cosmetic Act (FDCA). 21 U.S.C. § 321(h). The FDCA defines a device as an "instrument, apparatus, implement, machine, ... or other similar or related article, including any component,

part, or accessory, which is ... intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease in man" 21 U.S.C. § 321(h).

2. The 1999 Complaint alleged that Firm A and Individual A were violating the FDCA by introducing or delivering for introduction into interstate commerce devices adulterated within the meaning of 21 U.S.C. § 351(h), and by manufacturing, packing, and storing devices after shipment of one or more of their components in interstate commerce under conditions that resulted in the devices becoming adulterated. 21 U.S.C. §§ 331(a) and (k). At that time, defendants manufactured several devices including, but not limited to, an electrosurgical device (the Electro Probe) and a silicone chin implant (the Axis Implant). See Ex. 1 ¶¶ 6-8. The Electro Probe is used by doctors to control bleeding during various types of surgery; the Axis Implant is used to augment or reconstruct the chin. Id. Inspections performed by the Food and Drug Administration (FDA) prior to the filing of the 1999 Complaint revealed that defendants had failed, over a period of several years, to assure that the Electro Probe and Axis Implant were manufactured in conformity with FDA's current good manufacturing practice (CGMP) regulations -- regulations promulgated to assure that devices are safe and effective. See 21 U.S.C. § 360j(f) (1) and 21 C.F.R. Part 820.

3. The Decree permanently enjoined defendants Firm A and Individual A and any and all of their representatives, agents, employees, successors, and those persons in active concert or participation with any of them who received actual notice of the contents of the Decree from "directly or indirectly"

(1) introducing or causing to be introduced into interstate commerce, or delivering or causing to be delivered for introduction into interstate commerce, *any article of device* within the meaning of 21 U.S.C. § 321(h); and

(2) manufacturing, packing, or storing *any article of device* held for sale ... unless and until:

A. The methods used in, and the facilities and controls used for and by defendants for manufacturing, packing, or storing devices comply with the Food and Drug Administration's (FDA) good manufacturing practice (GMP) regulations for devices.

Ex. 2 ¶ I11 (emphasis added).

4. The Decree set forth conditions under which the defendants could resume operations. See Ex. 2 ¶ I11 B-E. Those bound by the Decree could begin shipment of devices in interstate commerce only after:

a. defendants hired an expert consultant to inspect Firm A's manufacturing, packing, and storing systems;

b. defendants certified to FDA that, based upon such inspection, the consultant had concluded that Firm A could in the future manufacture devices in conformity with FDA's CGMP regulations;

c. FDA made such inspections as it deems necessary; and

d. FDA gave defendants written authorization to begin manufacturing and distributing devices. Ex. 2 ¶ III B - E.

5. Approximately one year after the Decree was entered, Firm A certified to FDA that it could manufacture and distribute the Axis Implant in conformity with the law, and FDA provided Firm A written authorization to so do. Ex. 3. FDA did not authorize, and to date has not authorized, the manufacture and delivery of any other Firm A devices, including the Electro Probe.

DEFENDANTS HAD ACTUAL NOTICE OF THE DECREE

6. At the time the 1999 Complaint was filed, defendant Individual A was the President of Firm A and signed the Decree both on behalf of Firm A as its president as well as in his capacity as an individual defendant. Ex. 2 at 10. Upon the Decree's entry, defendant Individual B became Firm A's President, Ex. 4, and he signed a statement dated May 19, 1999, acknowledging receipt of the Decree. Ex. 5.

7. Defendant Individual C was a Firm A employee when the Decree was entered. *Id.* Firm A sent a copy to her by certified mail pursuant to Paragraph IX of the Decree, which required that Firm A provide copies of the Decree to all its officers and employees. Ex. 2 ¶ IX. She signed for receipt of the Decree on May 25, 1999. Ex. 5.

8. Individual D was also a Firm A employee when the Decree was entered. *Id.* He signed a statement dated May 19, 1999, stating that he had received a copy of the Decree from Firm A. See Ex. 5.

9. Soon after agreeing to and receiving notice of the Decree, Firm A and Individual B entered into negotiations with FDA to allow Firm A to export at least some of its inventory of pre-Decree devices to Europe under a provision in the Decree that allowed defendants to attempt to bring the devices into compliance with the law. Ex. 6. FDA worked with Firm A and Individual B to assure that any such export complied with the FDCA. *Id.* and Ex. 7. On October 19, 1999, this effort culminated in Firm A exporting its pre-Decree inventory to Med Dev Europe, an affiliate of Firm A's located in the Netherlands, which later distributed the devices to a company called Device Workshop, also in the Netherlands. Ex. 8.

10. Defendant Individual E was the director of Device Workshop and, therefore, a customer of Firm A's. To lawfully ship adulterated devices to Device Workshop, Firm A had to establish, among other things, that the devices accorded to Device Workshop's specifications. See 21 U.S.C. § 381(e) (1) (A). To do so, FDA suggested that Firm A inform Individual E that the devices he would receive had not been manufactured in conformity with CGMP. See Ex. 6, June 26, 1999, letter to Mark Able from FDA, at 3. Firm A did so and, on October 2, 2000, Individual E sent a letter to Firm A stating that he had read and understood the Decree. Ex. 9.

11. During the negotiations between Firm A and FDA over the circumstances of export of its inventory, Firm A requested permission to distribute in the United States components of some of its devices, including the Electro Probe. Ex. 7, July 24, 1999, letter to FDA from Michael Smith. FDA advised Firm A in writing that manufacturing, holding for sale, or selling in interstate commerce components of its devices would constitute a violation of the Decree because the components were devices that had not been brought into compliance with CGMP, as required by the Decree. Ex. 7; see also 21 U.S.C. § 321(h).

THE DEFENDANTS' VIOLATIONS OF THE DECREE

12. Despite FDA's efforts to work closely with Firm A to effect a lawful export of its inventory, Firm A's certification to FDA that the Axis Implant could be manufactured and

distributed in compliance with the CGMP regulations, and FDA's notice to Firm A that the unauthorized manufacture and distribution of device components would be a violation of the Decree, defendants flagrantly violated the Decree's requirements with respect to the Electro Probe. As shown below, the individual defendants violated the requirements of the Decree by establishing a successor corporation to Firm A called Firm B, transferring assets and employees to Firm B, and manufacturing and distributing components of the Electro Probe to Med Dev Europe. These components could be easily assembled by purchasers to form a finished Electro Probe device.

Defendant Firm A

13. Between entry of the decree on April 25, 1999, and at least until the beginning of an FDA inspection of Firm B on September 3, 2000, defendant Firm A caused the manufacture and distribution of the Electro Probe through defendants Firm B, Individual B, Individual C, and Individual D despite the fact that FDA had not authorized the manufacture and distribution in interstate commerce of the Electro Probe, as is required by the Decree. Ex. 2 ¶ 111. Firm A provided to Firm B critical business assets -- the plans and specifications for the Electro Probe, Ex. 10, and a list of its suppliers. Ex. 11. Firm B labeled the Electro Probes it manufactured to state that they had been manufactured by Firm A. Ex. 12. Firm A employees Individual C and Individual D worked for Firm B for several months while also on the Firm A payroll. Ex. 13 ¶¶ 4 and 5. And, Firm A's president directed Individual C and Individual D in the performance of their duties while they were employed by Firm B. Id. In short, Firm A knowingly and deliberately violated the terms of the Decree by causing Firm B to manufacture and introduce into interstate commerce components for the Electro Probe, even though FDA had not authorized such activities.

Defendant Firm B

14. On or about November 13, 1999, six months after entry of the Decree, defendants Individual A, Individual B, and Individual E filed papers incorporating Firm B in the Commonwealth of Virginia for the stated purpose of "servicing of electrosurgical or related medical devices" and "any activity reasonably incidental or reasonably necessary thereto." Ex. 14, Articles of Incorporation, 1. Defendant Individual E is the president of Firm B and defendants Individual A and Individual B serve as directors of that firm. Id. at 6 Defendant Individual A, a named defendant in the Decree, owns eighty percent of Firm B's stock. Id. at 8-10. Individual B and Individual E own the remainder of the stock. Id. at 8-10.

15. Between November of 1999 and September of 2000, Firm B manufactured and distributed devices intended for reconstruction of the nose and chin. Specifically, defendant Firm B:

a. Employed former Firm A employees Individual C and Individual D as vice presidents. Ex. 13 ¶¶ 4 and 5.

b. Received from defendants Individual B and Firm A specifications and plans to manufacture Firm A's devices, including the Electro Probe. These plans were labeled "Medical Device Research Partners" or "Firm A, Inc.," indicating that they were developed for use by Firm A and were the business assets of Firm A. See Ex. 10. As a result, Firm B received a significant business asset from Firm A and is a successor corporation to Firm A. As a successor corporation, Firm B is bound by the Decree. Ex. 2 ¶ 111.

c. Ordered Electro Probe parts identical to those previously ordered by Firm A from the same companies that had supplied Firm A. Some of these parts were ordered from companies outside of Virginia. Id. As a result, Firm B stored devices after shipment of one or more of their components in interstate commerce.

d. Used these parts to manufacture device components which could be assembled into devices identical to those manufactured by Firm A, including the Electro Probe. Ex. 13 ¶ 5. Such manufacture is expressly prohibited by the Decree. Ex. 2 ¶ III (2).

e. Labeled at least some of the finished device components "Firm A, Inc. Richmond, VA USA," although they had been manufactured by Firm B. Ex. 12. Such manufacture and distribution in interstate commerce are in direct contravention of the Decree's prohibitions. Ex. 2 ¶ III(1) and (2).

f. Stored the device components in Firm B's facility at Richmond, Virginia. Such storing is expressly prohibited by the Decree until such time as FDA authorizes storing devices by Firm A or others bound by the Decree. Id.

g. Delivered these device components to Highland International Forwarders for shipment to Med Dev Europe in the Netherlands, and then submitted invoices to Med Dev Europe for the device components. Ex. 15. Such distribution is expressly prohibited by the Decree until such time as FDA authorizes distribution in interstate commerce. Compare Ex. 2 ¶ III(1) with ¶ III E.

16. Firm B only manufactured and distributed device components that were previously manufactured and distributed by Firm A; it did not manufacture any other products.

17. During FDA's inspection, Firm B employees claimed that they were merely manufacturing components of devices. Ex. 13 ¶¶ 4 and 5. By law, components of devices are also devices, 21 U.S.C. § 321(h). Moreover, records indicate that Firm B shipped to customers the same number of components in each shipment that could easily be assembled to complete finished devices identical to Firm A's Electro Probe. Ex. 13 ¶¶ 5 and 9; Ex. 15. These components were ordered by "Individual B" at Med Dev Europe. See Ex. 15 at 2. FDA collected records at Firm B which show that Firm B shipped components for the assembly of at least 59 finished devices. Ex. 13 ¶ 6.

Defendant Individual A

18. Defendant Individual A signed the Decree both in his capacity as the president of Firm A and as an individual defendant. Ex. 2 at 10. He had direct and actual knowledge of the Decree's contents. See. Nevertheless, just seven months after signing the Decree, he agreed to serve as a member of the Board of directors of Firm B and purchased eighty percent of Firm B's stock, see Ex. 14, and while so serving, he manufactured device components consisting of one or more components that had been shipped in interstate commerce and, later, introduced the device components into interstate commerce. Such actions were in direct violation of the Decree because the Decree specifically prohibited Individual A's manufacture and distribution in interstate commerce of the Electro Probe unless and until FDA authorized such work. Ex. 2 ¶ III (I), (2), and E. To date, FDA has not so authorized.

Defendant Individual B

19. Defendant Individual B was the vice president of Firm A in 1998 and became its president in March 1999. Ex. 4. He signed a statement on May 19, 1999, acknowledging receipt of a copy of the Decree from Firm A. Ex. 5. Individual B also corresponded extensively with FDA after entry of the Decree, see Ex. 6, and certified to FDA that Firm A's Axis Implant manufacturing line was operating in compliance with the CGMP regulations. Ex. 3. In short, Individual B continually demonstrated that he understood the provisions of the Decree and Firm A's obligations under that Decree.

20. Despite the Decree's restrictions and Individual B's understanding of them, Individual B violated the Decree in several ways. First, Individual B served as a member of Firm B's Board of Directors. Ex. 14. Second, Individual B directed the contumacious activities of defendants Individual C and Individual D while they were employees at Firm A and, later, at Firm B. Ex. 13 ¶¶ 4 and 5. Third, Individual B delivered to Firm B the plans and specifications for Firm A's Electro Probe so that Firm B could manufacture the device components and ship sets of them to Med Dev Europe. Id. ¶ 4. Fourth, after FDA's inspection revealed to FDA that defendants were manufacturing and distributing components for Firm A's Electro Probe, Individual B wrote to defendant Individual C and stated that Med Dev Europe would not provide the money necessary to bring Firm B into compliance with CGMP, Ex. 16, as is expressly required by the Decree. Ex. 2 ¶ 111 A - E. Individual B resigned as president of Firm A soon after FDA's inspection of Firm B. Ex. 17.

21. Defendant Individual B's activities were in direct contravention of the Decree because he actively participated in a scheme to circumvent the requirements of the Decree through the manufacture and distribution of Firm A's Electro Probe despite the fact that the defendants had not certified to FDA that they could manufacture and distribute the Electro Probe in compliance with CGMP regulations and FDA had not authorized such activities.

Defendant Individual C

22. Defendant Individual C was an employee of Firm A at the time the Decree was entered by this Court. Ex. 18. She received notification of the Decree through certified mail by Firm A, Ex. 5, and was bound by its terms. Ex. 2 ¶ 111.

23. Despite the provisions of the Decree, while she was employed at Firm A, Individual C also worked for Firm B during evenings and weekends to help establish the company. Ex. 13 ¶ 4. She admitted doing so in order to assist defendant Individual B in his effort to supply Med Dev Europe with device components so that at least some of Firm A's devices could be sold overseas. Id. On March 29, 2000, Individual C began working full time for Firm B. Ex. 13 ¶ 4 and Ex. 18.

24. At Firm B, defendant Individual B was a vice president in charge of administrative matters. Ex. 13 ¶ 4. She was responsible for ordering and receiving parts, preparing invoices, and shipping devices to Med Dev Europe. See Ex. 15. She told FDA investigators that, while defendant Individual B was responsible for some managerial decisions at Firm B, she also made managerial decisions for the company. Ex. 13 ¶ 4. Individual C also carried out Individual B's instructions when necessary. Id.

25. Once FDA's inspection of Firm B was completed, Individual C requested financial support from Individual B to enable Firm B to come into compliance with CGMP, Ex. 16,

revealing Individual C's understanding that Firm B was required to comply with CGMP regulations.

Individual D

26. Defendant Individual D was an employee of Firm A at the time the Decree was entered by this Court. Ex. 18. He was notified of it by Firm A, Ex. 5, and was bound by its terms. Ex. 2 ¶ 111. Like Individual C, while employed at Firm A, he worked evenings and weekends to set up Firm B and later went to work for Firm B full time. Ex. 13 ¶ 5.

27. Individual D was Firm B's vice president for production. Id. He was responsible for producing all device components that Firm B manufactured, packed, and stored. Id. Individual D told FDA investigators that he produced approximately 100 to 200 subassemblies, or components, of devices according to training and device specifications that he received from defendant Individual B. Id. When questioned by FDA investigators about the similarity in the names for Firm B's and Firm A's electrosurgical devices (Firm A's Electro Probe is called the ER-8100 and Firm B's is called the ESU- 8100), Individual D acknowledged that they were the same device. Id.

28. The Decree prohibited Firm A, its employees, and all persons in active concert or participation with either of them, which language clearly includes Individual D, from manufacturing, packing, storing, and distributing all devices, including the Electro Probe, until FDA authorized such activities. Despite this clear prohibition, Individual C continued to oversee manufacture, packing, storage, and distribution of a device that had changed in name only. This is a clear violation of the Decree.

Individual E

29. By letter dated October 2, 1999, Individual E acknowledged that he knew of and understood the terms of the Decree. Ex. 6. Yet, in November of 1999, he began serving as the president of Firm B. With the help of Individual C and Individual D in 2000, he manufactured the Electro Probe, stored it, and introduced it into interstate commerce. All of these acts were in direct violation of the Decree's prohibitions of the manufacture and distribution in interstate commerce of devices that FDA had not, and has not, authorized in writing.

WHEREFORE, pursuant to Rule 42(b) of the Federal Rules of Criminal Procedure, the United States of America respectfully requests that this Court:

1. Issue an Order to Show Cause requiring defendants Firm A and Firm B, corporations, and Individual A, Individual B, Individual C, Individual D, and Individual E, individuals, to appear before this Court and to show cause why they should not be adjudged in criminal contempt of the Decree entered by this Court on April 25, 1999;

2. Following the issuance of the Order to Show Cause and an appropriate hearing, enter a judgment of criminal contempt against defendants Firm A and Firm B, corporations, and Individual A, Individual B, Individual C, Individual D, and Individual E, individuals, for violating the April 25, 1999 Decree;

3. Impose an appropriate fine against the defendant Firm B;

4. Impose an appropriate fine against the defendant Firm A.;

5. Impose an appropriate fine or term of imprisonment against the individual defendant Individual A;
6. Impose an appropriate fine or term of imprisonment against the individual defendant Individual B;
7. Impose an appropriate fine or term of imprisonment against the individual defendant Individual C;
8. Impose an appropriate fine or term of imprisonment against the individual defendant Individual D;
9. Impose an appropriate fine or term of imprisonment against the individual defendant Individual E; and
10. Grant such other relief as the Court deems just and proper.

Dated: _____

Respectfully submitted:
NAME IN CAPS
Assistant Attorney General

NAME IN CAPS
Chief Counsel

NAME IN CAPS
United States Attorney

NAME IN CAPS
Associate Chief Counsel
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857
301-827- _____

Assistant U.S. Attorney
Address
City, State Zip
Phone number

Office of Consumer Litigation
Department of Justice
P.O. Box 386
Washington, D.C. 20044

Exhibit 6-23**ORDER TO SHOW CAUSE**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF _____UNITED STATES OF AMERICA,)
Plaintiff,

)

)

v.)

Criminal Action No. _____

)

NAME IN CAPS

)

and

)

NAME IN CAPS.

)

Corporations

)

)

and

)

NAME IN CAPS,

)

NAME IN CAPS,

)

NAME IN CAPS,

)

NAME IN CAPS,

)

and

)

NAME IN CAPS,

)

Individuals,

)

Defendants

)

ORDER TO SHOW CAUSE

Upon consideration of the government's Petition for an Order to Show Cause why the defendants Firm A, Inc. (Firm A), Firm B, Inc. (Firm B), corporations, and, Individual A, Individual B, Individual C, Individual D, and Individual E, individuals, should not be held in criminal contempt, and it appearing to the Court from the allegations contained therein that the defendants have violated the terms of the Consent Decree of Permanent Injunction entered on April 25, 1999, it is therefore:

ORDERED, pursuant to Rule 42(b) of the Federal Rules of Criminal Procedure, that defendants Individual A, Individual B, Individual C, Individual D, and Individual E, and duly authorized representatives of defendants Firm A and Firm B shall appear before this Court in Room No. ____, _____ (address), City, State on ____ (date) at ____ (time), and show cause why they should not be held in criminal contempt of the permanent

injunction entered in the above-captioned case on April 25, 1999.

SO ORDERED:

Dated: _____, 2001.

Judge _____

United States District Judge

Exhibit 6-24**FORMAT FOR PROSECUTION SUMMARY AND RECOMMENDATION**Memorandum

FROM: _____ District/Division/Program _____

SUBJECT: PROSECUTION

Lead Sample Number, et al.

TO: Division of Enforcement, Office of Enforcement and Import Operations or
Center for Drug Evaluation and Research, Office of Compliance (HFD-300) or
Center for Food Safety and Applied Nutrition, Office of Compliance (HFS-600) or
Center for Veterinary Medicine, Office of Surveillance and Compliance (HFV-200) or
Center for Devices and Radiological Health, Office of Compliance (HFZ-300) or
Center for Biologics Evaluation and Research, Office of Compliance and Biologics Quality
(HFM-600)

SAMPLE NO., PRODUCT, DATE SHIPPED, AND RELATED INFORMATION

In a case where an element of the offense does not involve samples, outline the elements
which describe the offense.

CITATIONLEGAL STATUSALLEGED VIOLATIONHISTORYPRIOR NOTICEOTHER CORRESPONDENCEWITNESSES FOR INSPECTIONAL AND ANALYTICAL FINDINGSOTHER WITNESSESRECOMMENDATIONPERMANENT ABEYANCE OF SAMPLES AND/OR INDIVIDUALSSAMPLE DATA

1. Date Lot Shipped/Received

2. Date Lot Sampled/By
3. Description of Lot and Sample Size
4. Analysts
5. Analytical Method(s)
6. Number of Subs Analyzed
7. Analytical Findings verifying that part of offense based on laboratory analysis
8. 702(b) portion
9. Seizure(s)
10. Recall(s)
11. Documentation of Interstate Commerce

REMARKS

Signature of Compliance Officer

Signature of Director, Compliance Branch

Concurrence by: District/Division/Program Director(s)

Enclosures:

Case files

Exhibit 6-25**MODEL PROSECUTION SUMMARY AND RECOMMENDATION MEMORANDUM**

DATE:

FROM: _____District/Division/Program_____

SUBJECT: PROSECUTION
Lead Sample Number, et al.

TO: Division of Enforcement, Office of Enforcement and Import Operations

2.SAMPLE NO.	3.PRODUCT	4.DATE SHIPPED	5.RELATED INFORMATION
6.Sample No. 10.(Count I)	7.Lima Beans 11.	8.12/18/01 12.	9.Seized 13.
14.Sample No. 18.(Count II)	15.Lima Beans 19.	16.11/20/01 20.	17.Seized 21.
22.Sample No. 26.(Count III)	23.Peas 27.	24.11/31/02 28.	25.Vol. destroyed 29.
30.Sample No. 34.(Count IV)	31.Lima Beans 35.	32.11/30/02 36.	33.Seized 37.

CITATION

Issued to: Firm
Street Address
City, State Zip
a corporation

and
Individual A, President
Street Address
City, State Zip

and
Individual B
Street Address
City, State Zip
Individuals

There has been no new evidence developed since the Recommendation for Citation was submitted or at the 305 meeting on [date]. Therefore, the case was sent directly to the Division of Enforcement.

LEGAL STATUS

Firm, Inc. was incorporated under the laws of the State of _____ in 1978. Certified copies of the Articles of Incorporation have been obtained. The officers of the corporation are Individual A, President and Chief Executive Officer, and Individual B, Warehouse Distribution Manager. The responsible individuals at the Irving warehouse are the same now as at the times of violations.

ALLEGED VIOLATIONS

This storage warehouse has been storing peas and beans which have become rodent contaminated after receipt in interstate commerce. 21 U.S.C. 331(k), 342(a)(3), and (4). Lima beans represented by samples collected during the inspection of _____, are adulterated within the meaning of 21 U.S.C. 342(a)(3) in that the products contained rodent excreta pellets and live insects (Count I) and rodent hairs (Count II). Peas and lima beans are represented by samples collected during the inspection of _____, and are adulterated within the meaning of 21 U.S.C. 342(a)(3) in that the peas contained rodent excreta and rodent hairs (Count III) and the beans contained live insects (Count IV).

In addition, the products were adulterated within the meaning of 21 U.S.C. 342(a)(4) because they were held under conditions which could have resulted in their becoming contaminated with filth (Counts I-IV).

HISTORY

The proposed defendants have a long history of noncompliance with the Food, Drug, and Cosmetic Act. FDA first inspected the firm in February 1993. That inspection revealed widespread rodent and insect infestation. Products found in violation were voluntarily destroyed. Inspection in 1994 revealed continuing problems and two lots of rice were seized, No. _____, N.D. Texas (FDA reference FDC _____). Between 1995 and 2000, FDA and State of Texas, under contract with the FDA, inspected the Corporation on several occasions. Those inspections revealed some minor insanitary conditions and resulted in the voluntary destruction of some foods.

In June 2001, a joint inspection by FDA and the state again revealed extensive rodent infestation. No food was seized as Individual A voluntarily destroyed the contaminated lots. Follow-up inspections in May 2002 and December 2002 are the subject inspections upon which this recommendation is based.

PERMANENT ABEYANCE OF SAMPLES AND/OR INDIVIDUALS

Above named corporation (Sample No.) and individuals (Sample No.). We have recommended permanent abeyance of these two numbers only to restrict the proposed information to four counts per wishes of the local District Court.

SAMPLE DATA

COUNT I

38.	39. Sample No. - Lima Beans
40. Date Lot Received:	41. 1-27-2002
42. Date Lot Sampled/By:	43. 5-9-2002 by _____ (Name) _____ ORA Division/Program)
44. Description of Lot	46. Lot - 42 bales (12/2 lb. bags); 13 bales were examined, 6
45. and Sample Size:	had rodent excreta and 3 had rodent urine on their surfaces, 8 were rodent gnawed and in 5 bales the gnawing penetrated cello bags inside the bales. Cello bags in one bale contained insects and one cello bag was almost completely empty and contained rodent excreta. A nest containing three dead rodents was found between bales in the lot. An 11 sub selective sample consisting of 7 rodent gnawed cello bags collected from 5 different bales and 4 subs from the exterior of bales was collected
47. Analyst:	48. Name (____ - ORA District/Division/Program)
49. Analytical Methods:	50. Macroscopic, Microscopic, and Xanthidrol
51. Number of Subs	52. All
Analyzed:	
53. Analytical Findings:	54. <u>402(a)(3) Verification</u> 55. Subs 1B, 3, 3A, 4, 5, and 5A. poly bags of beans bearing rodent incisor marks penetrating bagging material. Sub 3A contained a fly. Sub 3 contained an insect pupa case. Subs 3A and 5 contained insect pupae. Subs 4 and 5A contained rodent excreta pellets. 56. <u>402(a)(4) Verification</u> 57. Other subs collected from exterior of lot revealed gnawed bagging material, urine stained paper, and rodent hairs.
58. 702(b) Portion:	59. Yes
60. Seizure:	61. Yes

Documentation of Interstate Commerce:

1. Dealer's Statement dated 5-09-2002 signed by Mr. _____, as General Foreman (Assistant Distribution Manager), Firm, Inc., City, State covering receipt of the lot on or about 1-27-2002 from Food Products, Inc., Dallas, Texas, and sampling.

Mr. _____ furnished copies of the following documents:

a. Firm, Inc. Purchase Order No. 0123 dated 1-18-2002 stamped "Hauled on Rogers truck" and marked "Date Received 1-27-2002."

b. Invoice No. 76543 dated 1/27/2002 issued by Food Products, Inc.

2. Affidavit dated 5/19/2002 signed by Mr. _____, Quality Assurance Manager, Food Products, Inc., Dallas, Texas, stating that the shipment of lima beans to Firm, Inc., City, State, under Invoice No. 7653 dated 1/27/2002, was packed by his firm from beans received from Downs Warehouse Company, Crows Landing, California. Mr. _____ furnished copies of the following documents:

a. Invoice No. 010305 dated 12/28/2001 issued by Downs Warehouse Co.

b. Bill of Lading (Shipper's No. 5520 and Agent's No. 43218) dated 12/28/2001 issued by Southern Pacific Transportation Company, covering the shipment of 194,000 pounds of dry beans from Downs Warehouse Company, Crows Landing, California, to Food Products, Inc., Dallas, Texas.

(Counts II through IV of this example would be listed with the factual information as in Count I above.)

REMARKS

We are not aware of any potential problem areas or weaknesses in the case. Individual A is in his mid-40's, while Individual B is reportedly 38.

OCI was contacted regarding the case and declined it.

Prosecution is the action of choice in this case. The evidence shows that this firm, under current management, had serious rodent and insect infestations as early as 1993, and despite repeated warnings, has allowed these grossly filthy conditions to persist.

Signature of Compliance Officer

Signature of Director, Compliance Branch

Concurrence by: District/Division/Program Director(s)

Enclosures:

cc: Notice of Hearing and Charge Sheet

cc: Record of Hearing and Hearing Exhibits

cc: Legal Status Sheet

cc: Articles of Incorporation

cc: Collection Reports, Labels, Worksheets, and state correspondence (5)

In separate envelope:

3 cys. Notice of Hearing and Charge Sheet

1 cy. Articles of Incorporation

3 cys. letter to firm dated 10-25-87

cc: HFS-605

HFA-224

Exhibit 6-26**MODEL LETTER REQUEST FOR ARTICLES OF INCORPORATION**

Dear Sir:

Re: Name of Firm
Address of Firm

Please furnish us with copies of the Articles of Incorporation and Certificate of Existence for the referenced firm. As these documents may be introduced as evidence in a court proceeding in accordance with Rule 44 of the Federal Rules of Civil Procedure (copy enclosed), it will be necessary for them to be authenticated by the officer having legal custody of these records, or by his deputy, and accompanied by a certificate that the individual is legal custodian of these records.

The documents should cover the existence of the firm for the period from on or about (earliest shipment date contained in the Information or Indictment) to the present time.

Sincerely,

Exhibit 6-27**RULE 44 – PROVING AN OFFICIAL RECORD**

To establish that a document, or an entry in it, to be used as evidence is an official record that is otherwise admissible:

See the Federal Rules of Civil Procedure at 28 USC § 44 – Proving an Official Record on www.gpo.gov.

(From the Federal Rules of Civil Procedure. Incorporates the revisions that took effect January 7, 2001.)

Exhibit 6-28**Rule 6. THE GRAND JURY**

See the Federal Rules of Criminal Procedure at 28 USC § 44 – Proving an Official Record at www.uscourts.gov > [Rules of Criminal Procedure](#).

(From the Federal Rules of Criminal Procedure. Includes text from 2011, 2014 amendments.)

Exhibit 6-29**EXAMPLE OF LETTER TO THE DEPARTMENT OF JUSTICE, RE: INJUNCTION AND CIVIL PENALTY**

Office of the Chief Counsel
Food and Drug Administration
5600 Fishers Lane, GCF-1
Rockville, Maryland 20857
Our Ref: INJ [insert number] [insert date]
[insert name], Director
Office of Consumer Litigation
Civil Division
Department of Justice
Post Office Box 386
Washington, D.C. 20044

Dear [insert name]:

Investigations conducted by the Food and Drug Administration (FDA) indicate that ABC Company, Inc. (ABC) and Alan R. Smith, its president, have violated the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. 301, et seq. Specifically, ABC and Alan R. Smith have: (1) manufactured and distributed into commerce 149 diagnostic x-ray systems which did not comply with the applicable performance standards prescribed in the Act, in violation of 21 U.S.C. 360oo(a)(1); (2) issued 22 certifications that 22 x-ray systems complied with the applicable performance standards, when they had knowledge that the certifications were false or misleading in a material respect, in violation of 21 U.S.C. 360oo(a)(5)(B); and (3) failed to notify the purchasers of 270 x-ray units that the units did not comply with the applicable performance standards, and failed to bring the 270 x-ray units into compliance with the standards, without charge, or to replace the x-ray units with like or equivalent x-ray units, or to refund the cost of the units, all in violation of 21 U.S.C. 360oo(a)(2). Therefore, we request the initiation of an action for permanent injunction and civil penalties against both the corporate and individual defendants.

A. BACKGROUND

ABC is a corporation organized under the laws of the State of Illinois, with headquarters in Peoria, Illinois, and trading and doing business in the State of Illinois. The firm became incorporated on March 23, 1967. Alan R. Smith has been President and Chief Executive Officer of the firm since 1989. He also holds the position of Corporate Treasurer. Prior to 1989, Alan R. Smith was the firm's Vice President. In his current position, Alan R. Smith is responsible for ABC's importation, production, sales, and complaint handling operations. ABC is engaged in the importation and manufacture of diagnostic x-ray systems. Since 1976, ABC has imported two basic x-ray units, models 11 and 12, from X-Ray Company in Japan. ABC

manufactures these x-ray units for use as portable, general purpose systems or as mobile, wall-mounted, or stationary podiatry systems.¹

Models 13, 14, 15, and 16 (mobile and wall-mounted podiatry x-ray systems), and models 17, and 18 (portable, general purpose x-ray systems), are the products at issue in the proposed injunction and civil penalties action.

B. APPLICABLE LAW

The Electronic Product Radiation Control Program (the Program), 21 U.S.C. 360hh - 360ss, is part of the Federal Food, Drug, and Cosmetic Act. Congress intended the Program to protect the public from the hazard of unnecessary exposure to radiation emitted by electronic products such as diagnostic x-ray systems. To achieve this end, the Program proscribes a manufacturer from introducing into commerce any electronic product that does not comply with the applicable standards promulgated by the Commissioner of Food and Drugs under authority delegated to him by the Secretary of Health and Human Services ("Secretary") under 21 CFR 5.10(a)(3). 21 U.S.C. 360oo(a)(1).

The standards promulgated by the Commissioner include a light localizer illuminance requirement, 21 CFR 1020.31(d)(2)(ii), and a contrast ratio requirement, 21 CFR 1020.31(d)(2)(iii). X-ray systems use a light localizer to define the light field so the operator of the equipment can adjust the x-ray field to the proper image receptor size. The contrast ratio requirement exists to permit the operator to align the film with the edges of the x-ray field. Failure of a system to meet these two requirements could cause the operator to visualize inaccurately the x-ray field, and could result in an x-ray field that is larger than necessary for the examination. An x-ray field that is too large or misaligned could overexpose the patient to radiation, and could unnecessarily expose sensitive body organs to radiation. If critical organs are exposed to radiation, there is an increased risk to the patient of cell damage and cancer.

ABC and Alan R. Smith, as importers of diagnostic x-ray equipment and manufacturers of complete diagnostic x-ray systems, are "manufacturers" within the meaning of 21 U.S.C. 360hh(3) and 21 CFR 1000.3(n).

In addition to prohibiting manufacturers from placing noncompliant products into commerce, the Program also requires that manufacturers certify that their products meet the applicable standards. 21 U.S.C. 360kk(h). The Program prohibits a manufacturer from certifying that a product complies with the applicable performance standards when the manufacturer, in the exercise of due care, would have reason to know that the certification is false or misleading in a material respect. 21 U.S.C. 360oo(a)(5)(B). Furthermore, the Program requires that manufacturers notify the users of equipment that it does not meet the performance standards and correct those systems that are violative. 21 U.S.C. 360oo(a)(2). Specifically, the manufacturers must notify promptly the Secretary and the dealers, distributors, and/or first

¹ ABC's models 11 and 12 x-ray systems are each made up of two different components. One component is comprised of a tube housing assembly, a high voltage generator, and an x-ray control. The second component, a collimator, is a beam-limiting device that provides a means to restrict the dimensions of the x-ray field. ABC has equipped both the models 11 and 12 x-ray systems with model 19 collimators. The only difference between the model 11 and 12 systems is that model 11 has a fixed output tubehead and model 12 has a variable output tubehead. The components of the systems are otherwise identical.

ABC's podiatry x-ray systems are designated as follows: stationary: models 20 and 21; mobile: models 13 and 14; and wall-mounted: models 15 and 16. ABC's portable, general purpose x-ray systems are designated as models 17 and 18.

purchasers of any electronic products that have a defect or that do not comply with any applicable performance standard. 21 U.S.C. 360ll(f). Manufacturers must also bring the violative product into compliance with the standards, without charge, or replace the product with a like or equivalent product that meets the standards, or refund the cost of the product. 21 U.S.C. 360ll(f).

A manufacturer who violates any of the provisions described above is subject to civil penalties of not more than \$1,000 per violation, up to a total of \$300,000 for any related series of violations. 21 U.S.C. 360pp(b)(1).

C. CHARGES AND SUPPORTING EVIDENCE

The attached complaint charges each defendant with 149 violations of 21 U.S.C. 360oo(a)(l), introducing into commerce electronic products that do not comply with the applicable standards. The complaint also charges each defendant with 22 violations of section 360oo(a)(5)(B), issuing 22 certifications that 22 x-ray products complied with the applicable performance standards, when, in the exercise of due care, they should have known that the certifications were false or misleading in a material respect. Finally, the complaint charges each defendant with 270 violations of 21 U.S.C. 360oo(a)(2), failing to notify users that the equipment was violative and failing to bring the equipment into compliance, without charge, or replace the violative equipment, or refund the cost of the equipment.

The employee from FDA's Winchester Engineering and Analytical Center (WEAC) who tested the defendants' x-ray system will testify that the defendants' mobile and wall-mounted podiatry x-ray systems and their portable, general purpose x-ray systems do not comply with the light illuminance, contrast ratio, and labeling and certification requirements, 21 CFR 1020.31(d)(2)(ii) and (iii) and 21 CFR 1010.2, respectively. A witness from the Center for Devices and Radiological Health (CDRH) will be available to provide expert testimony concerning the diagnostic x-ray standards and the health risks associated with x-ray systems that fail to meet the performance standards.

FDA investigators who conducted the inspections at ABC will testify that the defendants placed into commerce a total of 149 violative x-ray units between January 18, 1991 and August 8, 1995. The investigators will also testify that defendants sold 22 of these units, with certification, after they had knowledge that the units did not comply with the regulations. In addition, the investigators will produce evidence documenting that the defendants sold a total of 270 noncompliant units from January 21, 1988 through August 8, 1995. The defendants did not notify the users of the 270 x-ray systems about the violations, nor did the defendants take action to correct the violations.

D. DEFENDANTS' VIOLATIVE CONDUCT

1. The Initial Warning Letter and Follow-Up Correspondence

On August 9, 1993, CDRH issued a Warning Letter to the defendants, advising them that WEAC had tested their model 12 x-ray system and found that it did not comply with the required standards. Specifically, the unit did not comply with: (1) the x-ray tube current accuracy requirement, 21 CFR 1020.31(a)(4); (2) the light localizer illuminance and contrast ratio requirements, 21 CFR 1020.31(d)(2)(ii) and (iii); and (3) the labeling and certification requirements, 21 CFR 1010.2. The letter advised defendants that they could refute the findings

made by WEAC, request an exemption from the standards, or submit a corrective action plan that included notifying the purchasers of the violative equipment.

Following a meeting between CDRH and Alan R. Smith on September 24, 1993, CDRH sent a letter to the defendants, reiterating that defendants' mobile and wall-mounted podiatry x-ray systems and portable, general purpose x-ray systems did not comply with the above-referenced requirements. The letter also clarified an issue raised in the meeting concerning the meaning of the term "maximum SID [source to image receptor distance]."2 The letter stated that the "maximum SID," as used in 21 CFR 1020.31(d)(2)(ii) and (iii), is determined by equipment design and not by a label statement.

2. Defendants' Request for a Variance from the Applicable Standards

Defendants, in a letter to CDRH dated November 4, 1993, requested that CDRH grant them a variance from the technique factor accuracy requirement, 21 CFR 1020.31(a)(4), the light illuminance and contrast ratio requirements, 21 CFR 1020.31(d)(2)(ii) and (iii), and the labeling and certification requirements, 21 CFR 1010.2, for the model 12 x-ray systems that they had in stock and in production at that time. Citing the financial burdens that would befall the company if it had to cancel pre-existing orders or retrofit or discard the systems, and the fact that no significant risk of injury existed if the systems were used at a SID of 21 inches, defendants asked CDRH to allow them to distribute the remaining model 12 units that they had in stock.

3. The Second Warning Letter

CDRH sent defendants a second Warning Letter on January 6, 1994. The letter stated that the defendants' model 11 x-ray systems had the same light localizer and contrast ratio violations as the model 12. The letter demanded that defendants respond to CDRH within fifteen days to inform it whether the firm intended to refute the allegations, request an exemption from the standards, or provide purchaser notification and a corrective action plan.

4. CDRH's Response to Defendants' Request for a Variance

CDRH treated the defendants' November 4, 1993 request for a variance for the model 12 units as a request for a variance for the model 11 units as well. In a separate letter dated January 6, 1994, CDRH notified the defendants that their request for a variance was unacceptable for the portable, general purpose x-ray system.

By letter dated February 16, 1994, CDRH notified the defendants that their request for a variance and corrective action plan was approved for the mobile and wall-mounted podiatry x-

2 The performance standard for radiographic equipment is found in 21 CFR 1020.31. The visual definition standards that mobile and stationary general purpose x-ray systems must attain, including light illuminance and contrast ratio requirements, are found in 21 CFR 1020.31(d)(2)(ii) and (iii). These regulations both use the term "maximum SID" in defining the requirements.

Alan R. Smith contended that because his user manuals directed the user to place the x-ray system at a SID of 21 inches, 21 inches was the "maximum SID." Therefore, he argued, his x-ray units met the light illuminance and contrast ratio requirements because they complied with the performance standards at a SID of 21 inches. The design of defendants' mobile and wall-mounted podiatry x-ray systems and portable, general purpose x-ray systems, however, allows the systems to attain a maximum SID of 40 inches. WEAC tested a model 12 unit at a SID of 40 inches and found that it did not comply with the performance standards. CDRH notified the defendants that because the x-ray systems could be used at a maximum SID of 40 inches, the systems would have to comply at that distance. CDRH explained that it was not sufficient simply to instruct users to operate the equipment at 21 inches only.

ray systems. The variance and corrective action plan applied only to those systems that had been manufactured and imported by the defendants prior to August 9, 1993.³ The letter explained that the corrective action plan required the defendants to do the following: (1) affix a label to the collimator of all podiatry units introduced into commerce prior to August 9, 1993, which stated, "This collimator is certified under the provisions of variance number 99V dated February 16, 1994, for podiatry use only at a maximum source to image distance of 21 inches;" (2) confirm the calibration of the tube current accuracy when they attached the variance label to each unit; (3) notify the users of the mobile and wall-mounted podiatry x-ray systems about the recall; and (4) provide CDRH with a time frame for implementing the corrective action plan and details on how the corrective action plan would be accomplished.

5. Subsequent Correspondence Between CDRH and Defendants

CDRH sent letters to the defendants dated March 11, March 31, and May 3, 1994. These letters advised defendants that they had not yet (1) submitted a corrective action plan for the portable, general purpose x-ray systems; (2) applied the variance labels to the mobile and wall-mounted podiatry x-ray systems already in commerce; (3) provided any plan for accomplishing the approved corrective action plan for the mobile and wall-mounted podiatry x-ray systems; and (4) provided a user notification letter and a list of end-user addresses to FDA's District/Division/Program Office.

The defendants, in a letter to CDRH dated April 1, 1994, again questioned the definition of the term "maximum SID," contending that CDRH had incorrectly interpreted the language of the regulations. CDRH's May 3, 1994 letter to the defendants reiterated the definition of "maximum SID."⁴ The letter further advised the defendants that their testing and quality control program for the portable, general purpose x-ray systems had not been approved, and therefore, they could no longer sell or introduce their general purpose models into commerce until an acceptable replacement collimator had been located or designed.

6. Correspondence Between the Defendants and the----- Division/Program

On June 27, 1994, the defendants provided the District /Division/Program with draft versions of letters to be sent out to notify dealers who had purchased noncompliant x-ray systems from defendants. FDA's District /Division/Program Director wrote the defendants on July 5, 1994, suggesting some changes in the wording of these letters. The District /Division/Program Director's letter also notified defendants that they still had not met the conditions of the variance and they had not submitted any monthly recall status reports to the District/Division/Program.

³ Defendants subsequently requested, by letter dated March 3, 1994, that x-ray units en route from Japan be included in the variance. CDRH denied this request by letter dated March 31, 1994. The letter explained that units that had not yet been introduced into United States commerce at the time the variance was granted, i.e., those that had not passed through United States Customs, were to meet full compliance without applying a variance.

⁴ On October 5, 1994, the defendants sent another letter to CDRH requesting clarification of the term "maximum SID" in the performance standard. CDRH responded by letter dated December 6, 1994, reiterating the definition of the term previously stated in the letter to defendants dated May 3, 1994. CDRH's letter also delineated all of the violations associated with the defendants' podiatry and general purpose systems. The letter advised defendants that they were required to report to the _____ Division/Program and that they were to submit information to CDRH regarding the corrective action plan for the general purpose systems.

In a letter dated July 15, 1994, the defendants disputed that their recall was ineffective or failed to meet the conditions of the variance. The defendants stated that the letters notifying users that the systems did not comply with the standards could not be finalized yet. They estimated that they would notify the model 11 x-ray system users, by letter, during the first week of August 1994. The defendants explained that they could not establish a time frame yet for notifying the model 12 x-ray system users. The defendants also promised to submit monthly reports to FDA's District /Division/Program.

By letter dated September 12, 1994, FDA's District /Division/Program addressed some of the issues raised by the defendants' July 15, 1994 letter. The District /Division/Program informed defendants that: (1) they already should have sent out letters notifying users of the violative nature of the x-ray systems; and (2) they should have completed their corrective action plan for the mobile and wall-mounted podiatry x-ray systems. The defendants were further reminded that they had delayed initiating the corrective action plan for more than a year, and they were warned that further delays would not be tolerated.

7. The First Inspection

An inspection conducted on June 20, 1994 revealed that the defendants knowingly continued to distribute x-ray systems that did not comply with the applicable performance standards, even after receiving Warning Letters explaining that the machines violated the performance standards. Specifically, after February 16, 1994, the date on which the variance was approved for the podiatry x-ray systems that were in defendants' inventory as of August 9, 1993, defendants sold one model 13 unit that had been imported prior to August 9, 1993 and was already in stock. The inspection further revealed that a shipment of ten model 11 units was received from Japan on October 10, 1993, and of that shipment, five were configured and sold as model 13 systems and one as a model 15 system. Therefore, the units received on October 10, 1993 should have been excluded from the variance and corrected under the approved corrective action plan prior to distribution.

8. The Second Inspection

A reinspection of ABC held on July 18, 1995, revealed that since the previous inspection, the defendants had refurbished and resold eight podiatry x-ray units, two of which were sold without variance labels attached. The inspection also revealed that of twenty-four model 11 units imported and received on November 4, 1994, the defendants sold one model 13 unit. The invoice noted that this unit, which was shipped to Macomb, Michigan, was to be installed in Canada. The inspection further revealed that defendants had not yet submitted a corrective action plan for the portable, general purpose x-ray systems.

Both inspections conducted at ABC identified a total of 270 violative model 11 and 12 x-ray systems that defendants had sold between January 21, 1988 and August 8, 1995. Defendants sold 121 of the 270 violative units between January 21, 1988 and January 18, 1991. Between January 18, 1991 and August 8, 1995, defendants sold a total of 149 violative systems, including 22 systems that were sold after September 24, 1993, the date on which defendants were notified that the x-ray systems failed to meet the performance standards.

9. Defendants' Failure to Comply with the Act

Each defendant has committed 441 violations of the Act. Defendants placed into commerce 149 x-ray units that did not comply with the light illuminance, contrast ratio, and labeling and

certification requirements, 21 CFR 1020.31(d)(2)(ii) and (iii) and 21 CFR 1010.2, in violation of 21 U.S.C. 360oo(a)(1). Defendants certified that 22 of these units met the applicable performance standards, despite their knowledge that the units did not comply with the standards, in violation of 21 U.S.C. 360oo(a)(5)(B). Finally, defendants failed to notify the users of the 270 noncompliant systems already in commerce, and they failed to bring the 270 units into compliance, or replace the 270 units, or refund the cost of the 270 units, all in violation of 21 U.S.C. 360oo(a)(2).

To date, the defendants have failed to implement their corrective action plan for the mobile and wall-mounted podiatry x-ray systems, and they have failed to submit and implement a corrective action plan for the portable, general purpose x-ray systems. Furthermore, they have not provided notice to purchasers or provided any status reports of their activities to the District /Division/Program.

E. RESPONSIBILITY OF INDIVIDUAL DEFENDANT FOR THE ALLEGED VIOLATIONS

Mr. Smith, as president of ABC, has ultimate responsibility for all facets of the firm's operations. The Warning Letters and other pertinent correspondence from FDA, as well as the investigators' verbal discussions concerning the violations found, were all directed specifically to Mr. Smith. Mr. Smith personally responded to FDA's letters, has personally met with CDRH to discuss the problems, and has had both the knowledge and authority to initiate the necessary corrections.

As the most responsible company official, Mr. Smith is legally liable in his individual capacity for civil penalties under the Act. 21 U.S.C. 360pp(b)(1); United States v. Park, 421 U.S. 658 (1975); United States v. Dotterweich, 320 U.S. 277 (1943); United States v. Hodges X-Ray, Inc., 759 F.2d 557 (6th Cir. 1985).

F. ISSUES RAISED BY THE REFERRAL

By this referral, we are seeking an injunction and civil penalties rather than a seizure of products. The seizure remedy is inadequate in this case because the stock of units on hand is small and the units cannot be identified as violative until configuration, consignment, and sale of the final components and accessories.⁵ Furthermore, an injunction would allow us to require the defendants to: (1) implement the approved corrective action plan for the mobile and wall-mounted podiatry x-ray systems; (2) submit and implement a corrective action plan for the portable, general purpose x-ray systems; and (3) notify the Secretary and affected users of the violations.

Also, please note that WEAC only tested the portable, general purpose model 12. We know, however, that the portable, general purpose model 11, and the mobile and wall-mounted models 11 and 12 podiatry x-ray systems, all violate the same performance standards as the portable, general purpose model 12. The certifiable parts of all of these systems are exactly the same. The defendants were notified that none of these units complied with the performance standards in their meeting with CDRH on September 24, 1993, and they received a written Warning Letter to that effect on January 6, 1994.

⁵ A model 11 or model 12 unit in the stationary podiatry configuration meets all of the required performance standards, whereas the same unit in a mobile or wall-mounted podiatry configuration would violate the performance standards.

Several other issues are raised by this referral. First we recommend two charges against defendants for their reintroduction of refurbished, used units into commerce. Mr. Smith claimed to have sold eight reconditioned units under the variance provisions, stating that the firm placed the proper variance label on the units. FDA inspectors checked six of the eight units and found that two of them did not contain variance labels. Accordingly, we have recommended charging defendants only with placing two of these reconditioned units into commerce with false certification. Second, although the defendants may claim that they have notified some dealer distributors to obtain end-user locations, defendants have not followed-up or attempted to notify end-users and correct the units at the user level, as CDRH instructed them to do as part of the variance granted by letter dated February 16, 1994. Finally, it is possible that ABC and Alan R. Smith will claim that they will be driven into bankruptcy if forced to pay \$300,000 each in civil penalties. The financial solvency of the firm or the individual is irrelevant to the imposition of liability, although it is an equitable factor that the district court may take into consideration when determining the proper amount of penalties. Hodges X-Ray, 759 F.2d at 564.

G. CASE PROCESSING

We are enclosing a copy of our recommended Complaint for Injunction and Civil Penalties. The principal witnesses in the case will be the person who performed the test on the x-ray systems at WEAC, the FDA representatives who conducted the inspections and obtained pertinent records and affidavits, and experts from CDRH.

Please inform us promptly of the name of the attorney in your office to whom you assign this referral. [insert name and telephone number] is the assigned attorney in our office. We expect that she will participate fully in all phases of the case. All questions regarding this referral should be directed to her. If your office decides to forward this matter to the U.S. Attorney's office, please notify us promptly of the date you do so and, if known, the name of the Assistant U.S. Attorney assigned to the case.

Very truly yours,

Chief Counsel
Food and Drug Administration

Enclosures

Exhibit 6-30**EXAMPLE OF COMPLAINT FOR INJUNCTION AND CIVIL PENALTY**

IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF ILLINOIS

EASTERN DIVISION

62.UNITED STATES OF AMERICA,	63.)	64.
65.Plaintiff,	66.)	67.Civil Action
68.v.	69.)	70.No.
71.ABC COMPANY, INC., a corporation,	72.)	73.Judge
74.And	75.)	76.
77.ALAN R. SMITH, an individual,	78.)	79.
80.Defendants	81.)	82.

COMPLAINT FOR PERMANENT INJUNCTION AND FOR CIVIL PENALTIES

The United States of America, plaintiff, by its undersigned attorneys, respectfully represents to this Honorable Court as follows:

INTRODUCTION

1. This action is brought pursuant to the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. 360pp to:
 - a. enjoin and restrain the defendants from violating 21 U.S.C. 360oo(a)(1), (a)(2), and (a)(5)(B), and
 - b. enforce the Act's radiological health civil penalty provisions, 21 U.S.C. 360pp(b)(1), in accordance with 28 U.S.C. 1355.

JURISDICTION AND VENUE

2. This Court has jurisdiction over this action pursuant to 21 U.S.C. 360pp(a) and 28 U.S.C. 1331, 1337, 1345, and 1355.
3. Venue in this district is proper pursuant to 21 U.S.C. 360pp(c), 28 U.S.C. 1391(b), and 28 U.S.C. 1395(a).

COUNT ONE**(Presenting a Cause of Action to Restrain Violations of 21 U.S.C. 360oo)**

4. Defendant ABC Company, Inc. (ABC), is a corporation organized and existing under the laws of the State of Illinois and at all times relevant to the allegations in this Complaint, trading

and doing business at 38 Main Street, Peoria, Illinois, within the jurisdiction of this Court. The firm became incorporated on March 23, 1967.

5. Defendant, Alan R. Smith, an individual, is and has been since 1989, the President and Chief Executive Officer of ABC. Prior to that time, Mr. Smith was the firm's Vice President. He also currently holds the position of Corporate Treasurer. At all times relevant to this action, Mr. Smith performed his duties at 38 Main Street, Peoria, Illinois, within the jurisdiction of this Court. Mr. Smith has ultimate responsibility for all facets of the firm's operations.

6. Defendants are, and at all times relevant to this action have been, engaged in the business of importing and manufacturing diagnostic x-ray systems which are "electronic products" within the meaning of 21 U.S.C. 360hh(2). Accordingly, each defendant was and is a "manufacturer" of electronic products within the meaning of 21 U.S.C. 360hh(3).

Failure to Cease Introduction of Violative Products Into Commerce

7. Pursuant to 21 U.S.C. 360ii(a), the Commissioner of Food and Drugs under authority delegated to him by the Secretary of Health and Human Services ("Secretary") under 21 CFR 5.10(a)(3), promulgated regulations prescribing performance standards for diagnostic x-ray systems and their major components. These regulations are codified, in pertinent part, at 21 CFR 1020.30-33.

8. On August 9, 1993, the United States Food and Drug Administration ("FDA") notified defendants that their model 12 x-ray systems failed to meet, inter alia, the light localizer illuminance requirements, the contrast ratio requirements, and the labeling and certification requirements, 21 CFR 1020.31(d)(2)(ii) and (iii) and 1010.2, respectively.

9. X-ray systems use a light localizer to define the light field so the operator of the equipment can adjust the x-ray field to the proper image receptor site. The contrast ratio requirement exists to permit the operator to align the film with the edges of the x-ray field. Failure of a system to meet these two requirements could cause the operator to visualize inaccurately the x-ray field, and could result in an x-ray field that is larger than necessary for the examination. An x-ray field that is too large or misaligned could overexpose the patient to radiation, and could unnecessarily expose sensitive body organs to radiation. If critical organs are exposed to radiation, there is an increased risk to the patient of cell damage and cancer.

10. Defendants met with FDA's CDRH on September 24, 1993. At that time, CDRH notified defendants that their mobile and wall-mounted podiatry x-ray systems, models 13, 14, 15, and 16, and their portable, general purpose x-ray systems, models 17 and 18, all failed to meet the requirements cited in the Warning Letter of August 9, 1993. By follow-up letter dated October 5, 1993, and by second Warning Letter dated January 6, 1994, CDRH reiterated to defendants that all of the above-mentioned units were noncompliant. On February 16, 1994, CDRH approved a corrective action plan for the podiatry units defendants placed into commerce prior to August 9, 1993. CDRH notified defendants that they were to submit a corrective action plan for the general purpose x-ray systems. From August 9, 1993 through March 30, 1995, the defendants exchanged numerous correspondences with CDRH and FDA's Chicago District regarding the noncompliance of the x-ray units.

11. Nevertheless, after September 24, 1993, the date on which FDA notified defendants that their mobile and wall-mounted podiatry x-ray systems and their portable, general purpose x-ray systems did not comply with the applicable performance standards, the defendants sold

the following 22 units in violation of applicable performance standards, including 16 model 13 units, 1 model 15 unit, 1 model 17 unit, and 4 model 18 units:

Model 13 Units (16 total)

<u>83.SHIPPING DATE</u>	<u>84.INVOICE#</u>	<u>85.SERIAL#</u>	<u>86.SOLD TO</u>
87.03/16/94	88.20603	89.16226	90.Podiatry Supply Co. (Heights, OH)
91.05/05/94	92.21004	93.16218	94."
95.12/01/94	96.22625	97.16996	98."
99.	100.	101.16997	102."
103.05/25/94	104.21175	105.16645	106."
107.	108.	109.16646	110."
111.	112.	113.16649	114."
115.06/06/94	116.21235	117.16235	118."
119.	120.	121.16648	122."
123.	124.	125.16651	126."
127.03/28/94	128.20668	129.16232	130.Healthcare (Brooklyn, NY)
131.10/04/94	132.22221	133.15549	134.Podiatry (Stony Brook, NY)
135.11/11/93	136.19660	137.13682	138.Supply Service (Gettysburg, PA)
139.04/20/94	140.20885	141.16231	142."
143.12/13/94	144.22708	145.16223	146."
147.02/07/95	148.23194	149.17002	150."

Model 15 Unit (1 total)

<u>151.SHIPPING DATE</u>	<u>152.INVOICE#</u>	<u>153.SERIAL#</u>	<u>154.SOLD TO</u>
155.03/23/94	156.20635	157.16650	158.Podiatry (Stony Brook, NY)

Model 17 Unit (1 total)

<u>159.SHIPPING DATE</u>	<u>160.INVOICE#</u>	<u>161.SERIAL#</u>	<u>162.SOLD TO</u>
163.09/28/93	164.19359	165.16116	166.Supply Service (Gettysburg, PA)

Model 18 Units (4 total)

<u>167.SHIPPING DATE</u>	<u>168.INVOICE#</u>	<u>169.SERIAL#</u>	<u>170.SOLD TO</u>
171.10/15/93	172.19486	173.16360	174.Tech, Inc. (Walnut, CA)
175.01/06/94	176.20033	177.16357	178.Ocean, Ltd. (San Jose, CA)
179.	180.	181.16363	182."
183.03/09/94	184.20495	185.16361	186.A.S. (Calcutta, India)

By introducing into commerce these 22 x-ray systems that did not comply with the applicable performance standards, defendants committed 22 violations of 21 U.S.C. 360o(a)(1).

12. Between March 20, 1991 and September 24, 1993, the date on which defendants were notified that their mobile and wall-mounted podiatry x-ray systems and their portable general purpose x-ray systems violated the applicable performance standards, defendants introduced into commerce the following 121 x-ray systems in violation of applicable performance standards, including 27 model 15 units, 1 model 16 unit, 49 model 13 units, 10 model 14 units, 15 model 17 units, and 19 model 18 units:

Model 15 Units (27 total)

<u>187.SHIPPING DATE</u>	<u>188.INVOICE#</u>	<u>189.SERIAL#</u>	<u>190.SOLD TO</u>
191.08/01/91	192.13639	193.14418	194.Medical Equipment Co. (Chicago, IL)
195.06/09/93	196.18608	197.16119	198.X-Ray Supply Corp. (Miami, FL)
199.12/18/91	200.14629	201.14424	202.Podiatry Supply Co. (Heights, OH)
203.	204.	205.14427	206."
207.01/29/92	208.14906	209.14576	210."
211.04/23/92	212.15588	213.15434	214."
215.03/11/93	216.17949	217.16040	218."
219.09/06/91	220.13904	221.14262	222.Healthcare (Brooklyn, NY)
223.10/02/91	224.14066	225.14423	226."
227.12/05/91	228.14507	229.14432	230."
231.01/24/92	232.14858	233.14582	234."
235.04/23/92	236.15577	237.15446	238."
239.05/22/92	240.15824	241.15439	242."
243.06/12/92	244.15966	245.15444	246."
247.	248.15967	249.15435	250."
251.04/02/91	252.12728	253.14258	254.Equipment Distributors (Syossett, NY)
255.12/05/91	256.14465	257.14428	258."
259.01/03/92	260.14691	261.14585	262."
263.01/22/92	264.14827	265.14580	266.Podiatry, Inc. (Freeport, NY)
267.02/14/92	268.15029	269.14567	270."
271.05/21/91	272.13100	273.14259	274.Supply Service (Tyler Hill, PA)
275.01/21/93	276.17558	277.16031	278."
279.02/11/93	280.17753	281.16034	282."
283.	284.	285.16045	286."
287.03/16/93	288.17993	289.16030	290."
291.	292.	293.16041	294."
295.04/21/93	296.18296	297.16123	298."

Model 16 Unit (1 total)

<u>299.SHIPPING DATE</u>	<u>300.INVOICE#</u>	<u>301.SERIAL#</u>	<u>302.SOLD TO</u>
303.01/28/93	304.17633	305.15339	306.Podiatry, Inc.(Freeport, NY)

Model 13 Units (49 total)

307. 308.	309. <u>INVOICE#</u>	310. <u>SERIAL#</u>	311. <u>SOLD TO</u>
312.03/20/91	313.12628	314.14256	315.Flag X-Ray (Bay, NY)
316.08/20/92	317.16439	318.15542	319.Medical Equipment Co. (Chicago, IL)
320.09/15/92	321.16629	322.15544	323."
324.11/11/92	325.17068	326.15975	327."
328.02/12/93	329.17768	330.16042	331."
332.02/23/93	333.17830	334.16049	335."
336.03/22/93	337.18030	338.16033	339."
340.08/04/93	341.18990	342.16121	343."
344.03/20/91	345.12630	346.14260	347.Supply Co. (Akron, OH)
348.	349.	350.14264	351."
352.	353.	354.14269	355."
356.12/18/91	357.14629	358.14421	359."
360.03/10/92	361.15245	362.13669	363."
364.04/08/92	365.15490	366.14583	367."
368.04/23/92	369.15588	370.15437	371."
372.	373.	374.15442	375."
376.06/01/92	377.15893	378.15427	379."
380.09/11/92	381.16610	382.15533	383."
384.	385.	386.15538	387."
388.	389.	390.15543	391."
392.	393.	394.15551	395."
396.09/25/92	397.16721	398.15545	399."
400.03/11/93	401.17949	402.15977	403."
404.09/01/93	405.19202	406.16236	407."
408.	409.	410.16237	411."
412.03/20/91	413.12631	414.14261	415.Podiatry Supply (Islip, NY)
416.	417.12632	418.14266	419."
420.04/23/91	421.12893	422.14255	423."
424.12/19/91	425.14620	426.14417	427."
428.	429.	430.14577	431."
432.02/26/92	433.15144	434.14584	435.Healthcare Distributors, Inc. (Palo Alto, CA)
436.03/10/92	437.15235	438.14425	439."
440.05/27/92	441.15843	442.15436	443."
444.06/30/92	445.16111	446.15430	447."
448.09/15/92	449.16609	450.15540	451."
452.11/11/92	453.17070	454.15973	455."
456.	457.	458.15980	459."
460.11/11/92	461.17073	462.15978	463.Medical Supply (Reno, NV)
464.04/12/91	465.12829	466.14253	467.Medical Healthcare (Montauk, NY)
468.07/30/92	469.16326	470.15537	471.Stone & Palo, Inc. (Plainview, NY)
472.08/27/93	473.19180	474.16222	475."
476.06/20/91	477.13341	478.14263	479.Best Service (Philadelphia, PA)
480.12/12/91	481.14600	482.14419	483."
484.12/23/91	485.14653	486.14570	487."
488.09/14/92	489.16605	490.15547	491."
492.09/15/92	493.16630	494.15539	495."
496.02/11/93	497.17753	498.16037	499."
500.03/16/93	501.17993	502.16036	503."

Model 14 Units (10 total)

<u>307.SHIPPING DATE</u>	<u>308.INVOICE#</u>	<u>309.SERIAL#</u>	<u>310.SOLD TO</u>
311.11/09/92	312.17043	313.15340	314.Equipment & Supply (Denver, CO)
315.02/12/93	316.17768	317.15471	318."
319.08/04/92	320.16348	321.15475	322.B & S Supply Co. (Pittsburgh, PA)
323.05/26/93	324.18584	325.16271	326."
327.01/21/93	328.17562	329.15219	330.Chris & Sons (Las Vegas, NV)
331.03/25/92	332.15347	333.15224	334.Pebbles & Sam Co. (Phoenix, AZ)
335.01/04/93	336.17435	337.15215	338."
339.11/20/92	340.17127	341.15338	342.Foot Service Inc. (Maspeth, NY)
343.01/21/93	344.17558	345.15335	346."
347.06/09/93	348.18619	349.16282	350.Southern Supply (San Jose, CA)

Model 17 Units (15 total)

<u>351.SHIPPING DATE</u>	<u>352.INVOICE#</u>	<u>353.SERIAL#</u>	<u>354.SOLD TO</u>
355.01/07/92	356.14739	357.14430	358.BB X-Ray (Detroit, MI)
359.01/14/92	360.14781	361.14575	362."
363.09/23/92	364.16689	365.15541	366."
367.07/08/91	368.13452	369.14270	370.Advantage Podiatry (Atlanta, GA)
371.06/03/91	372.13203	373.14429	374.Veterinary Supply (Baldwin, NY)
375.05/05/92	376.15670	377.15432	378.Tech, Inc. (Walnut, CA)
379.03/22/93	380.18029	381.16044	382.Podiatry Supply Co. (Heights, OH)
383.04/09/93	384.18210	385.16118	386."
387.05/17/93	388.18470	389.16047	390."
391.12/16/92	392.17335	393.16035	394.Brokerage (Orlando, FL)
395.	396.	397.16048	398."
399.11/13/91	400.14354	401.14420	402.S & S X-Ray Service (Pittsburgh, PA)
403.06/25/93	404.18729	405.16032	406."
407.10/04/91	408.14089	409.14251	410.X-Ray Supply (Provo, UT)
411.05/05/92	412.15682	413.15440	414.B.C.A. Inc. (San Francisco, CA)

Model 18 Units (19 total)

415.SHIPPING DATE	416.INVOICE#	417.SERIAL#	418.SOLD TO
419.04/22/93	420.18309	421.16270	422.36 X-Ray (Greenwood Lake, NY)
423.05/05/92	424.15670	425.15222	426.Tech, Inc. (Walnut, CA)
427.05/14/93	428.18592	429.16364	430.Tech, Inc. (Walnut, CA)
431.	432.	433.16365	434."
435.08/23/93	436.19135	437.16359	438."
439.05/11/93	440.18424	441.16273	442.Industries Inc. (Atlantic City, NJ)
443.04/07/93	444.18195	445.15216	446.X-Ray Service (Terra Haute, IN)
447.09/22/92	448.16680	449.15224	450.Available Supply (Boise, ID)
451.11/06/92	452.17034	453.15341	454."
455.	456.	457.15477	458."
459.02/02/93	460.17662	461.14878	462."
463.	464.	465.15342	466."
467.03/17/93	468.17999	469.15224	470."
471.04/13/93	472.18234	473.16268	474."
475.04/14/93	476.18238	477.16272	478."
479.06/07/93	480.18605	481.16275	482."
483.08/09/93	484.19019	485.16274	486."
487.	488.	489.16283	490."
491.05/07/93	492.18400	493.16276	494.California Labs (Los Angeles, CA)

By introducing into commerce these 121 x-ray systems that did not comply with the applicable performance standards, defendants committed 121 violations of 21 U.S.C. 360oo(a)(1).

Failure to Meet Certification Requirements

13. Pursuant to 21 U.S.C. 360kk(h), every "manufacturer" of an electronic product to which a performance standard is applicable is required to certify that such product conforms to all applicable performance standards. Such certification shall be based upon a test, in accordance with the performance standards, of the individual article to which it is attached. The manufacturer must furnish that certification to the dealer or distributor, in the form of a label or tag permanently affixed to or inscribed on such product. 21 CFR 1010.2.

14. Defendants failed to comply with the certification requirements for electronic products when they certified that the 22 podiatry units described in paragraph 11 met all applicable performance standards. The defendants, in the exercise of due care, had reason to know that such certifications were false or misleading in a material respect, in that FDA had notified them that the units failed to meet the applicable performance standards. Therefore, by affixing materially false or misleading certifications to the 22 units described in paragraph 11, the defendants committed 22 violations of 21 U.S.C. 360oo(a)(5)(B).

Failure to Notify and Failure to Repair, Replace, or Refund

15. Pursuant to 21 U.S.C. 360ll, every manufacturer of electronic products who discovers that an electronic product produced, assembled, or imported by him does not comply with the performance standards, must immediately notify the Secretary and the dealers, distributors, and/or first purchasers of any electronic products that have a defect or that do not comply with any applicable performance standard, and must also: (1) without charge, bring such product into conformity with the applicable standard or remedy such defect; (2) replace each product with a like or equivalent product which complies with each applicable standard; or (3) refund

the cost of such product. The Commissioner has promulgated regulations, 21 CFR 1002, 1003, and 1004, which prescribe how such notification and correction shall be accomplished.

16. FDA determined that the 143 units described in paragraphs 11 and 12 did not comply with the light localizer, contrast ratio, and labeling and certification requirements, 21 CFR 1020.31(d)(2)(ii) and (iii) and 1010.2, respectively.

17. Moreover, defendants sold 127 units in violation of applicable performance standards from January 21, 1988 to February 19, 1991. The sales of the 127 units included 71 model 15 units, 50 model 13 units, and 6 model 17 units, and were as follows:

Model 15 Units (71 total)

696.SHIPPING DATE	697.INVOICE#	698.SERIAL#	699.SOLD TO
700.01/21/88	701.4217	702.11549	703.Medical Co. (Brook, MN)
704.05/09/88	705.5060	706.11944	707."
708.06/15/88	709.5335	710.12007	711."
712.	713.	714.12008	715."
716.11/07/88	717.6421	718.12428	719."
720.01/13/89	721.6901	722.12314	723."
724.07/17/89	725.8314	726.12903	727."
728.05/02/90	729.10435	730.13670	731."
732.01/21/88	733.4218	734.11551	735.Podiatry Supply Co. (Heights, OH)
736.01/28/88	737.4261	738.11550	739."
740.	741.	742.11559	743."
744.	745.	746.11566	747."
748.05/04/88	749.5026	750.11953	751."
752.	753.	754.11955	755."
756.	757.	758.11964	759."
760.01/13/89	761.6902	762.12425	763."
764.	765.	766.12426	767."
768.02/01/89	769.7043	770.12320	771."
772.08/22/89	773.8537	774.12910	775."
776.09/11/89	777.8671	778.12902	779."
780.10/18/89	781.8949	782.12891	783."
784.	785.8950	786.12890	787."
788.01/30/90	789.9727	790.13020	791."
792.	793.	794.13031	795."
796.04/07/90	797.10264	798.13028	799."
800.04/10/90	801.10271	802.13664	803."
804.08/14/90	805.11180	806.13776	807.Flower Podiatry Supply (Morristown, NJ)
808.12/05/89	809.9295	810.13032	811.Dental/Medical and Co. (Blacksburg, VA)
812.	813.	814.13038	815."
816.01/29/89	817.7026	818.12423	819.Equipment Distributors (Monticello, NY)
820.02/24/89	821.7264	822.12420	823."
824.	825.	826.12430	827."
828.03/14/89	829.7387	830.12325	831."
832.05/09/89	833.7874	834.12664	835."
836.	837.	838.12670	839."
840.06/21/89	841.8161	842.12892	843."
844.06/21/89	845.8162	846.12900	847."
848.07/25/89	849.8362	850.12893	851."
852.08/30/89	853.8592	854.12887	855."
856.10/16/89	857.8952	858.12895	859."
860.02/05/90	861.9794	862.13021	863."
864.04/03/90	865.10220	866.13674	867.New York Distributors (Albany, NY)
868.05/14/90	869.10532	870.13665	871."
872.09/11/90	873.11377	874.14056	875."
876.	877.	878.14062	879."

880.11/29/90	881.11878	882.14217	883.New York Medical Co. (Geneva, NY)
884.12/21/90	885.12035	886.14218	887.*
888.12/11/89	889.9337	890.13040	891.Green Surgical Supply (Dayton, OH)
892.02/22/89	893.7263	894.12315	895.Supply Service (Groton, CT)
896.	897.	898.12317	899.*
900.	901.	902.12318	903.*
904.	905.	906.12326	907.*
908.	909.	910.12328	911.*
912.08/23/89	913.8590	914.12897	915.*
916.09/13/89	917.8690	918.12915	919.*
920.	921.	922.13041	923.*
924.	925.	926.13049	927.*
928.10/10/89	929.8891	930.12888	931.*
932.	933.	934.12908	935.*
936.	937.	938.12916	939.*
940.11/29/90	941.11879	942.14223	943.*
944.	945.	946.14224	947.*
948.01/20/91	949.12210	950.14230	951.*
952.12/08/89	953.9327	954.13024	955.C & R X-Ray (Birmingham, AL)
956.	957.	958.13036	959.*
960.	961.	962.13045	963.*
964.08/15/90	965.11195	966.13773	967.*
968.	969.	970.13780	971.*
972.	973.	974.13782	975.*
976.	977.	978.13787	979.*
980.	981.	982.13790	983.*

Model 13 Units (50 total)

<u>984.SHIPPING DATE</u>	<u>985.INVOICE#</u>	<u>986.SERIAL#</u>	<u>987.SOLD TO</u>
988.01/27/88	989.4243	990.11571	991.Equipment Co. (Olney, MD)
992.	993.4244	994.11568	995."
996.03/21/88	997.4687	998.11059	999."
1000.	1001.	1002.11569	1003."
1004.05/05/88	1005.5039	1006.11954	1007."
1008.	1009.	1010.11957	1011."
1012.06/15/88	1013.5334	1014.12018	1015."
1016.	1017.	1018.12031	1019."
1020.07/06/88	1021.5490	1022.11948	1023."
1024.10/07/88	1025.6178	1026.12022	1027."
1028.10/26/88	1029.6317	1030.12020	1031."
1032.12/06/88	1033.6631	1034.12024	1035."
1036.02/03/89	1037.7054	1038.12319	1039."
1040.05/22/90	1041.10587	1042.13673	1043."
1044.01/18/91	1045.12198	1046.14252	1047."
1048.03/22/88	1049.4735	1050.11507	1051.Podiatry Supply Co. (Heights, OH)
1052.05/04/88	1053.5027	1054.11952	1055."
1056.	1057.	1058.11958	1059."
1060.02/07/89	1061.7068	1062.12323	1063."
1064.03/27/89	1065.7537	1066.12019	1067."
1068.04/04/89	1069.7603	1070.12673	1071."
1072.	1073.	1074.12675	1075."
1076.05/08/89	1077.7860	1078.12667	1079."
1080.	1081.	1082.12669	1083."
1084.11/10/89	1085.9133	1086.13025	1087."
1088.02/13/90	1089.9884	1090.13468	1091."
1092.03/29/90	1093.10182	1094.13668	1095."
1096.	1097.	1098.13677	1099."
1100.04/07/90	1101.10264	1102.13034	1103."
1104.08/28/90	1105.11277	1106.14063	1107."
1108.06/21/89	1109.8175	1110.12913	1111.Podiatry Supply (Buffalo, NY)
1112.07/17/89	1113.8317	1114.12896	1115."
1116.08/14/89	1117.8493	1118.12889	1119."
1120.01/26/90	1121.9697	1122.13465	1123."
1124.03/01/90	1125.9987	1126.13464	1127."
1128.03/29/90	1129.10204	1130.13679	1131."
1132.07/19/90	1133.10984	1134.13774	1135."
1136.01/29/89	1137.7026	1138.12421	1139.Medical Equipment Inc. (New Orleans, LA)
1140.08/30/89	1141.8591	1142.12914	1143."
1144.01/28/90	1145.9698	1146.13023	1147."
1148.05/14/90	1149.10531	1150.13672	1151.New York Supply (Tarrytown, NY)
1152.09/11/90	1153.11377	1154.14058	1155."
1156.12/11/90	1157.11962	1158.14229	1159.Medical Equipment Inc. (Erie, PA)
1160.09/06/89	1161.8632	1162.13035	1163.Surgical Supplies (Louisville, KY)
1164.02/02/90	1165.9783	1166.13473	1167."
1168.03/21/89	1169.7491	1170.12322	1171.Service for Surgery (Dover, DE)
1172.	1173.	1174.12427	1175."
1176.11/29/90	1177.11880	1178.14225	1179."
1180.01/02/91	1181.12106	1182.14216	1183."
1184.01/20/91	1185.12210	1186.14221	1187."

Model 17 Units (6 total)

<u>1188.SHIPPING DATE</u>	<u>1189.INVOICE#</u>	<u>1190.SERIAL#</u>	<u>1191.SOLD TO</u>
1192.02/08/91	1193.12356	1194.14226	1195.S-5 X-Ray (St. Louis, MO)
1196.02/19/91	1197.12433	1198.14228	1199.Associate Radiology (Seattle, WA)
1200.01/01/91	1201.12157	1202.13997	1203.A & A X-Ray (Scranton, PA)
1204.01/23/91	1205.12213	1206.14055	1207."
1208.11/02/90	1209.11741	1210.13997	1211.X-Ray Supply (Dallas, TX)
1212.11/29/90	1213.11881	1214.14226	1215.SMA Surgical Supply (Houston, TX)

18. On February 16, 1994, FDA notified defendants that for all of the 270 violative units that were already in commerce, they were required to notify the first purchasers, dealers, or distributors of the x-ray units, and the end-users of such products, as required by 21 U.S.C. 360ll(e), and they were further required to: (1) without charge, bring such products into conformance with the standard; (2) replace the products with like or equivalent products; or (3) make a refund of the cost of the products, as required by 21 U.S.C. 360ll(f).

19. Nevertheless, defendants failed to notify the first purchasers, dealers, or distributors and end-users of the 270 x-ray units described in paragraphs 11, 12, and 17, and they failed to (1) without charge, bring such products into conformance with the standard, (2) replace the products with like or equivalent products, or (3) refund the cost of the products, thereby committing 270 violations of 21 U.S.C. 360oo(a)(2).

COUNT TWO

(Presenting a Cause of Action to Enforce the Civil Penalties Provisions of 21 U.S.C. 360pp(b)(1))

20. This Count realleges and incorporates by reference paragraphs 1 through 19 of this Complaint as if fully set forth herein.

21. Pursuant to 21 U.S.C. 360pp(b)(1), any person who violates 21 U.S.C. 360oo shall be subject to a civil penalty of not more than \$1,000. Any violation with respect to any act or omission made unlawful by 21 U.S.C. 360oo constitutes a separate violation for purposes of 21 U.S.C. 360pp(b)(1), and the maximum civil penalty imposed on any person for any related series of violations is not to exceed \$300,000.

22. Each defendant committed a total of 435 violations of 21 U.S.C. 360oo, including: (1) 143 violations of 21 U.S.C. 360oo(a)(1); (2) 22 violations of 21 U.S.C. 360oo(a)(5)(B); and (3) 270 violations of 21 U.S.C. 360oo(a)(2). For each violation, a civil penalty of \$1,000 may be imposed. Therefore, under 21 U.S.C. 360pp, a civil penalty of \$300,000 per defendant may be imposed.

WHEREFORE PLAINTIFF PRAYS:

I. That defendants, ABC and Alan R. Smith, and all of their officers, agents, representatives, employees, successors, assigns, heirs, attorneys, and any and all persons in active concert or participation with them, or any of them, be permanently restrained and enjoined under the provisions of 21 U.S.C. 360pp(a) from directly or indirectly doing or causing to be done any of the following acts:

- a. Introducing, or delivering for introduction into commerce as defined in 21 U.S.C. 360hh(4), any diagnostic x-ray system subject to, but not in compliance with, applicable performance standards in 21 CFR 1010 and 1020;
- b. Issuing certification that x-ray equipment meets the applicable standards when they, in the exercise of due care, would have reason to know that such certification is false or misleading in a material respect;
- c. Failing to comply with 21 U.S.C. 360oo(a)(2), which specifically requires manufacturers to (1) notify the purchasers of x-ray equipment that it does not comply with the performance standards; and (2) without charge, bring their manufactured diagnostic x-ray systems into conformity with the applicable standards prescribed in 21 CFR 1010 and 1020, or replace such products with a like or equivalent product that complies with the applicable standards, or refund the cost of the violative products;
- d. Failing to implement the FDA-approved corrective action plan for ABC's mobile and wall-mounted podiatry x-ray systems, models 13, 14, 15, and 16; and
- e. Failing to submit and implement a corrective action plan for ABC's portable, general purpose x-ray systems, models 17 and 18.

II. That the defendants, ABC and Alan R. Smith, each be required to pay to the plaintiff a civil penalty, pursuant to 21 U.S.C. 360pp(b)(1), in the amount of \$300,000, for the violations herein above alleged in paragraphs 7 through 19. This amount represents a penalty to each defendant of \$1,000 per violation of 21 U.S.C. 360oo, up to the maximum penalty of \$300,000 per defendant allowed pursuant to 21 U.S.C. 360pp(b)(1).

III. That the plaintiff be granted judgment for its costs herein, and that this court grant such other and further as it deems just and proper.

Dated this [insert date] day of [insert month and year].

495.
497.
499.

502.
504.

507.
509.

515.
517.

OF COUNSEL:
[insert name]
Chief Counsel

[insert name]
Trial Attorney
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857
[insert telephone number]

496. Respectfully submitted,
498.
500. [insert name]
501. Assistant Attorney General
503.
505. [insert name]
506. United States Attorney
508.
510. [insert name]
511. Assistant U.S. Attorney
512. [insert address]
513. [insert telephone number]

516.
518. [insert name]
519. Trial Attorney
520. Office of Consumer Litigation
521. U.S. Department of Justice
522. P.O. Box 386
523. Washington, D.C. 20044
524. [insert telephone number]

Regulatory Procedures Manual

Chapter 7: RECALL PROCEDURES

This chapter contains the following sections:

Section Topic	Page
7-1 PURPOSE	4
7-2 BACKGROUND	4
7-3 SUMMARY OF FDA RESPONSIBILITIES AND PROCEDURES	5
7-3-1 Responsibilities of the Office of Strategic Planning and Operational Policy/Division of Enforcement/Recall Operations Branch (OSPOP/DE/ROB)	6
7-3-2 Responsibilities and Procedures – ORA/Office of Partnerships and Operational Policy (OPOP)	6
7-3-3 Responsibilities and Procedures – Office of Information Systems Management/ Division of System Solutions (DSS) /Enforcement Systems Branch.....	6
7-4 RECALL ENTERPRISE SYSTEM	6
7-4-1 Enforcement Report.....	7
7-5 INITIATION OF A RECALL	7
7-5-1 Firm Initiated Recalls	8
7-5-2 FDA Requested Recall	13
7-5-3 FDA Mandated and Ordered Recalls	14
7-5-4 Removals and corrections involving products exported from the U.S. and products imported to the U.S.	18
7-6 RECALL CLASSIFICATION AND STRATEGY	22
7-6-1 Health Hazard Evaluation	22
7-6-2 Classification Process	23
7-6-3 Recall Strategy.....	24
7-7 NOTIFICATIONS AND PUBLIC WARNING	25
7-7-1 Reports and Reporting Procedures.....	25
7-7-2 Notification to Other Government Agencies.....	28
7-7-3 Public Warning.....	30
7-8 RECALL MONITORING.....	33
7-8-1 Background.....	33

7-8-2	Managing FDA's Recall Audit Check (RAC) Strategy	33
7-8-3	Requesting and Reviewing Recall Status Reports	40
7-8-4	State Audits	40
7-9	RECALL TERMINATION	41
7-10	ATTACHMENTS, EXHIBITS, AND APPENDIX	42
	ATTACHMENTS:	43
	EXHIBITS:	44
	APPENDIX:	45
	Attachment A – Recall Alert Information	46
	Attachment B – Recommendation for Recall Classification	48
	Attachment B1 – Recommendation for Recall Classification and Termination	53
	Attachment C – Recall Termination or Recommendation for Termination	54
	Attachment D – Health Hazard Evaluation Worksheet	55
	Attachment D1 – 21 CFR Part 7, Guidance to Health Hazard Evaluation Committees	58
	Attachment E – Recalls Of Radiation Emitting Electronic Products Under Subchapter C - Electronic Product Radiation Control Of Chapter V Of The Federal Food, Drug, And Cosmetic Act (The Act), Formerly The Radiation Control For Health And Safety Act Of 1968 (RCHSA).....	62
	Attachment F – Recalls of Infant Formula.....	66
	Attachment G – Recalls of Medical Devices, Section 518(e).....	67
	Attachment H – Methods for Conducting Recall Effectiveness Checks	72
	Attachment I – Mandatory Recall of Tobacco Products	74
	Attachment J – Mandatory Recall Authority for Foods.....	76
	Attachment J1 – Recommendation Memorandum.....	88
	Attachment J2 – Notification of Opportunity to Initiate a Voluntary Recall	89
	Attachment J3 – Prehearing Order to Cease Distribution and Give Notice.....	91
	Attachment J4 – Denial of Hearing Request.....	93
	Attachment J5 – Hearing Report Cover Letter	94
	Attachment J6 – Hearing Report.....	95
	Attachment J7 – Vacated Order	96
	Attachment J8 – Amended Order	97
	Attachment J9 – Modified Order	98
	Attachment J10 – Mandatory Food Recall Process Flow Chart.....	99

Attachment K – Notification, Nondistribution, and Recall of Controlled Substances for Human or Animal Use.....	100
Attachment K1 – Order of Nondistribution	110
Attachment K2 – Hearing Report Cover Letter	111
Attachment K3 – Hearing Report.....	112
Attachment K4 – Vacated Order of Nondistribution	113
Attachment K5 – Continued order of Nondistribution.....	114
Attachment K6 – Amended Order to Include Recall	115
Attachment K7 – Notification, Nondistribution, and Recall of Controlled Substances for Human or Animal Use Process Flow Chart	116
Attachment L – Models for Standardized Recall Audit Check (RAC) Levels and Effectiveness of the Recall Notification System for Human Food Recalls	117
Attachment M – Medical Device Safety Alerts	122
Exhibit 7-1 Model Effectiveness Check Letter (Industry)	123
Exhibit 7-2 Model Effectiveness Check Response Format (Industry)	124
Exhibit 7-3 Model Effectiveness Check Questionnaire for Telephone or Personal Visits (Industry)	126
Exhibit 7-4 Model Recall Letter (Generic, All Centers).....	128
Exhibit 7-5 Model Recall Return Response Form.....	130
Exhibit 7-6 Model Recall Envelope	132
Exhibit 7-7 Model FDA Requested Recall Letter	133
Exhibit 7-8 Model Acknowledgement (to be used when RES automated email request cannot be used due to the RES not functioning or the firm not having an email address).....	135
Exhibit 7-9 Model Notification of Classification Letter (FDA to Recalling Firm).....	138
Exhibit 7-10 Model Recall Ineffective Recall Letter.....	139
Exhibit 7-11 Model Recall Termination Letter	140
Exhibit 7-12 Model Combined Recall Notification of Classification and Termination Letter	141
Exhibit 7-13 Model Recall Audit Check Memo Assignment	142
Exhibit 7-14 Initiating RAC by Mail or Email	143
Exhibit 7-15 Weekly Class I Recall Status Report (Optional).....	144
Exhibit 7-16 Recall Status Report Request Letter (to be used when RES automated email request cannot be used due to the RES not functioning or the firm not having an email address)	145
Exhibit 7-17 Model Reconditioning Proposal Template (FDA to Recalling Firm)	147
Exhibit 7-18 Market Withdrawal Designation Template	150

Exhibit 7-19 Market Withdrawal Designation – Additional Information Requested ..	151
Exhibit 7-20 Market Withdrawal Close Out to be Used when additional information was requested.....	152
Appendix A FDA Food Recall/Action Initiation Process Flow/Timeline for Class I Human Food Recalls (SAHCODH)	153

7-1 PURPOSE

This chapter provides definitions, responsibilities, and procedures for agency components to initiate, review, classify, publish, audit and terminate recall actions. It implements 21 CFR Part 7 Subpart C – Recalls (Including Product Corrections) – Guidelines on Policy, Procedures, and Industry Responsibilities. See also [Investigations Operations Manual \(IOM\)](#) Chapter 7 - Recall Activities. It also discusses FDA non-voluntary recalls and includes a reference to the procedures for implementing each of these authorities, including recalls of Medical Devices, Radiation Emitting Electronic Products, Biological Products, Human Tissue Intended for Transplantation, Infant Formula, Tobacco Products, and Food Products.

7-2 BACKGROUND

Recalls are an effective method for removing or correcting marketed products, their labeling, and/or promotional literature that violate the laws administered by the Food and Drug Administration (FDA). Recalls afford equal consumer protection but generally are more efficient and timely than formal administrative or judicial actions, especially when the product has been widely distributed.

FDA regulated firms may initiate a recall at any time to fulfill their responsibility to protect the public health from products that present a risk of injury or gross deception or are otherwise defective. Firms may also initiate a recall following notification of a problem by FDA or a state agency, in response to a formal request by FDA, as statutorily mandated or as ordered by FDA.

All agency components are expected to follow the requirements of this chapter. Although this chapter primarily implements 21 CFR Part 7 Subpart C, some deviation from the policy, definitions, responsibilities, and procedures under 21 CFR Part 7 Subpart C may occur with statutorily mandated and ordered recalls. See [Section 7-5-3](#). These deviations are noted throughout this chapter.

Guidelines delineating the responsibilities of industry in conducting recalls are in 21 CFR 7.40-7.59. Industry Guidance is available on the Internet at the FDA web site. It is designed for all FDA regulated industry and provides guidance both in the conduct of recalls and in the information needed by FDA to classify, monitor, and assess the effectiveness of a recall.

7-3 SUMMARY OF FDA RESPONSIBILITIES AND PROCEDURES

FDA responsibilities are summarized below. This chapter is arranged according to the following outline:

1. Initiation of a Recall. Includes voluntary, and non-voluntary recalls.
2. Determination that the Action is a Recall; Strategy; Classification. FDA formalizes the recall action by determining that the action meets the definition of a recall under 21 CFR 7.3(g)¹ or the applicable definitions for recalls conducted under different regulatory or statutory authorities. FDA reviews the information, including the recall strategy provided by the firm, assesses the health hazard presented by the recalled product, and classifies the recall in accordance with 21 CFR 7.41.
3. Notification and Public Announcement. FDA reviews a firm's recall strategy and suggests changes, including the issuance of a public announcement. FDA notifies the firm of the classification of the recall. The agency may issue its own public announcement of a firm's recall. FDA posts information about recalls at various locations on the FDA's Internet site: www.fda.gov/. FDA provides recall information to other federal and state government agencies and to foreign governments.
4. Monitoring and Auditing the Recall. FDA develops and implements a recall audit strategy to ensure that the recall action has been effective.
5. Termination of a Recall. FDA determines when a recall should be terminated.

FDA may take appropriate regulatory action or other measures when the firm fails to recall violative product or when a recall action fails. Regulatory actions will be taken in consultation and coordination with the appropriate compliance branch, the appropriate center recall and compliance staffs, OSPOP/DE/ROB, and when indicated, the Office of Chief Counsel, when:

a firm refuses to recall or sub-recall after being requested or ordered to do so by the FDA;

or

the agency has reason to believe that the firm's recall strategy is not effective, or is not being **implemented** effectively

¹ As defined in 21 CFR 7.3(g), "Recall means a firm's removal or correction of a marketed product that the Food and Drug Administration considers to be in violation of the laws it administers and against which the agency would initiate legal action, e.g., seizure. Recall does not include a market withdrawal or stock recovery." As defined in 21 CFR 7.3(j), "Market withdrawal means a firm's removal or correction of a distributed product which involves a minor violation that would not be subject to legal action by the Food and Drug Administration or which involves no violation, e.g., normal stock rotation practices, routine equipment adjustments and repairs, etc."

7-3-1 Responsibilities of the Office of Strategic Planning and Operational Policy/Division of Enforcement/Recall Operations Branch (OSPOP/DE/ROB)

OSPOP/DE/ROB responsibilities are detailed in [SMG 1121.81](#). OSPOP/DE/ROB serves as the agency focal point for guidance on recall plans and recall procedures; directs and coordinates field activities in support of all product recalls; and maintains communication with other agency components, industry, and domestic and foreign government agencies to ensure proper implementation and completion of recall plans and activities.

7-3-2 Responsibilities and Procedures – ORA/Office of Partnerships and Operational Policy (OPOP)

The responsibilities of Office of Strategic Planning and Operational Policy (OSPOP), in Office of Partnerships and Operational Policy (OPOP), are detailed in [SMG 1121.70](#). OSPOP develops, coordinates, and reviews compliance policies and regulatory procedures that can relate to recalls.

7-3-3 Responsibilities and Procedures – Office of Information Systems Management/ Division of System Solutions (DSS) /Enforcement Systems Branch

OISM/DSS/ESB responsibilities are detailed in [SMG 1121.812](#). DSS/ESB supplies recall information to internal FDA entities, in response to Freedom of Information Act (FOIA) requests, and, as appropriate, to applicable government agencies under the Government-Wide Quality Assurance Program (GWQAP). DSS/ESB is the business owner for the Enforcement Report application.

7-4 RECALL ENTERPRISE SYSTEM

The Recall Enterprise System (RES) is an electronic data system used by FDA recall personnel to submit, update, classify, and terminate recalls. It is also used to capture medical device Safety Alerts, see [Attachment M](#). Market withdrawals and stock recoveries, are not normally entered into RES. However, divisions may, consistent with agency policy, be directed by the Center Recall Unit (CRU) or OSPOP/DE/ROB to enter a specific market withdrawal into RES and to monitor and audit the action in the same manner as a recall.

There may also be some instances where a division enters an action into RES and the CRU determines that the action does not meet the definition of a recall. The CRU will designate the action in RES as a market withdrawal or stock recovery. The CRU may also non-concur with the recall recommendation, for example in instances where a product is not under FDA jurisdiction and the recall is referred to another agency.

RES User Guides contain the detailed information needed for the use of RES. Electronic copies of the guides have been provided to field and center recall

coordinators. The RES application currently has help information available for each screen. The RES increases efficiency in processing recall information by:

1. allowing field and center recall coordinators to input recall information via an on-line, Intranet system that captures all stages of the recall;
2. increasing communication of recall information between the field, headquarters, and the appropriate center(s) offices and reducing duplication of efforts;
3. providing a central, searchable database to more efficiently track information and generate and disseminate reports of recall activities.

The information entered in RES is gathered from various sources, including, the firm, ORA and the CRU. ORA is the business owner for the RES database. A RES account can be obtained by providing a FACTS User ID and completing the RES Account Request Form available on [Inside FDA](#). Submit the form via the preferred method of electronic mail to ORA Recall OE and indicate "RES Account Request" on the subject line. A Recall Operations Branch member will contact the requestor for the type of account or access that is requested and needed. Issues with RES (e.g. data entry, inability to access a record, failure of auto-generated emails delivered or sent) should be directed to the ORA Apps Desk.

Requests for deletion of RES events (such as duplicate events) should be directed to the OSPOP/DE recall staff, except for CBER events contact the CBER CRU.

7-4-1 Enforcement Report

The Enforcement Report is an online weekly publication of all recalls monitored by FDA once they are classified (21 CFR 7.50) and may be listed prior to classification when FDA determines the firm's removal or correction of a marketed product(s) meets the definition of a recall. Those records published prior to classification are referred to as "not yet classified" records. Recalls and "not yet classified" records are directly sourced from RES and are compiled into weekly reports based on the classification date or the date the record is determined to meet the definition of a recall. Recalls and "not yet classified" records are posted to the Enforcement Report when Centers set the recall to be posted in RES. More information can be found on the [Enforcement Report home page](#).

Note: Change requests to the Enforcement Report should be directed to the CRU.

7-5 INITIATION OF A RECALL

A manufacturer or distributor may voluntarily initiate a recall at any time. Initiation of a recall means a recalling firm's first communication about a voluntary recall, to its direct accounts or to the public. FDA may conduct informal discussions with a manufacturer or distributor that include voluntary recall as an option. FDA may also request a recall, as provided for under 21 CFR 7.45. Under certain authorities, FDA may mandate a recall.

If the firm that has primary responsibility for the manufacture or distributing or marketing of the product to be recalled is out of business or is unable to conduct an effective recall for any reason, the division should notify the CRU and OSPOP/DE/ROB. The division and the CRU should develop an appropriate course of action. In significant situations involving a serious health hazard, this could involve issuance of press to notify the public and/or FDA notifying consignees directly.

Note: FDA Food Recall/Action Initiation Process Flow – Timeline for Class I Human Food Recalls (SAHCODH) is in Appendix A. It describes a timeline for FDA to follow in pursuing Class I food recalls and provides options to follow should a firm not initiate a recall.

7-5-1 Firm Initiated Recalls

If a recall is firm-initiated under 21 CFR 7.46, the agency will review the information provided by the recalling firm under 21 CFR 7.46(a). This includes reviewing and suggesting changes to the firm's recall strategy, recall communication, and press release (if necessary).

FDA may inform a firm that a product violates the law and recommend they cease distribution and recall the product without specifically requesting a recall.

Evidence to support FDA's recommendation may be collected by FDA, a federal or state partner, or a third party.

If a firm decides to recall under these circumstances, the firm's action is considered a firm-initiated recall under 21 CFR 7.46(c). If a firm asks whether FDA is requesting a recall, FDA should explain that it is not requesting a recall, as a determination under 21 CFR 7.45 has not been made and that the agency has not exercised its authority under 21 CFR 7.45, or invoked its mandatory recall authority. This recommendation does not preclude FDA from considering other actions in the future.

When considering FDA's authority to request that a firm initiate a recall, see 21 CFR 7.45 and RPM Section 7-5-2, FDA Requested Recall.

When considering cease distribution and voluntary recalls under section 423(a) of the Act, see RPM Section 7-5-3, FDA Mandated Recalls.

Discussions with firms about firm-initiated recalls pursuant to a recommendation shall be conducted by: (1) the Program Director or designee, with the concurrence of the Center Director of the Office of Compliance or designee; or (2) the Center Director of the Office of Compliance or designee, with the concurrence of the Program Director or designee.

- These discussions may occur during conversations with the firm(s), the firm's US agent (for a foreign firm), or the firm's legal representative. Such discussions

should be documented in internal meeting minutes or notes, in accordance with agency's procedures.

If the firm does not agree to cease distribution and/or recall following FDA's recommendation, the agency may consider further action, as appropriate, including, but not limited to: public notification to consumers, healthcare practitioners, etc., an FDA-requested recall letter, an FDA-mandated recall (in the case of certain regulated products), seizure, administrative detention, or injunction. ORA and the Center(s) will consider taking appropriate follow-up action. ORA and the Center(s) will also determine whether the potential recall could cause a shortage of a regulated product and identify appropriate timeframes in which to accomplish these tasks based on the degree of risk associated with the recall.

The agency will conduct a health hazard evaluation (HHE), (precedent HHEs or written classification policies may be used), will classify the recall, and will advise the firm in writing of the assigned recall classification. The letter to the firm will recommend any appropriate changes in the firm's recall strategy and advise the firm that its recall will be placed on the FDA web site. FDA will also assign audit checks as appropriate, will monitor the effectiveness of the recall communication, correction or removal, will verify appropriate product disposition, and will terminate the recall when appropriate.

The division:

- submits a Recall Alert;
- gathers information about the recall. It may conduct an establishment inspection and collect samples of the recalled or other suspect products;
- submits a Recall Recommendation and other information about the recalled product to the appropriate center;
- offers guidance to the recalling firm;
- monitors the recall; and,
- terminates Class II and III recalls and recommends termination for Class I recalls.

When program divisions need assistance (recall associated with an emergency, high volume of recalls, etc.) the division should seek assistance from other divisions within their program and follow local and/or program procedures. If the entire program is experiencing a resource issue, seek assistance outside of the program after consulting with Program Directors.

1. Recall Alert

The division will submit a recall alert through RES within one working day after the division recall coordinator has learned that a recall has been initiated and the division recall coordinator has obtained the necessary information as described in Attachment A. Alerts may also be submitted before a recall has been initiated. The purpose of the recall alert is to notify the appropriate CRU and OSPOP/DE/ROB of a

firm's correction or removal, the reason for recall, and anticipated classification. For recalls where the manufacturing site or responsible firm is located outside the monitoring division, copy the division recall staff where the manufacturing site or responsible firm is located.

2. Recall Recommendation and Related Information

The purpose of a recall recommendation is to notify the CRU and OSPOP/DE/ROB Recall that the firm's action is recommended as a recall and its anticipated classification. Additionally, it serves as a notification to the CRU that the necessary information is available and entered in RES for the CRU to review and classify the recall. The division must submit a complete Recall Recommendation (RR) through RES within five working days after the recalling firm has provided the information necessary for the RR. When the information is submitted through the RES system, it automatically alerts the appropriate CRU and OSPOP/DE/ROB via e-mail. See [Attachment B](#) for guidance on the information required by the CRU to review and classify the recall. When sending recommendations where the manufacturing site or responsible firm is located outside the monitoring division, copy the division recall staff where the manufacturing site or responsible firm is located.

If the recall has been completed before FDA's knowledge of it, division personnel should obtain documentation of actions taken to dispose of or recondition the recalled products and document the recall per normal procedure. This documentation may include processing records or laboratory analysis, process validation protocols and reports, signed destruction receipts, salesperson's written receipts, corporate official's signed statement on firm's stationery, etc. The division should update RES with the recommendation information within 10 working days of learning of the completed recall.

In the case of potential class I recalls (or some urgent Class II recalls that, while not rising to Class I hazards, still present a serious hazard to health), if a firm has not provided adequate information to submit a recall recommendation after a reasonable request has been made, the division should consider assigning or conducting a directed inspection to obtain the information. If information is needed from a firm in another division, the monitoring division should request an inspection from that division.

If there is insufficient information to submit an RR, the division recall coordinator should telephone or email the appropriate CRU and OSPOP/DE/ROB for advice on a course of action.

Notes:

1. When requested by OSPOP/DE/ROB or the CRU, submit an RR for a product removal as a result of actual or alleged tampering with individual unit(s) where there is no evidence of manufacturer or distributor responsibility. They should recommend the action be designated as a market withdrawal since, although the situation may present a health hazard, there is no one identified as responsible for the violation. This RR

submission and market withdrawal recommendation will allow documentation and monitoring of the market withdrawal. For additional tampering related information see [RPM Chapter 8 – Emergency Procedures](#) and [IOM Chapter 8 – Investigations](#)

2. FDA does not ordinarily classify or audit interstate milk shippers (IMS) and Interstate Shellfish Shippers (ISS) product recalls where such actions have been, or are being, handled expeditiously and appropriately by the state(s). The FDA division office in which the recalling firm is located must be ensured that all state(s) involved in an IMS plant's recall are participating in ensuring removal of the product from commerce and that, when appropriate, state(s) issue warnings to protect the public health. In the event that FDA determines that the states are unable to effect the recall actions necessary, the agency will classify, publish, and audit the recall, including issuance of a public warning when indicated.
3. Exported products may not be documented in RES when the following scenarios apply:
 - The product(s) are labeled for export only, and/or
 - The product(s) are labeled for foreign distribution only (e.g. all labeling in foreign language), and/or
 - The recall is already monitored by competent foreign authority (e.g. the U.S. firm contract manufactured for a foreign firm, no U.S. distribution, and the foreign firm assumes responsibility for recalling marketed product and has reported the recall to be monitored by the foreign authority, and/or
 - Foreign firm is the recalling firm and has no U.S. distribution.

3. Establishment Inspection

For domestic firms, the division will contact the firm to obtain recall information and, in the case of recalls that have been classified as or appear to be class I or significant class II recalls, the situation should be evaluated to determine if an establishment inspection should be assigned to determine the root cause of the problem and document violations for possible regulatory action. See the [IOM Chapter 7 – Recall Activities](#) for information on how to conduct recall related inspections.

In many recall situations, the firm's production facility may differ from the recalling facility, typically a headquarters or corporate office. The recall also may have been initiated due to a problem at a supplier or another separate establishment. If the monitoring division determines an inspection is needed at an establishment located in another division, the monitoring division will contact that division and request an inspection. The investigating division, in turn, should keep the monitoring division informed of the inspectional progress and findings. If an inspection is needed at a

foreign facility, ORA Headquarters or a Center may request an inspection at that facility. Requests for these inspections vary for each program area, depending on a variety of factors (e.g. the firm's inspectional history).

4. Official Samples

The division must determine the need for an official sample, either physical or documentary. Typically collect samples when they best demonstrate the defect and potential hazard. The decision to collect an official sample is a division management prerogative unless required by specific headquarters' initiated assignments, or the occasional direct request from the CRU or OSPOP/DE/ROB. Samples collected should document interstate movement as well as the violation.

5. Firm Recall Communication and Notification

The FDA Division Recall Coordinator (DRC) should offer guidance to the recalling firm and will offer to review the text of recall communications to consignees so that the product will be promptly removed or corrected. The CRU and OSPOP/DE/ROB staff are available, if necessary, to assist the DRC. Recall communications can be in multiple forms including press releases, telephone calls, telegrams, telefaxes, mailgrams, or first class letters. For tobacco products, the Center for Tobacco Products should be contacted for guidance on any recall communications and notifications submitted by the recalling firm.

The recalling firm should discuss any recall communications and notifications with the FDA DRC before issuance. The possible need for bilingual or multilingual communications should be explored between the FDA DRC and the firm.

All recall communications should be written in accordance with the following guidelines: be brief and to the point; clearly identify the product(s) such as the product name, size, brand name, serial numbers(s), potency, dosage, type, model, lot number(s), UPC codes, Unique Device Identifier (UDI) if applicable, and any other pertinent descriptive information to enable accurate and immediate identification of the product; contain a concise statement of the reason for the recall; state known or potential hazard(s), and instructions for consignees to follow in handling the recall. If possible, the recall letter may provide the initial shipping date and quantities shipped. See [Exhibit 7-4](#) Model Recall Letter.

If a firm has voluntarily initiated a recall of any product(s), then it is responsible for promptly notifying each of its direct accounts. If the depth of the recall is beyond the direct accounts, then the direct accounts should be instructed by the recalling firm to contact sub-accounts that may have received the product.

Sub-accounts, which further distributed the product, should continue the recall to the depth established in the recall strategy. A written recall communication to sub-accounts should be in addition to any other means of communication, such as monthly sales bulletins, manufacturer representative visits, or recorded phone messages. These actions may aid in a sub-recall effort, but they are an inadequate communication of the recall.

Ensure that the recalling firm conspicuously marks the outside (e.g. the envelope) and the enclosed information (e.g., the recall letter or other type of message) of the recall communication “DRUG (or FOOD, BIOLOGIC, MEDICAL DEVICE, TOBACCO PRODUCTS, etc.) RECALL (or CORRECTION).” Additionally, the outside and enclosed information should be marked “URGENT” for all Class I and Class II recalls, and, when appropriate, for Class III recalls.

Recall communications should be sent in the most expeditious manner and commensurate with the hazard of the product being recalled, and, where appropriate, sent with proof of receipt (e.g., by certified mail). All communication methods related to the firm’s recall should be documented accordingly.

Recall communication, particularly letters to direct accounts and sub-accounts should include a postage-paid, self-addressed post card, envelope, or other arrangement to enable the consignee to report the amount of the product available and its disposition. Recall communications should direct that the consignee submit a report regardless of whether or not any of the products are on hand. It should also stress prompt return of the post card or other report. (See Exhibits 7-4, 7-5, 7-6, [FDA Recall Industry Guidance](#) webpage for model letters, envelopes, and recall return response forms.) The guidelines referenced above and additional information on Recall Communications can be found in 21 CFR 7.49.

7-5-2 FDA Requested Recall

This section only applies to FDA requested recalls in accordance with 21 CFR 7.45. FDA Requested Recalls are ordinarily reserved for urgent situations where mandatory recall authority does not exist or is not appropriate. Additionally, FDA Requested Recalls should only be pursued following informal recall discussions with a firm per the procedure in RPM 7-5-1.

FDA recall requests are directed to the firm that has primary responsibility for the manufacture or marketing of the product when the firm does not undertake a product recall on its own initiative. FDA requested recalls are most often classified as Class I. Generally, before FDA formally requests a recall action, the agency will have evidence capable of pursuing an action such as seizure, injunction, warning letter, etc. The completion of either a firm initiated or FDA requested recall does not preclude FDA from taking further regulatory action against a responsible firm. The Associate Commissioner for Regulatory Affairs (ACRA) approves all FDA requests for firms to conduct recalls.

FDA requested recalls may begin with various communications between the field and headquarters units but will be formally initiated when the division/center creates a compliance action in CMS “FDA Requested Voluntary Recall.” All data and documentation related to the problem, as indicated above under the Recall Recommendation and the Establishment Inspection paragraphs, will be obtained and uploaded into CMS. The Division/Center which created the action will schedule a call between the division, center, OSPOP/DE/ROB, and OCC to discuss the merits of the action and make a decision whether or not to pursue FDA Requested Recall. If the

decision is to pursue, the CRU will process the recommendation as outlined in the following paragraphs on Recall Classification and Strategy and submit an Action Memorandum and draft FDA Requested Recall Letter to the ACRA through OSPOP/DE/ROB. The draft letter will specify the violation(s), health hazard involved, recommended recall strategy, timeframe for the firm's response to FDA, and any other instructions appropriate to effectively conduct the recall (See Exhibit 7-7). The Center will upload the recommendation package into CMS and notify OSPOP/DE/ROB that the recommendation is ready for review.

OSPOP/DE/ROB will review the Action Memorandum and promptly prepare and forward to OCC a recommendation through CMS which includes the draft FDA Requested Recall Letter. After OCC review and approval, OSPOP/DE/ROB will forward the final package to the ACRA for final review and signature of the FDA Requested Recall Letter.

If the center's recommendation is approved by the ACRA and the letter to the recalling firm signed, OSPOP/DE/ROB will send the ACRA signed letter to the firm indicating FDA's determination of the need to immediately begin a recall.

When the division receives a copy of the letter sent to the responsible firm by the ACRA, division personnel should verify the firm's receipt of the letter and, where appropriate, make arrangements to visit and/or inspect the firm as soon as possible. Coordination with the CRU, Office of Criminal Investigations, or other offices may be necessary in special situations.

The division office will offer the same guidance to the recalling firm as outlined above in Firm Recall Communication and Notification and will assist the firm in arranging the text of recall communications to consignees so that the product will be promptly removed or corrected. Once the recall has been initiated, the DRC will enter the recall into RES and ensure the CMS Action includes the RES Event number for future data tracking.

All parties will work collectively with the Office of External Affairs to draft, clear, and promptly release, if warranted, a public statement regarding the FDA Requested Recall. Although only one statement will be used, two statements should be drafted and cleared, one which indicates the firm initiated a recall and one which indicates the firm refused to recall. If the product is related to an ongoing issue, i.e. outbreak, previously released public statements can be used and/or amended in lieu of creating a new statement.

7-5-3 FDA Mandated and Ordered Recalls

Various sections of the law authorize FDA to order a firm to recall a product or mandate recall requirements. Additionally, recalls may be ordered by a consent decree. Below is a listing of mandated and ordered (via statute or consent decree) recall types as well as links existing statutes, regulations, procedures and guidance documents.

1) Ordered recalls

a. Commodity: Foods other than infant formula

Statute: [Section 423 of the FD&C Act \[21 U.S.C. § 350\]](#)

Implementing Regulations: N/A

Criteria: Gives the FDA the authority to order a responsible party to recall an article of food where the FDA determines that there is a reasonable probability that the article of food (other than infant formula) is adulterated under section 402 of the FD&C Act [21 U.S.C. § 342] or misbranded under section 403(w) of the FD&C Act [21 U.S.C. § 343(w)] and that the use of or exposure to such article will cause serious adverse health consequences or death to humans or animals (SAHCODHA).

Procedures: Regulatory Procedures Manual (RPM), Chapter 7, Attachment J

Industry Guidance: [Guidance for Industry and FDA Staff: Questions and Answers Regarding Mandatory Food Recalls](#)

b. Commodity: Medical Devices for Human Use

Statute: [Section 518\(e\) of the FD&C Act \[21 U.S.C. § 360h\]](#)

Implementing Regulations: [21 CFR 810](#)

Criteria: Gives the FDA the authority to order a recall of a device where there is a reasonable probability that a device intended for human use would cause serious, adverse health consequences or death.

Procedures: Regulatory Procedures Manual, Chapter 7, Attachment G

Industry Guidance: N/A

c. Commodity: Tobacco Products

Statute: [Section 908\(c\) of the FD&C Act \[21 U.S.C. § 387h\(c\)\]](#)

Implementing Regulations: N/A

Criteria: Where there is a reasonable probability that a tobacco product contains a manufacturing or other defect not ordinarily contained in tobacco products on the market that would cause serious, adverse health consequences or death, gives FDA the authority to issue an order requiring the appropriate person (including the manufacturers, importers, distributors, or retailers of the tobacco product) to immediately cease distribution of such tobacco product. The order shall provide the person subject to the order with an opportunity for an informal hearing, to be held not later than 10 days after the date of the issuance of the order, on the actions required by the order and on whether the order should be amended to require a recall of such tobacco product. If, after providing an opportunity for such a hearing, the FDA determines that inadequate

grounds exist to support the actions required by the order, the Secretary shall vacate the order.

Procedures: Regulatory Procedures Manual, Chapter 7, Attachment I

Industry Guidance: N/A

d. Commodity: Controlled Substances

Statute: [Section 569D of the FD&C Act \[21 U.S.C. § 360bbb-8d\]](#)

Implementing Regulations: N/A

Criteria: Where there is a reasonable probability that a controlled substance would cause serious adverse health consequences or death, the FDA may, after providing the appropriate person with an opportunity to consult with the agency, issue an order requiring manufacturers, importers, distributors, or pharmacists, who distribute such controlled substance to immediately cease distribution of such controlled substance.

Procedures: Regulatory Procedures Manual, Chapter 7, Attachment K

Industry Guidance: N/A

e. Commodity: Biological Products

Statute: [Public Health Service Act \(PHS Act\) recall authority for biological products \(42 U.S.C. 262\)](#)

Implementing Regulations: N/A

Criteria: If a determination is made that a batch, lot, or other quantity of a product licensed under the PHS Act presents an imminent or substantial hazard to the public health, the FDA has the authority to issue an order for its immediate recall.

Procedures: N/A

Industry Guidance: N/A

f. Commodity: human cell, tissue, and cellular and tissue-based product (HCT/P)

Statute: [legal authority of section 361 of the Public Health Service Act \(PHS Act\) \(42 U.S.C. 264\)](#)

Implementing Regulations: [21 CFR Part 1271.440](#)

Criteria: Upon a FDA finding that there are reasonable grounds to believe that an HCT/P is a violative HCT/P because it was manufactured in violation of the regulations in 21 CFR part 1271 and, therefore, the

conditions of manufacture of the HCT/P do not provide adequate protections against risks of communicable disease transmission; or the HCT/P is infected or contaminated so as to be a source of dangerous infection to humans; or an establishment is in violation of the regulations in this part and, therefore, does not provide adequate protections against the risks of communicable disease transmission

Procedures: Regulatory Procedures Manual Chapter 5 - Administrative Actions, Order of Retention, Recall, Destruction, and Cessation of Manufacturing Related to Human Cell, Tissue, Cellular and Tissue-Based Products (HCT/Ps)

Industry Guidance: N/A

2) Mandated Recall Requirements

a. Commodity: Infant Formula

Statute: [350a\(f\)](#)

Implementing Regulations: [21 CFR Part 107, Subpart E](#)

Criteria: When the Food and Drug Administration determines that an adulterated or misbranded infant formula presents a risk to human health, a manufacturer shall immediately take all actions necessary to recall that formula, extending to and including the retail level, consistent with the requirements of 21 CFR Part 7 Subpart E.

Procedures: Regulatory Procedures Manual, Chapter 7, Attachment F

Industry Guidance: N/A

b. Commodity: Recalls of Radiation Emitting Electronic Products Under Subchapter C - Electronic Product Radiation Control of Chapter V of The Federal Food, Drug, And Cosmetic Act (The Act), Formerly the Radiation Control For Health And Safety Act Of 1968 (RCHSA)

Statute: mandated recall provisions written into the Act ([Sec. 535\(a\)](#)) [[21 U.S.C. 360lll](#)]

Implementing Regulations: [21 CFR 1000 – 1050](#)

Criteria: The law requires a manufacturer, when he learns that a product he manufactures is either defective or not in compliance with a published performance standard, to notify the Secretary of Health and Human Services (delegated to CDRH Director), and to notify the first purchaser (and known subsequent transferees) of the defect(s) or noncompliance(s). Subchapter C is specific as to the method of notification and procedure, and contains "repair, replace or refund" provisions.

Procedures: Regulatory Procedures Manual, Chapter 7, Attachment E

Industry Guidance: See [FDA Homepage for Radiation-Emitting Products](#)

3) Recalls Ordered by Consent Decree

Recalls may be ordered by FDA in accordance with the terms of a consent decree when FDA determines, based on the results of an inspection, the analysis of a sample, data received from the defendants, an expert, an auditor, or any other method, that the defendants have failed to comply with the provisions of a consent decree, have violated the Act or applicable regulations, and/or additional corrective actions are necessary to achieve compliance with the consent decree. In such cases, the recall will be initiated and monitored within the timeframes and manner prescribed by the consent decree. Correspondence to the recalling firm should include the injunction number and/or other identification of the injunction (example: United States v. ABC Firm, Inc., et al, [Injunction number]). Consent decrees typically authorize FDA to bill defendants for expenses associated with recalls initiated under a consent decree including, as applicable: inspections, investigations, supervision, analyses, examinations, sampling, testing, reviews, document preparation, travel, and subsistence expenses to implement and monitor recalls. Consequently, time spent reviewing and monitoring the recall should be recorded.

7-5-4 Removals and corrections involving products exported from the U.S. and products imported to the U.S.

In most instances, removals and corrections of violative products exported from the U.S. will be entered, processed, and classified in RES. For example, when a firm removes/corrects a violative product(s) manufactured in the U.S. where some or all of the products/lots were distributed outside of the U.S., the action should be documented as a recall in RES.

Similarly, removals and corrections of imported products should be documented in RES. Removals and corrections of imported products may be conducted by the foreign firm, the importer of the product, or by a US affiliate of the foreign firm.

OSPOP/DE/ROB may receive reports of removals and corrections from firms that export products into the U.S. or from foreign authorities that may need to be documented in RES. These include foreign food inspections resulting in firms removals, emails from foreign firms, foreign government.

In such cases, OSPOP/DE/ROB's responsibility is to:

1. Acknowledge receipt of the information from the foreign authority or firm.
2. If the information is received from a foreign authority, ascertain whether requests for additional information should be made to the authority or directly to the recalling firm. Request, if necessary, contact information for the firm official who will provide FDA with recall information.

3. If necessary, request additional information: reason for recall, product description and codes, product labeling, firm's U.S. consignee/distribution list, firm-owned or affiliated U.S. facilities, firm's U.S. affiliate, agent, or importer.
4. Upon receipt of the information from the firm or foreign regulator, forward to the appropriate CRU for their situational awareness and include the ORA Recall Coordinator for the appropriate division, once a division has been identified. OSPOP/DE/ROB may request the CRU to confirm a violation or potential for health hazard, as necessary.
5. Refer the recall to an ORA Recall Coordinator for the appropriate Program Division. OSPOP/DE/ROB will consider available information when determining which Program Division should handle the matter to assign the recall. Some factors for consideration may include the location of the foreign firm's U.S. facilities (U.S. corporate headquarters or sister company), location of importer(s), the U.S. firm listed on the product packaging, location of US agent or firm's affiliate and any existing contractual agreements with the foreign firm. In instances when there is more than one US Importer or more than one US firm affiliated with the recalling firm, OSPOP/DE/ROB will designate the Monitoring Division as the Division where the highest amount of distribution occurred.

However, some removals and corrections of imported/exported products may not be documented in RES. Divisions should consult the CRU and OSPOP/DE/ROB when confronted with the following scenarios:

- 1) The product(s) are labeled for export only, and/or
- 2) The products are labeled for foreign distribution only (e.g. all labeling in foreign language), and/or
- 3) The recall is already being monitored by a foreign authority (e.g. the US firm contract manufactured for a foreign firm and the foreign firm is taking responsibility for recalling marketed product and has reported the recall to be monitored by the foreign authority).

Pharmaceutical Inspection Co-operation Scheme (PIC/S)

FDA is a member of PIC/S, a non-binding, informal co-operative arrangement between Regulatory Authorities in the field of Good Manufacturing Practice (GMP) of medicinal products for human or veterinary use. Recall information is shared between PIC/S members who follow the PIC/S SOP "[Procedure for Handling Rapid Alerts and Recalls Arising from Quality Defects.](#)"

1) OSPOP/DE

- Manages FDA's PICS/RANS Outlook mailbox by forwarding incoming Rapid Alerts to appropriate centers, sending Rapid Alerts generated by FDA centers to PIC/S members, and facilitating responses to inquiries received from PIC/S members

2) CDER, CVM, and CBER Recall Units

- Review incoming Rapid Alerts from PIC/S members to determine whether FDA follow-up is necessary and direct the follow-up
- Review incoming FDA recalls to determine whether they fit the PIC/S SOP criteria for generating a Rapid Alert to other PIC/S members, generate the rapid alert and forward it to the PICS/RANS mailbox for OSPOP/DE to disseminate
- As needed, respond to additional inquiries from other PIC/S members

3) CFSAN Recall Unit and International Affairs Staff (IAS)

During an outbreak situation that may trigger into a recall, CFSAN Recall Product Recondition Team (RPRT) requests via the CFSAN Foreign Food Inspection Coordination Team mailbox a 'for cause' inspection at a foreign firm as a follow-up to the recall of an imported product, as deemed necessary. This action is also conducted on an ad-hoc basis once RPRT has assessed the need for an inspection.

Office of Compliance/Division of Enforcement submits recommendations for foreign firm to be placed on Import Alert (IA)/Detention Without Physical Examination (DWPE) and or Import Bulletin (IB) to DIO as deemed necessary.

CFSAN International Affairs Staff (IAS) will notify foreign govt when product has been distributed to foreign country other than Canada. Notification is facilitated through FAS and foreign offices. (during outbreak situations that result in Class I and Class II recall)

CFSAN IAS will adhere to their internal procedures to gather information in situations when implicated product was imported to the United States and further re-exported to another country. (especially during outbreak situations)

CFSAN IAS will assist with coordination with foreign competent authorities for follow-up as needed for Class I and Class II recalls triggered from an

outbreak. Information sharing is dependent on whether there is a confidentiality commitment in place. Information may include: distribution, laboratory analysis, and/or regulatory actions (e.g. import alerts, import bulletin, inspectional findings, investigation updates) being conducted.

CFSAN IAS consults with ORA HAF Division and DIO during recalls (I and II) and outbreaks in securing sampling information, analytical worksheets or relevant testing documents pertaining to a recalled product manufactured in the US with foreign distribution or a product that has originated in another foreign country distributed in the US.

4) FDA Division Recall Coordinators

- For potential class I and II pharmaceutical recalls, list any foreign direct consignees in the RES Recall Recommendation

Rapid Alert System for Food and Feed (RASFF)

RASFF or the Rapid Alert System for Food and Feed is a platform that enables information sharing from the European Union regarding Food & Feed Safety Events.

RASFF sends notifications via email when a food or feed poses a serious health risk in the European market and a rapid action is warranted. The RASFF member that identifies the problem, takes the relevant actions (e.g. recalls) and triggers the rapid alert. FDA's Office of Crisis Management (OCM) receives these rapid alerts, including ones that list US consignees for products that have been recalled by foreign firms. OCM transmits recall related RASFF information in an email to the OSPOP/DE/ROB, the appropriate Center Recall Unit (CRU) and the respective HAF Divisions where consignees are located.

Subsequently the following steps take place:

- The CRU reviews the information to determine if expedited follow up will be needed based on the following two criteria: the recalled product is in violation of the FD&C Act and may cause serious health consequences. If those criteria are met, the appropriate Center advises the respective HAF Division to monitor the event.

A domestic recall may not be necessary if, for example, the product is past its shelf life or has not been distributed by the initial importer.

There are other factors that may justify additional follow up outside of normal regulatory procedures. Examples of these factors may include the population affected by the problem and/or the possible public concern or other stakeholder attention to the problem.

- If there is more than one US consignee located under different HAF Divisions, OSPOP/DE/ROB designates the monitoring division. In this instance the foreign firm is considered the recalling firm.

-The respective HAF Division enters the event in Recall Enterprise System (RES) and monitors the recall. The appropriate Center classifies the event.

Note: For instances when a recall may warrant an import alert, please refer to RPM Ch 9.

7-6 RECALL CLASSIFICATION AND STRATEGY

The Center Recall Unit (CRU):

1. initiates a health hazard evaluation;
2. finalizes a recall strategy;
3. determines that the firm's action is a recall, classifies the recall, and, for Class I recalls, prepares an Action Memorandum for Center Director or his/her designee concurrence and,
4. updates RES with classification, audit strategy, and any recommendations.

7-6-1 Health Hazard Evaluation

The agency will conduct or obtain health hazard evaluations (HHE) for each recall scenario. Precedent HHEs will be used where the product is identical or similar with basically the same defect or violation as a recall action previously classified. Precedent HHEs will be re-evaluated and updated periodically. Established precedent recall policies such as those established by CDRH may also be used.

Upon receipt of each recall recommendation or other information, from any source, which indicates a recall may be necessary, the CRU determines whether an up-to-date health hazard precedent exists covering the situation. If not, it forwards the appropriate information to the Center Health Hazard Evaluation Committee for review. Additional information received during the progress of a recall should also be forwarded to the committee for timely health hazard reevaluation.

The Health Hazard Evaluation Committee in each center should use the Health Hazard Evaluation Worksheet ([Attachment D](#)) to record their evaluations. This evaluation will take into account the factors listed in 21 CFR 7.41(a) and [Attachment D1](#) of this chapter. The health hazard evaluation form must be prepared by knowledgeable center personnel and should reflect their written concurrence. The HHE committee may use a precedent health hazard evaluation in lieu of conducting a new HHE for a similar situation. It is the responsibility of the HHE Committee to ensure itself that all reviewers are familiar with the intent of the evaluation.

The HHE Committee will complete, endorse, and forward the health hazard evaluation form to the center recall unit within two (2) working days after receiving a recall recommendation unless additional information is required. It is the responsibility of the HHE Committee to notify the CRU when further information is needed. If the recall

recommendation indicates that the product is no longer in distribution channels, they will complete, endorse, and forward the HHE to the CRU within five (5) working days.

The Health Hazard Evaluation Committee must promptly reevaluate the initial health hazard when additional data regarding injury, illness, medical, or scientific findings is received by the center. Where additional data are being received on a continuing basis, the committee is to routinely meet and reevaluate the health hazard at least biweekly.

The CRU should coordinate their review with other centers when necessary. Any questions about lead center responsibility or jurisdiction should be promptly referred to OSPOP/DE/ROB.

7-6-2 Classification Process

The CRU documents the recall determination and/or recall classification in the appropriate fields in RES.

If the recall determination is made before the recall is classified, then the CRU documents and sends the determination decision in RES and enters the classification as “not yet classified.” Once the action has been determined to meet the definition of a recall, with or without a classification, the information should be posted to the [Enforcement Report](#). The Enforcement Report will display the recall designated as “not yet classified” or the product classification, if available. Once classification occurs, the Enforcement Report designation of “not yet classified” is updated by the CRU to reflect the classification.

For ongoing recalls, the CRU will normally classify recalls within two days after receiving the health hazard evaluation or confirming the classification through precedent review. They will add classification information to the recall document in RES and transmit the classification electronically to the monitoring district and OSPOP/DE/ROB.

The CRU is responsible for reviewing, correcting, editing and or adding necessary information in the RES public information fields.

The ACRA has approval authority for all Class I recalls. However, the ACRA has delegated approval of voluntary firm-initiated Class I recalls to center directors. This has been done to streamline the recall classification process in the center, expedite the handling of the recall by industry and FDA division offices, and in certain situations, to have it universally understood that these recalls represent potentially serious to life-threatening health hazards. The center director may further delegate within the center compliance office the authority for review and classification of recall actions.

NOTE: FDA will normally evaluate, prepare, and approve necessary action memorandum on infant formula manufacturers' notifications submitted in compliance with section 412 of the Act within five calendar days.

The CRU may classify Class II and III recalls without management review. However, unusual and/or potentially high profile recall issues should be brought to center management's attention.

7-6-3 Recall Strategy

Each recall is unique and requires its own recall strategy. The DRC initially works with the firm to develop an appropriate recall strategy. The CRU will review the firm's recall strategy for voluntary recalls and recommend necessary changes. The recall strategy includes the type of notification and depth of the recall. It also contains the depth and level of audit checks and the need for public warning. Recall strategies are based on the individual recall circumstances and are not necessarily dependent on the recall classification.

1. Elements of a Recall Strategy

As specified in 21 CFR 7.42(b), a recall strategy takes into account the following factors, based on the individual recall circumstances.

- A. Depth of recall. Depending on the product's degree of hazard and extent of distribution, the recall strategy will specify the level in the distribution chain to which the recall is to extend. In general, Class I recalls may extend to the consumer or user level, Class II recalls may extend to the retail level, and Class III recalls may extend to the wholesale level.
- B. Public warning. See Section 7-7-3
- C. Effectiveness Check Level. The purpose of a firm's effectiveness checks is to verify that all consignees at the recall depth specified by the strategy have received notification about the recall and have taken appropriate action. This includes the method(s) to be used for and depth of recall effectiveness checks.

The firm's recall strategy should consider the disposition of recalled products (e.g., carcinogenic products) when normal disposition means, landfill, crushing, denaturing, etc., are inadequate. The DRC should advise firms to follow any applicable regulations regarding disposition, e.g. disposal of hazardous waste.

Firms wanting to recondition their product should develop a written formal reconditioning proposal and submit the proposal to the division for CRU review.

CFSAN requests all reconditioning proposals for recalled FDA regulated food products be submitted through MARCS-CMS. See Exhibit 7-17 to see a model of all the information that should be considered as part of a firm's CFSAN Reconditioning Proposal. The CFSAN Reconditioning Proposal should be written on a case-by-case basis and tailored to each unique recall situation but following the information found in [CFSAN ENFORCEMENT BULLETIN No. 2](#). When submitting a reconditioning proposal to CFSAN, division should ensure:

- The division includes a submission memo that describes the problem and the

input the division is requesting from CFSAN.

- All pertinent documents are loaded into the MARCS-CMS case file
- Documents are loaded separately under the proper tabs
 - For example, labels should be loaded under the “Documents - Evidence - Labeling” tab; recommendation memos, FDA Form 766 and attachments under the “Documents - Recommendation - ORA” tab.

For re-submissions, that all prior CMS cases that describe the product's history, if this is not the first reconditioning proposal that is submitted for the same product, are linked to the current one

2. Recall Strategy Review or Development

In reviewing or developing a recall strategy, the DRC and CRU should take into account the health hazard evaluation, type or use of the product, the ease in identifying the product, the degree to which the product's deficiency is obvious to the consumer or user, the amount of product remaining unused in the marketplace, distribution pattern, planned correction or removal, and the continued availability of essential products.

For firm initiated recalls the CRU will review and recommend or concur with the firm's recall strategy and the division's recommendations for the FDA recall audit strategy e.g. recall audit check level, depth. The center will communicate recommended changes in the firm's recall strategy and effectiveness checks and the FDA recall audit strategy to the Division Recall Coordinator and OSPOP/DE/ROB and update RES.

Instances when a responsible firm is out of business or is unable to conduct a recall for any reason. The CRU, working with the involved division, will consult with OSPOP/DE/ROB.

The Division Recall Coordinator and the CRU should discuss any corrections/modifications to the recall strategy, as necessary, for follow-up and correction by the recalling firm.

7-7 NOTIFICATIONS AND PUBLIC WARNING

7-7-1 Reports and Reporting Procedures

1. Identification of Recall Documents

All units referencing recall actions should identify them by the RES generated “Recall Event ID.” After classification, the product recall number(s) may be added, but the primary identification will still be the Recall Event ID. This will allow all FDA personnel operating in the RES to immediately locate the required recall record.

2. Updating Recall Status in RES

Division recall coordinators will update the "Recall Status" field in RES when they become aware that a recall's status has changed from "Not Initiated" to "Ongoing" to "Completed" to "Terminated."

A recall is considered completed when the recall action reaches the point at which the firm has retrieved and impounded all outstanding product that could reasonably be expected to be recovered, or has completed all product corrections.

Recall terminated is used to indicate that FDA has determined that all reasonable efforts have been made to remove or correct the violative product in accordance with the recall strategy, and proper disposition has been made according to the degree of hazard. See RPM Ch 7, 7-9 Recall Termination

For certain Class I recalls and Class II recalls, OSPOP/DE/ROB will request the monitoring Division send periodic reports on the progress of the recall to the CRU and OSPOP/DE/ROB until the recall is completed or until advised otherwise by OSPOP/DE/ROB. OSPOP/DE/ROB will specify the details of the progress report.

3. Division Notification to Firm of Recall Acknowledgement

Once the Division Recall Coordinator has been made aware of a recall and the 24-hour alert has been submitted, the DRC will request that recalling firms begin sending periodic recall status reports, per 21 CFR 7.53. The DRC will send a written acknowledgement to the recalling firm including the following: request the firm to submit periodic recall status reports, notify FDA prior to voluntary product destruction or product reconditioning, and to conduct effectiveness checks. This written acknowledgement can be sent via auto generated email in RES. In the event that the firm does not have an email address or RES is not functioning, the letter can be sent via any preferred method (e.g. fax or mail). If manually preparing and sending the acknowledgement letter, consider making note of this under View Activity in RES. Additionally, if the DRC is sending a hard copy acknowledgement letter, they should include hard copies of the guidance documents referenced in the model as enclosures. A model Recall Acknowledgement Letter is attached as Exhibit 7-8.

4. Division Notification to the Recalling Firm for Determination, Classification, and Termination

Recalling firms are notified of recall determination, classification, and termination via auto generated emails from RES. The notifications are sent to the email address of the most responsible person and the firm recall contact identified in RES. The notifications can be manually sent to additional firm recall contacts by utilizing the resend button and manually entering the contact's email address into the CC field. A copy of the email will be automatically filed under associated documents in RES.

If the recalling firm does not have an email address or RES is not functioning, the letters can be sent via any preferred method (e.g. fax or mail). If manually preparing and sending the letters, record the date sent under the View Activity

Tab in RES. A copy of the letter can be filed under associated documents in RES. Model letters can be found under the exhibits.

In unique recall situations, DRC has the option to manually prepare and send letters tailored to the specific situation and a firm may receive additional correspondence from the Center regarding the management of the recall.

Recall Determination

In situations where the Center determines that the event meets the definition of a recall prior to classification, the recalling firm will be notified of this determination via auto generated email from RES. This email will be sent automatically when the Center Recall Coordinator determines that the action meets the definition of a recall in RES.

In the event that the Center determines that the action meets the definition of a recall and classifies the event at the same time, the recalling firm will be notified of the recall determination and classification via the classification letter.

Recall Classification

The recalling firm will be notified of the recall classification via auto generated email in RES. This correspondence will be sent automatically when the Center classifies the recall.

This notification of classification will provide the recall number(s), the classification of the recall, product description, codes, and a reminder to conduct recall effectiveness checks. The notification will also remind the firm that the recall will be posted FDA's Enforcement Report. The notification will encourage proper corrective action and remind the firm to submit periodic status reports as described in 21 CFR 7.53(b). The notification will include a statement that FDA may take further action, as appropriate, to remedy the underlying violation to address a product found to be in violation of the law, including, but not limited to, public warning to consumers, health practitioners, etc., seizure, or injunction.

The notification will also include email address of the division's recall coordinator to assist the firm in answering any questions related to the recall classification.

A model Notification of Classification Letter is attached as Exhibit 7-9.

Classification and Termination

In situations where the recall is terminated at the same time it is classified, the recalling firm will be notified of the classification and termination via auto generated emails in RES. This email will be sent automatically when the Center Recall Coordinator classifies and terminates the recall at the same time.

If the notification of classification and termination is being prepared manually, a template for the Classification and Termination Letter is attached as Exhibit 7-12.

Recall Termination

The recalling firm will be notified of the recall termination via auto generated email in RES. This correspondence will be sent automatically when the Division Recall Coordinator (for Class II and III) or Center Recall Coordinator (for Class I) terminates the recall. A model Recall Termination Letter is attached as Exhibit 7-11.

5. Recall Audit Check Reports

Report all FDA recall audit checks on form FDA 3177, Recall Audit Check Report. Please refer to RPM Ch 7, 7-8-2 Managing FDA's Recall Audit Check Strategy for instructions on reporting Recall Audit Checks.

7-7-2 Notification to Other Government Agencies

FDA maintains contacts with state and local officials regarding recalls.

FDA is also obligated through existing agreements, to notify certain partner government agencies and foreign governments when recalled products have been distributed to consignees of interest to those agencies or governments. These agreements include, but are not limited to, memorandums of understanding, systems recognition, and Pharmaceutical Inspection Co-operation Scheme (PIC/S). The existing agreements specify which FDA office is responsible for sharing the information and those offices should establish internal procedures to assure their responsibilities are met. Sections below identify certain FDA offices responsible for sharing this consignee information.

The sections below also identify the specific consignees of interest that division offices need to enter in RES "Consignee Details" field that is found on the "Events Detail" page at the time the recall recommendation is submitted. For each consignee identified, enter the consignee's name, complete address and telephone number.

1. Notification of State and Local Officials

1.1 Responsibility of division offices

Division offices should consider appropriate notification to state and/or local officials of recall actions that may be pertinent to them. The divisions should also consider requesting necessary assistance from state and local officials either in conducting or auditing recalls. For more information, see [FMD 50 State Correspondence](#).

1.2 Responsibility of the Office of Communications and Project Management (OCPM)/Division of Communications (DC)/Public Affairs Branch (PAB)

OCPM/DC/PAB informs state and local officials by electronic mail system of selected recalls presenting serious health hazards, where intense publicity is anticipated, and/or where state assistance is requested. The OCPM/DC/PAB also distributes other publicity prepared to these officials.

2. Notification to Foreign Governments

2.1 Responsibility of Division Offices

Division offices should review recalling firm's distribution lists and provide specific direct account foreign consignee information for the following recalls:

- CDER Class I and Class II
- CBER Class I (CBER regulated devices only)
- CFSAN all recalls (food and cosmetic)
- CVM Class I and Class II (animal food and drugs)

2.2 ORA headquarters and center offices responsibility for sharing direct account foreign consignee information with foreign governments

OSPOP/DE/ROB is responsible for sharing consignee information for foods with the Canadian Food Inspection Agency and for cosmetics with Health Canada. CFSAN International Affairs Staff is responsible for sharing consignee information with countries other than Canada.

Office of Partnerships/Division of Integration/International and Federal Engagements Group (OP/DI/IFE) supports OSPOP/DE/ROB when ORA non-public materials are requested by OSPOP/DE/ROB to share with a regulatory foreign partner. OP/DI/IFE provides assistance to OSPOP/DE/ROB to facilitate the sharing of information such as sample results, analytical findings and establishment inspection findings, as per the request of other foreign government agencies/entities. OP/DI/IFE will determine the type of redaction consistent with the corresponding [FDA Confidentiality Commitment](#) and will in turn work with ORA/OSPOP/Division of Information Disclosure Policy to provide redacted materials requested back to ROB for transmission or directly to the foreign regulatory partner, as appropriate.

3. Notification to Department of Defense/Defense Logistics Agency Military

3.1 Responsibility of Division Office

Division offices should review recalling firm's distribution lists and provide specific direct account Defense (DoD) and Veterans Affairs (VA) consignee information for all recalls.

3.2 OSPOP/DE/ROB's Responsibility

OSPOP/DE/ROB is responsible for sharing consignee information for human/animal food, cosmetic, and tobacco recalls with Defense Logistics Agency (DLA).

OSPOP/DE/ROB notifies GWQAP when medical products under recall (Class I, II, and III) have been distributed to Defense Logistics Agency (DLA) and the Department of Veterans Affairs (DVA) facilities.

3.3 Responsibilities and Procedures - Compliance Systems/Enforcement Systems Branch (HFC-240)

The Government-Wide Quality Assurance Program (GWQAP), managed by DSS/ESB, supplies recall information to applicable government agencies.

- a. Reviewing the RES notices provided from the OSPOP/DE/ROB to assure that it contains VA and/or DoD distribution
- b. Providing the DVA and DLA Troop Support (DLA) formerly the Defense Supply Center Philadelphia (DSCP) the RES when conditions are met.
- c. Assisting the agencies with questions about RES notifications.

4. Notification to United States Department of Agriculture (USDA)

4.1 Division office responsibility

Division offices should review recalling firm's distribution lists and provide the following specific direct account consignee information for all CFSAN food recalls

1. USDA regulated firms who received the recalled FDA regulated product.
2. If the recalling firm knows they have consignees who received product specifically procured for, manufactured for, or distributed to the National School Lunch Program, the DRC will notify OSPOP/DE/ROB via RES.

4.2 OSPOP/DE/ROB responsibility

OSPOP/DE/ROB notifies the USDA Food Nutrition Service (FNS) of recalls of FDA regulated products that have been distributed to any USDA agency that may have involvement with the school lunch program.

7-7-3 Public Warning

The purpose of a public warning is to alert the public that a product being recalled presents a serious hazard to health. FDA recall staff should review [Public Warning and Notification of Recalls Under 21 CFR Part 7, Subpart C Guidance for Industry and FDA Staff \(PDF - 71KB\)](#). The purpose of this guidance is to assist and provide recommendations to industry and FDA staff regarding the use, content, and circumstances for issuance of public warnings and public notifications for firm-initiated or FDA-requested recalls under 21 CFR Part 7, Subpart C – Recalls (Including Product Corrections) – Guidance on Policy, Procedures, and Industry Responsibilities. The guidance also discusses what information should be included in a public warning, as well as the parties responsible for issuing it.

Note that a firm may wish to issue public recall announcement, such as a press release, for a recall whose hazard level does not meet the threshold for a public warning. In those instances, FDA recall staff should follow the same procedures as for public warning below.

1. Responsibilities and Procedures – Division Recall Coordinators

DRC's will review proposed recall strategies for incoming recalls to determine whether they fit the criteria for public warning. For those instances where it is not clear (no precedent for public warning for previous recalls for a similar product/problem, additional information needed for center to conduct HHE, not clear if a public warning will be beneficial, etc.) the DRC should engage with the CRU and OSPOP/DE/ROB for advice. In instances where no health hazard evaluation precedent exists or where the preliminary information is not sufficient to decide, CRU's may need to request and review additional supporting documentation before deciding the need for public warning.

If a public warning is indicated, the DRC should provide the firm with a model press release. Models are located on [FDA's Industry Guidance](#) page. Note that only certain food press release models already have appropriate hazard statements incorporated into the model. Otherwise the DRC should obtain an appropriate hazard statement from the CRU to provide to the firm. Additionally, the DRC should encourage the firm to include an image of the recalled product with their public warning.

Once the firm has provided the DRC with a draft public warning, the DRC should review the draft and work with the firm to address deficiencies. When they have been addressed, the district may forward the draft to the CRU and OSPOP/DE/ROB for further review (include CORE Communications for human food recalls associated with outbreaks being coordinated by CORE). However, this is not a requirement, particularly if the draft closely follows the model.

The DRC should request that the firm provide the division with a copy of the final version of the public warning once it has been released. If the firm intends to issue it via their website, request the firm's permission for FDA to capture text and images from the website (since the website is usually copyrighted). If the firm issues the public warning via a press service, obtain a copy directly from the firm - not a copy as it appears on the press service's copyrighted website.

The DRC will send a copy of the firm's final version public warning (or web page link) to OSPOP/DE/ROB with a request that it be posted to FDA's website. Also send an image of the recalled product to be posted but do not delay forwarding the public warning pending receipt of an image of the recalled product – the image can be later sent separately. If the recall involves numerous products, the DRC may consult with OSPOP/DE/ROB regarding the posting of representative images instead of an image of each recalled product.

If the firm has issued its public warning without input from the FDA, the DRC will obtain a copy (or web link with the firm's permission for FDA to copy text and any images that are associated with it) and forward it to OSPOP/DE/ROB for posting.

In instances where the firm issues a corrected or updated public warning or an additional public warning for a recall expansion, the DRC should follow the same procedures for reviewing the public notification and submitting it for posting.

The DRC should engage with the CRU and OSPOP/DE/ROB if there are problems such as:

- The firm declines to issue public warning for a recall which fits the criteria for public warning
- The firm commits to issue public warning but does not issue one in a timely manner
- There are serious deficiencies in the firm's public warning which the firm refuses to address such as incorporating a hazard statement that minimizes the hazard posed by the recalled product

Note: There are some instances where a state government issues a public warning for a recall. FDA may post a copy of the state-issued public warning, particularly if the recalling firm does not issue its own. In such instances, the DRC should obtain a copy of the state's public warning, along with the state's permission for FDA to post it, and forward the state's public warning to OSPOP/DE/ROB for posting.

2. Responsibilities and Procedures - Center Recall Unit (CRU)

- Advise DRC's regarding the need for public warning for a recall
- When model press releases do not include a hazard statement, provide DRC's with an appropriate hazard statement to provide to the firm
- Promptly review a firm's draft public warning when requested by the DRC
- Advise, when requested by OSPOP/DE/ROB, whether a firm's public warning is appropriate to post to FDA's website
- In instances where a firm declines to issue public warning or when a firm's public warning is inadequate, initiate process for issuance an FDA public warning

3. Responsibilities and Procedures – OSPOP/DE/ROB

- Promptly review a firm's draft public warning when requested by the DRC
- In instances where the firm's public warning appears inadequate, discuss with the CRU whether to post the firm's public warning to FDA's website
- Post firm's, State's or FDA's recall public warning and images to the "Recalls, Market Withdrawals, and Safety Alerts" page of FDA's website

- When necessary, coordinate with FDA Web Staff to set up and populate “Major Product Recall” web pages. These are established to display related public warnings, for example, the recall of an ingredient and downstream firms that utilized that ingredient in a finished product.
- Upon assignment, review FDA-issued recall public warnings and other announcements related to recalls

7-8 RECALL MONITORING

7-8-1 Background

It is the recalling firm’s responsibility to determine whether its recall is progressing satisfactorily. The firm has an obligation to conduct effectiveness checks as part of its recall strategy. The purpose of effectiveness checks is to verify that all consignees at the recall depth specified by the strategy have received notification about the recall and have taken appropriate action.

In some instances, a recalling firm may be unable to check the effectiveness of its recall. This could occur when the customer list is non-existent (e.g. cash and carry store customers) or confidential business records of a firm’s customers are not accessible, e.g. the sub account does not provide their distribution to the recalling firm. In such cases, FDA may directly assist in this activity by conducting recall audit checks and, where necessary, seek assistance from cooperating state and local agencies and third party contracts.

Furthermore, the FDA recognizes that effectiveness checks also serve an audit function, and the agency reaffirms its expectation for closely monitoring recalls and assessing the adequacy of a firm’s recall efforts. Therefore, as part of its audit responsibilities, FDA may selectively conduct audit checks separately from the effectiveness checks of the recalling firm.

7-8-2 Managing FDA’s Recall Audit Check (RAC) Strategy

The purpose of FDA recall audit checks is to determine if a recalling firm’s consignees received notification of the recall, and followed the instructions listed in the notification. The division that is monitoring the recall event is responsible for ensuring the FDA audit strategy is implemented. This section pertains to both voluntary and ordered recalls.

1. Determine if a RAC Assignment is Necessary

The DRC monitoring the recall event will consider issuing an audit check assignment for potential class I and II recalls. Some factors that may cause the DRC to decide not to issue a RAC assignment are:

- Audit checks are not normally performed for Class III recalls. However, in rare situations the CRU or OSPOP/DE/ROB may request RACs be conducted for a class III recall.

- All recalled product was distributed outside the United States
- All recalled product is expired or past shelf life
- The recall was completed before the FDA was made aware of it, and due to the length of time since products were available, RACs are not likely to be beneficial

The DRC will indicate in RES if a RAC assignment is necessary using the drop down option on the Event Details page. If the DRC indicates that a RAC assignment is not needed, a justification is to be entered in RES, and no further action is needed unless the CRU does not concur.

The CRU will review RES during the classification process, and if they do not concur with the DRC's recommendation, they will indicate as such in RES. In this situation, the DRC may need to issue/re-issue a RAC assignment. If the division disagrees with the CRU's recommendation, OSPOP/DE/ROB will assist in making a final determination.

2. Determine Who Should Conduct the RACs

A. FDA Divisions

Depending on the distribution of the product, RACs are conducted by the monitoring division or extended beyond your own division, in order to have the most thorough results from which to determine a recall's effectiveness. The instructions in this section's #4-7 are for recall audit checks conducted by FDA

B. Third Party Contractors

Depending on availability, there may be third party contractors available to the field to conduct RACs. OSPOP/DE/ROB coordinates and monitors the assigning and completion of third party RAC assignments. You may choose to have a portion of, or all of your RAC assignment completed by the third party. For inquiries related to the third party contract, contact OSPOP/DE/ROB.

C. State Contract

Some states have contracts with the FDA which include conducting audit checks. Follow your division's procedures for coordinating the assignment of state-conducted RACs. See section 7-8-4 of the RPM for more information.

3. Determine How Many RACs to Assign

The DRC needs to determine how many RACs are needed to be able to evaluate the effectiveness of the recall. For human food recalls, please see Attachment L for a recommended number of recall audit checks to assign. If you assign a different

amount of RACs than the table suggests, please indicate in the Recall Audit Check information section on the Summary/Termination page in RES your justification. There are some factors that may be reason to do an increased number of RACs for a recall, for example: a recalled product is implicated in an ongoing outbreak, the recalled product target population is immunocompromised individuals, the recalled product is a bulk ingredient and may have been used to manufacture new products, etc. There are some factors that may be reason to do less RACs, for example: all consignees of the recalled product are in the same store chain with a streamlined recall communication process, etc.

The monitoring division may consult with the CRU regarding the appropriate level of audit checks but should not delay issuance if CRU concurrence is not received within two working days.

The DRC will recommend a level of RACs to assign in RES. If it seems likely that product was further distributed past the direct accounts, determine how many sub-account RACs to assign and also indicate as such in RES. The CRU will review the level of RACs recommended in RES during the classification process, and if they do not agree with the DRC's recommendation, they will indicate as such in RES. In this situation, the DRC may need to re-issue their RAC assignment. If the division disagrees with the CRU's recommendation, OSPOP/DE/ROB will assist in making a final determination.

4. Preparing the RAC Assignment

The DRC will provide specific instructions using a RAC Assignment Memo (see Exhibit 7-13 for an example format) for RACs conducted by FDA. The memo will include the RES Event ID number, PAC code to be used, recalling firm name and FEI information, recalled product and code information, the reason for recall, the firm's recall strategy, number of audit checks to be conducted and depth to which they should be conducted, type of audit checks to be conducted (phone, visit, email, etc.), and applicable attachments described below, at a minimum. Some things to consider when creating the RAC assignment are:

- There may be some situations where the DRC will want to indicate specific consignees to be audited, for example if the recalling firm identifies specific consignees who received recalled food product(s) that were purchased for use in a domestic nutrition assistance program (e.g. National School Lunch Program), those consignees should be included in the audit checks. You also may choose to assign audit checks at accounts where certain segments of the population at greatest risk (e.g., infants, children, elderly, surgical patients, pets, and livestock) are exposed to or obtain the recalled products. When specifying what consignees should be audited, try to assign RACs at a variety of locations to make better use of FDA resources. For example, if possible avoid assigning RACs to many locations within one corporate

structure which uses an electronic recall notification system. Note: Do not assign RACs at USDA, VA, or DOD facilities, including military commissaries.

- Consideration should be given towards the type of RAC being assigned. Visits, rather than telephone calls, are preferable for recall audit checks especially Class I recalls. However, resource constraints may make it necessary to conduct the audit checks by telephone. Ineffective telephone audit checks may need to be followed by a visit to ensure effectiveness of the recall action. In some cases, audit checks may be initiated by mail and/or email, then completed by telephone (e.g. recalls of dietary supplements purchased online, where limited customer information is provided). When initiating the audit check process by mail or email, take care to protect the privacy of the individual you are trying to contact. See Exhibit 7-14 for an example template for recall audit checks initiated by mail and/or email. Audit checks by visit are not to be conducted at consumer homes unless OSPOP/DE/ROB specifically instructs that they be conducted.
- Some RAC assignments should include specific instructions on additional information the performing divisions should gather. For example, if the recalled product is a bulk ingredient product, consider including instructions for the RAC to cover how the ingredient was used and what documentation should be collected to determine if a new recall is necessary (manufacturing records, labeling, etc.). OSPOP/DE/ROB or the CRU may also request additional information be gathered during a RAC assignment to help assess the scope and/or hazard of the recall.
- Include the due date in your RAC assignment. The due date should be 10 working days from the issuance of the RAC assignment.
- In some cases, OSPOP/DE/ROB or the CRU may request audit check status updates on a regular basis to keep them updated on the status of the RAC assignment. In these instances, you may include that request in your RAC assignment.
- RAC assignments which show there are potential distributors of the recalled product should include instructions for conducting sub-account RACs to the appropriate depth, if the depth is beyond the distributor level. Include the amount of sub-account RACs to conduct in your RAC assignment.
- For those recalls which are corrections where the correction will be completed at a later date, the monitoring division should consider whether it's appropriate to split the assignment with a portion of audit checks conducted to determine consignees have been notified of the correction (e.g. new

software/equipment being installed, serviceman's visit to correct item, revised user guides, etc.) and another portion of audit checks to confirm the correction has been completed.

- RAC assignments should include attachments which will aid in conducting the RAC, such as the firm's notification letter, labeling, press release (if applicable), and distribution list when specific consignees are not indicated.

5. Routing the RAC Assignment

In those instances where the monitoring division anticipates that the recall will be classified Class I or II, the audit check assignment should be issued within 10 working days after the distribution chain has been notified of the recall (issuing it earlier may result in ineffective audit checks since consignees may not have received and complied with the formal recall notification). It is critical that the agency ensure that the products are off the market or corrected, and that consignees have been notified of the recall action. This means the audit check assignment will typically be issued before the recall is determined or formally classified. Note: These timeframes do not apply for radiation emitting devices and electronic product recalls. For these recalls, follow CDRH recommended recall audit check strategy.

Email the audit check assignment and attachments using the following subject line: "RAC Request – RES Number – Recommended/Actual Classification – Due Date – Recalling Firm Name" to each division from which you are requesting RACs be conducted. The monitoring division should upload a copy of the RAC assignment memo into RES upon issuance. Indicate in RES the date the RAC assignment was issued on the Event Details page.

6. Conducting and Returning the RAC Assignment

The division receiving audit check assignments should consider them high priority and should accomplish them by the due date listed, if possible. If instructed to in the assignment, provide audit check status updates to the monitoring division at the requested intervals. It is the responsibility of the performing division to notify the monitoring division of circumstances which will adversely delay the completion of the assignment. Copies of any such communication should be forwarded to the CRU and to OSPOP/DE/ROB.

The performing division will conduct RACs to the depth requested in their RAC assignment. Follow Chapter 7 of the Investigations Operations Manual (IOM) for detailed instructions on conducting RACs. The performing division supervisory investigator will complete and endorse the Form FDA-3177 per the IOM Chapter 7 and send the endorsed form to the monitoring division recall coordinator. Accurate endorsements are necessary as they give the monitoring DRC an idea of the effectiveness of the firm's recall.

Sub-Recalls

A sub-recall is an action taken by a recalling firm's consignee to notify their own consignees of the recall, as long as no changes were made to the recalled product. If the recalling firm's account further manufactured the recalled product (for example, if they used the product as a component of a new product, re-labeled the product to obscure the original product name and/or lot code, repackaged the product, etc.) the account has created a new product which could warrant a new recall, instead of a sub-recall.

If a sub-recall has been or should be initiated (e.g. the consignee further sold the product, and the recall depth has not been met), the performing division will collect documentation and all relative information about the sub-recall. The performing division will also ensure audit checks are performed of subsequent consignees, when applicable. It is preferred that the performing division conduct the sub-recall audit checks themselves, regardless of the geographical location of the sub-accounts. Sub-recall checks may be initiated/conducted by telephone, email, and/or mail in lieu of visits in these instances, unless the assignment states otherwise.

If a consignee of the recalled product refuses to initiate a sub-recall promptly, the performing division supervisory investigator will advise the assigning DRC, OSPOP/DE/ROB, and appropriate CRU of the situation, and indicate what additional steps the division is taking to achieve a satisfactory sub-recall. Options for consideration include meetings between division management and top management of the recalling firm and/or sub-recalling firm, notification of consignees directly, reporting to State and local officials, recommendation for FDA requested or ordered recall, and initiation of administrative proceedings or enforcement actions.

7. Evaluating and Tracking Incoming RACs

The monitoring division will track the completion of the RACs they assigned, evaluate RACs when received to ensure that they are adequate and then retain them. If, during the evaluation, the division discovers any issues with the recall or audit checks, the division must ensure that appropriate and timely follow-up action is taken. If a RAC assignment is late, insufficient information has been collected, or the endorsement is incorrect, the monitoring division recall coordinator will advise the endorsing supervisory investigator in the performing division and request follow-up or correction.

The monitoring division will follow up with the recalling firm for each recall audit check endorsed as Ineffective Notifying Firm, if the notifying firm is the recalling firm. The recalling firm may have evidence to support that they did notify their direct account consignee, which could be useful in determining the effectiveness of the recall. For downstream consignee recall audit check, see [Sub-Recalls](#).

If the monitoring division discovers recalled product(s) were purchased for use in a domestic nutrition assistance program (e.g., National School Lunch Program), the division will forward the information to OSPOP/DE/ROB.

The monitoring division recall coordinator is responsible for uploading all Form FDA-3177s into RES Associated Documents. If RACs were conducted by third party, upload the results of the third party RACs into RES Associated Documents.

Reconciliation of Distribution Lists

The monitoring division should consider issuing an assignment to reconcile the direct consignee distribution list provided by the recalling firm if there is suspicion that the list is inaccurate. Discrepancies may be found while evaluating RACs or through other information related to the direct consignees provided by the recalling firm.

These discrepancies may include but are not limited to:

- (1) during RAC review, the DRC finds that direct consignees are reporting that they received product, but they were not notified of the recall by the recalling firm. DRC follow up indicates that they should have been notified and the recalling firm cannot provide evidence of the recall notification. This could be an indication that the consignee list used for notification is different than the consignee list provided to FDA.
- (2) firm provides a list of known recipients of the recalled product, however during RAC review, the DRC finds that consignees on this distribution list state that they did not receive the recalled product.
- (3) the DRC receives information from another source (e.g. industry or State) that a direct consignee was not notified of the recall and the DRC's review of the direct consignee distribution list finds this consignee is not listed. This could be an indication that the consignee list is incomplete.
- (4) evidence of malfeasance relating to a firm's records.

The reconciliation can be conducted by evaluating shipping records, bills of lading, invoices, etc. If discrepancies are found, the monitoring division should ask the recalling firm to notify the correct direct consignees. Modification or reissuance of the RAC assignment, based on the corrected direct consignee distribution list, should also be considered.

8. Ineffective Recalls

If the monitoring division recall coordinator's evaluation of the Form FDA-3177s or third party RAC results indicates issues with the effectiveness of the recall, the monitoring division must ensure that appropriate and timely follow-up action was taken with the recalling firm or a downstream consignee (whichever firm's action resulted in the recall being ineffective). If action by the recalling firm is appropriate to improve the effectiveness of the recall, the monitoring division should discuss the situation with the firm and determine what action the firm intends to take to improve its recall efforts such as issuance of additional recall communications, etc. The division may choose to send an Ineffective Recall Letter (see Exhibit 7-9).

For human food recalls, please see Attachment L for instructions on evaluating the effectiveness of the firm's notification system using the result of the RACs.

If the monitoring division determines the firm's action is not sufficient, the monitoring division will notify the CRU and OSPOP/DE/ROB of the situation and may recommend appropriate action. Actions to be considered include actions such as FDA-requested or ordered recall, initial or further public warning, multiple seizures, and injunction.

The issuance of another recall audit check assignment may be necessary to determine if the recall has become effective after the issuance of additional notification or other actions to improve recall effectiveness.

The monitoring division is responsible for the day-to-day management of a recall. They will ensure adequate progress and timely completion of the recall by the recalling firm. If the firm is not providing necessary information, an establishment visit may be necessary. If the monitoring division encounters unreasonable delays by the recalling firm in conducting the recall, contact the CRU and OSPOP/DE/ROB to discuss options.

7-8-3 Requesting and Reviewing Recall Status Reports Requesting and Reviewing Recall Status Reports

The recalling firm is initially made aware of the request for recall status reports via the recall acknowledgement (RPM 7-7-1) and they are reminded to submit updates upon receipt of the recall classification letter.

If the recalling firm fails to submit recall status reports or fails to submit the reports within the requested frequency, the DRC or designee should request a status report. This request can be sent via RES auto generated email. In the event that the firm does not have an email address or RES is not functioning, a letter can be sent via any preferred method (e.g. fax or mail). If manually preparing a request via letter for status reports, consider making note of this request under View Activity in RES. A model Letter Status Report Request is attached as Exhibit 7-16.

Upon receipt of the status report or as soon as possible, the DRC or designee should review the firm's recall status report to assess the progress of the recall. When necessary, the DRC should reach out to the recalling firm to further discuss the recall's progress.

Recall status reports can be filed in RES under Associated Documents.

7-8-4 State Audits

Food inspection state contract(s) may have an elective for states to conduct recall audit checks. If this elective has been exercised the state will conduct recall audit checks at the direct account level to facilitate collection of direct account distribution records, determine the need for a new recall, and/or to witness any product destruction. States will use the FDA Form 3177 to document the results of audit checks conducted under this elective.

Assignments under the RAC elective can be used to facilitate the submission of direct account consignee lists to the FDA when FDA has determined a need to post retail consignees. Further auditing to the retail level will be conducted by recall audit check assignments to FDA field staff and/or the FDA third party RAC contract.

State food regulatory programs may also conduct recall audit checks separate from the RAC option under state food inspection contracts, in accordance with their state recall procedures. These state recall audit check efforts are not directed or mandated by FDA; collaboration between FDA divisions and state food regulatory programs when conducting recall audit checks is strongly encouraged to support consolidation of recall audit check data and avoid redundancy.

7-9 RECALL TERMINATION

A recall will be terminated when the Food and Drug Administration determines that all reasonable efforts have been made to remove or correct the product in accordance with the recall strategy, and when it is reasonable to assume that the product subject to the recall has been removed and proper disposition or correction has been made commensurate with the degree of hazard of the recalled product. Written notification that a recall is terminated will be issued by the appropriate Food and Drug Administration division office to the recalling firm.

The monitoring division will make this determination by reviewing completed recall audit checks, the recalling firm's status reports, and product disposition records. Additionally, FDA will take into account any additional reports suggesting recalled products may still be on the market.

The division office should advise recalling firms that FDA will not terminate a recall until the firm has brought the product into compliance or disposed of it in an acceptable manner. DRC's will request and review product disposition records, which demonstrate the firm's actions to destroy, rework, or otherwise bring recalled product into compliance. In the case of Class I recalls and high-risk Class II recalls, a limited close-out inspection to verify recall completion and observe/document product disposition, may be conducted at the discretion of the division recall coordinator and division management. For those recalls where FDA or the state has witnessed disposition of the recalled product during a close-out inspection, the DRC will maintain in the recall file a copy of the EIR/investigation memo and/or any other documents created or collected by the investigator, which document disposition of the product.

The division will notify the recalling firm by letter that FDA considers the recall terminated. See Exhibit 7-11 for a Model Recall Termination Letter.

Termination of a Class I recall requires center concurrence. When the monitoring division office concludes that such a recall is ready for termination, the division recall coordinator will enter the information required for termination in RES on the "Summary and Termination" page. This page includes fields to provide the: complete reason for recall, quantity recovered or number of units corrected, product disposition, root cause of the problem, section of the law violated, preventative action taken by the firm, legal

action by FDA, and name and date of division official approving the termination recommendation. Centers may request additional documentation. When all required fields have been completed, the coordinator clicks on “continue” at the bottom of the page, which brings up the Summary and Termination validation page. After verifying that all data is correct, clicking on the “Save/Send Termination Recommendation” button will send an email to the CRU recommending termination.

Upon receipt of the termination recommendation email, the CRU will access RES, review the termination information and, if in agreement with the recommendation for termination, provide concurrence in RES (at the bottom of the Summary and Termination page) by inserting the name of the concurring center official. The CRU will change the “recall status” field to “terminated” and click on the “Save/Send Termination Concurrence” button which updates the recall action and generates an email to the division and OSPOP/DE/ROB advising that the recall is terminated.

Center approval is not required for Class II or III recall terminations. The division offices will follow the same basic procedure as outlined above for Class I recalls, but will just change the “status” field to indicate “terminated” and click on the “Save/Send Class II/III Termination” button. The RES then generates an email to the center and OSPOP/DE/ROB that the recall has been terminated by the division office.

FDA should terminate the recall within three months after the firm completes the recall. The division office should not wait for compliance actions to be initiated or executed to terminate a recall. A firm may request termination of a recall. However, recalls may be terminated absent a request from the recalling firm if termination is warranted. If the division office feels that the recalling firm is unable to ensure that violative goods will not reenter channels of distribution, the division office should consult with the CRU and/or OSPOP/DE/ROB for the best course of action. Division offices should contact the CRU and/or OSPOP/DE/ROB for directions on terminating recalls when there is inadequate information to determine recall effectiveness e.g. the recalling firm is out of business

7-10 ATTACHMENTS, EXHIBITS, AND APPENDIX

Note: For each recall action, the RES provides a single record that is initiated at the beginning of the recall with an Alert. The record is continually updated in order to provide information for the Recall Recommendation, Classification, FDA website posting, any updates, and finally, Termination. The RES requires submission of some information not previously required. As the RES is finalized, detailed instructions will be provided for division and center coordinators. At the present time, the information provided or requested in the following attachments remains pertinent and appropriate for all steps of the recall process.

ATTACHMENTS:

- A Recall Alert Information
- B Recommendation for Recall Classification
- B1 Recommendation for Recall Classification and Termination
- C Recall Termination or Recommendation for Termination
- D Health Hazard Evaluation Worksheet
- D1 21 CFR 7.41(a) Guidance to Health Hazard Evaluation Committees
- E Recalls of Radiation Emitting Electronic Products Under Subchapter C - Electronic Product Radiation Control Of Chapter V Of The Federal Food, Drug, And Cosmetic Act (The Act), Formerly The Radiation Control For Health And Safety Act Of 1968 (RCHSA)
- F Recalls of Infant Formula
- G Recalls of Medical Devices, Section 518(e)
- H Methods for Conducting Recall Effectiveness Checks
- I Mandatory Recall of Tobacco Products
- J Mandatory Recall Authority for Foods
- J1 Recommendation Memorandum
- J2 Notification of Opportunity to Initiate a Voluntary Recall
- J3 Prehearing Order to Cease Distribution and Give Notice
- J4 Denial of Hearing Request
- J5 Hearing Report Cover Letter
- J6 Hearing Report
- J7 Vacated Order
- J8 Amended Order
- J9 Modified Order
- J10 Mandatory Food Recall Process Flow Chart
- K Notification, Nondistribution, and Recall of Controlled Substances for Human or Animal Use
- K1 Order of Nondistribution
- K2 Hearing Report Cover Letter

- K3 Hearing Report
- K4 Vacated Order of Nondistribution
- K5 Continued Order to Include Recall
- K7 Notification, Nondistribution, and Recall of Controlled Substances for Human or Animal Use Porcess Flow Chart
- M Medical Device Safety Alerts

EXHIBITS:

- 7-1 Model Effectiveness Check Letter (Industry)
- 7-2 Model Effectiveness Check Response Format (Industry)
- 7-3 Model Effectiveness Check Questionnaire for Telephone or Personal Visits (Industry)
- 7-4 Model Recall Letter (Generic, All Centers)
- 7-5 Model Recall Return Response Form
- 7-6 Model Recall Envelope
- 7-7 Model FDA Requested Recall Letter
- 7-8 Model Acknowledgement (FDA to Recalling firm)
- 7-9 Model Notification of Classification Letter (FDA to Recalling Firm)
- 7-10 Model Recall Ineffective Recall Letter
- 7-11 Model Recall Termination Letter
- 7-12 Model Combined Recall Notification of Classification and Termination Letter
- 7-13 Model Recall Audit Check Memo Assignment
- 7-14 Initiating RAC by Mail or Email
- 7-15 Weekly Class I Recall Status Report (Optional)
- 7-16 Recall Status Report Request Letter (to be used when RES automated email request cannot be used due to the RES not functioning or the firm not having an email address)
- 7-17 Model Reconditioning Proposal Template (FDA to Recalling Firm)
- 7-18 Market Withdrawal Designation Template
- 7-19 Market Withdrawal Designation – Additional Information Requested
- 7-20 Market Withdrawal Close Out To be used to close out when additional information was requested

APPENDIX:

Appendix A FDA Food Recall/Action Initiation Process Flow/Timeline for Class I Human Food Recalls (SAHCODH)

Attachment A – Recall Alert Information

The following fields are required to submit an alert to the CRU and OSPOP/DE/ROB via RES. For fields marked with (Int), do not include commercial, confidential, proprietary information.

On the Edit/Start Recall Page:**Center**

Drop down list of centers which will review the RES entry. The division entering the event into RES should choose the appropriate center.

Recalling Firm FEI

This is the FEI of the firm conducting the recall.

If an FEI does not exist for the firm conducting the recall, contact your OEI Coordinator to request an FEI for the firm. If the rest of Attachment A information has been obtained, send an alert via email to the CRU and OSPOP/DE/ROB with information about the recall and that an alert will be submitted via RES once an FEI is created. Add an activity on the View Activity screen in RES explaining the reason for the delay in submitting an alert.

Firm Name (Int)

Name of the firm conducting the recall. This is auto-populated once the Recalling Firm FEI is selected.

Public Reason For Recall

General succinct description of the reason for recall for all products involved in the recall.

Note: No commercial, confidential, proprietary information or firm name is to be entered here.

On the Product Details page in RES:**Industry-Product Code**

Industry-Product Code of the recalled product(s). In instances where the products are mispackaged, enter a product code based on the labeling rather than the contents of the package.

Product Description (Int)

Identify recalled products as preferred by the specific Center. If a complete list of products or all specific product information has not been obtained, enter a generic product description and indicate details are pending.

Product Public Reason for recall (Int)

Public Reason for Recall for the selected product.

Code Information (Int)

Codes that identify the selected product (e.g. batch codes, lot codes, expiration dates, serial numbers) that describe the scope of the recall. If all code information has not been obtained, indicate that code information is pending.

District Recommended Classification

Drop down list where the division indicates their preliminary recommended classification of the selected product, or if the product removal or correction is believed to be a market withdrawal, safety alert, or stock recovery.

Attachment B – Recommendation for Recall Classification

Update and transmit the electronic record in RES with the required information necessary for the CRU to review and classify the recall. RES will, via Outlook Email, automatically notify the appropriate center and OSPOP/DE/ROB personnel of the recommendation through established Outlook lists. Guidance for information to be included in the recommendation is as follows:

1. Product Description (INT), Trade Name, and Product Usage fields- (Product Details and Center Specific Pages)
 - a. For each product, provide as applicable: Pertinent labeling to identify the product to include the product name (brand and generic) and the intended use or indications. Model and/or catalog numbers which further define the exact product. Describe how it is packaged such as box, flexible plastic, glass bottle or vial; the type such as tablet, sugar coated, or liquid, capsule, or powder; strength; sizes; form; route of administration; shipping or unit package. Provide a brief description of the product and its use. If product labeling does not indicate how the product is to be used, and the health hazard is dependent on use, consult the firm's catalog, the Red Book, or similar sources for the information.

If a drug product, indicate Rx or OTC and include the NDA/ANDA and NDC or UPC codes. For medical devices, obtain and include the 510(k), IDE, or PMA numbers as well as any related Corrections and Removals numbers.

If it is determined that the product must be examined physically for health hazard evaluation and/or to determine the efficacy of the corrective action, collect and ship an appropriate sample to the designated unit via the most expeditious and practical means available. Notify the center of the time, how sent, and estimated time of arrival.

- b. For each product give: brand name; name, address, and type of responsible firm on label; number and description of private labels. Submit a complete copy of all labeling (including product inserts or information sheets) to the appropriate CRU by an expeditious method, such as Facsimile, Federal Express, or Overnight Mail, depending on the circumstances involved.
2. Code Information (RES Product Details page)

Code Information (INT) field - List all lot and/or serial numbers, product numbers, packer or manufacturer numbers, sell or use by dates, etc., which appear on the product or its labeling.
3. Recalling Firm/Manufacturer/Responsible Firm (for the violation) – (RES Firm/Contact Details pages)

Recalling Firm Information fields:

FEI field- provide FEI number and click search. If the firm is in the Official Establishment Inventory (OEI) the firm name and address is provided. Complete any fields not automatically populated. If FEI is unknown, or does not exist, type in "unknown" in the FEI field and then fill in all following information fields. Under the "Comment" box, identify the type of firm, i.e., manufacturer, importer, broker, repacker, own label distributor.

Manufacturer Information field – Same as FEI field. In the "Comment" box, add any information to clarify relationships with either the recalling or responsible firm.

Responsible Firm Information field – Same as FEI field. In the "Comment" box explain the firm's relation to the product such as processor, contract sterilizer, distributor, component supplier, etc.

4. Reason for Recall Recommendation (RES Event Details pages)

Complete Reason for Recall field - provide detailed information as to how the product is defective and violates the FD&C Act or related statutes. Refer to the [IOM](#) Chapter 7, Subchapter 810 for inspectional guidance.

- a. Include any analytical findings in qualitative and/or quantitative terms, indicating whether firm, FDA, State, or private firm analysis. Indicate the analyzing laboratory. Explain all State involvement in the recall, including sample collection or analysis, recall agreement or initiation, recall monitoring, and product disposition.
- b. Provide inspectional (GMP) or other evidence where appropriate.
- c. In cases where a veterinary drug product is being recalled due to sub potency of active ingredients prior to labeled expiration date, provide the following information:
 1. The firm's stability testing plan (including analytical methodology) which established the labeled expiration date.
 2. Specific batch numbers in the stability studies and assay values that are the basis of the firm's recall.
 3. Potency specifications which the firm uses for recall purposes.
 4. Final assay values for the active ingredients which were the basis of the initial release of the batch.

It should be noted whether or not information regarding stability data on file with the firm and the Quality Control procedures used by the firm to determine the potency of the active ingredients, is available in the EIR.

Root Cause field - provide any information available which identifies circumstances which resulted in, or contributed to, the problem which resulted in the recall.

Type of Injury Field – List in chronological order any complaints, injuries, or associated problems with the recalled product(s). Note: specific reference to MDRs and Corrections and Removals Reports are reported elsewhere.

5. Volume of Product in Commerce (RES Event Details page)

Quantity Manufactured field – This calls for the total “event” quantity for the product or products recalled.

Quantity Distributed field (Internet) – This is the total of all products distributed and should be the sum of quantities distributed for all product(s).

Note: Each product has its own field for quantity of product distributed.

Manufactured From field – Provides dates.

Expected Life - This could include products such as pacemakers, which have a calculable life span.

Shelf Life - This primarily references perishable foods but may also be used for medical devices, biologics, and certain drugs.

NOTE: If the recommendation is for a FDA Requested Recall, assure that there is, in fact, product remaining in commerce before preparing and submitting the recommendation.

6. Distribution Pattern (RES Event Details page)

Distribution Pattern field (Internet) – This field is to provide the public with the general area of distribution such as, “Distributors in 6 states: NY, VA, TX, GA, FL and MA; the Virgin Islands; Canada and Japan”. The term “nationwide” is defined to mean the fifty states or a significant portion of them scattered across the United States. The six United States territories, Guam, Puerto Rico, American Samoa, Virgin Islands, and the Canal Zone, are to be reported separately.

Consignee Details fields

List of Consignees or Comments – This field should be used to list U.S. government, military and/or civilian units/agencies to which product(s) has been distributed. This would include the Defense Personnel Support Center (DPSC), Department of Defense (DOD) Hospitals, Department of Veterans Affairs (DVA), US Department of Agriculture (USDA) (especially any product which may reach the school lunch program), or other government agency sales/distribution. If the consignee list is long, it may be submitted separately through the division Recall Coordinator to OSPOP/DE/ROB. Indicate whether these were direct or contract sales. If there have been contract sales, report the contract number, contract date, and implementation date. Any discussion of product sales, products expected to remain on the market at time of recall, or related topics may

be included in comments. (This information is not published on the Internet)

Number of Domestic Consignees – Provide number

Number of Foreign Consignees – Provide Number

Chart - As best you can, check off the types and approximate number of consignees in the chart.

7. Firm's Recall Strategy (RES Event Details page)

Recall Strategy field - If the firm was advised of FDA findings and the problem was discussed with them, report its reactions and recall plans in detail. Similarly, if the firm advised FDA of the problem, report and explain the firm's own analytical results and/or information that resulted in the firm's decision to conduct a recall. Obtain the date that the firm realized the need for recall. (Firm Awareness Date on Start Recall page). Describe the firm's planned recall strategy, comment on its adequacy from the division's viewpoint, and evaluate the firm's ability to complete an effective recall. Sections 7.42 and 7.46 of 21 CFR, Part 7 - Enforcement Policy, Subpart C, provide information to be obtained from the firm for CRU evaluation. The firm's strategy should address the depth of the recall, the consideration of a public warning, and an appropriate effectiveness check division. It should also include the firm's intended course of action when an account which distributed the recalled product is found out of business. Include date recall was initiated, if already underway. If product is to be removed from the market place and recovered, its final disposition should be identified. Provide details of any publicity issued or to be issued by FDA, the firm, the state, or local government.

8. Firm Officials/FDA Contact/Public Contacts (RES Firm/Contact Details page)

Most Responsible Individual field - Provide name, address, and phone number (if available) for the most responsible corporate individual for the recalling firm. If someone other than the most responsible corporate official, or the FDA contact person, are to receive the original or copy of recall classification or termination letters, provide the name(s) under the "Comment" box.

Recall Contact field – list the name, address, phone number, email address, fax number, etc. of the person that is the FDA contact for recall operations.

Public Contact field – list for the recalling firm, either a person or staff such as "Public Relations Staff" that can handle contacts from the public. Include name, address, phone number, facsimile, and email address as applicable.

9. Division Audit Strategy (RES Event Details page)

Effectiveness Check Level field – Provide the firm's planned or division recommended effectiveness level.

Audit Check Level field – Provide the division's recommended audit check level, i.e. the level that the division believes will satisfactorily verify the recall's effectiveness.

Audit/Effectiveness Check Modification box - This box should be used to provide any modifications to the recommended levels, e.g. "Recommend level C (10%) audit checks at distributor accounts and level D (2%) not to exceed five sub accounts of each distributor audited."

Provide the firm's recall effectiveness history when recommending low levels of, or no audit checks, and monitoring of recall status from the firm's own records. This box may also be used to provide the division's proposed strategy for monitoring the recall, including the time table for follow-up visits or firm contacts for reviewing the recall status. State what actions have already been taken by FDA such as inspections, sample collections, etc.

Attachment B1 – Recommendation for Recall Classification and Termination

Note: Under RES, this information will be a continuation of the electronic recall record and many of these fields will be pre-populated as the recall recommendation data is inputted. However, the following fields need to be completed to justify termination.

Product: See Attachment B.

Codes: See Attachment B.

Recalling Firm/Manufacturer: See Attachment B.

Reason for Recall Recommendation: See Attachment B.

Volume of Product in Commerce, Quantity Recovered, and Disposition:

Provide total volume of product distributed and under the recalling firm's control. Provide quantity of product recovered or corrected by the recalling firm. If no or little product was found in the market, explain why (i.e., expired, short shelf life, rapid turnover, etc.).

Indicate the recall was completed and provide verification of disposition or correction of recalled product.

Distribution: See Attachment B.

Firm's Recall Strategy:

Describe the level of distribution to which the recall was extended. Provide complete description of the firm's recall notification and/or correction efforts. List the number of consignees responding to the firm's notification. Provide effectiveness checks accomplished and their findings, and/or other means the firm has to document the recall effectiveness. Provide conclusion as to the adequacy of the firm's actions. If known, indicate steps the firm has taken to prevent similar occurrences.

Violation:

Provide the section of law violated.

Preventive Action:

Provide the action taken by the firm to prevent recurrence of the violation.

Division Audit Strategy:

Describe actions taken by FDA (inspections, sample collections, etc.). Provide details of any publicity issued. Provide results of any FDA audit checks or auditing of records at the firm. List any legal action planned or underway.

Attachment C – Recall Termination or Recommendation for Termination

A Recall Termination (Summary) or Termination Recommendation must be prepared and submitted for those recall actions not terminated at the time of classification. As indicated above under Recommendation for Recall Classification and Termination Format, the Summary and Termination page in RES is also an update to the continuous record. Class I recalls require Center concurrence for termination. Class II and III recalls and market withdrawals may be terminated at the division's discretion. RES requires the completion of all fields on the Summary and Termination page as well the recall status being "completed" and a date completed provided. Therefore update the recall record to contain the information listed above under Attachment B1. The division coordinator will have to determine that all applicable and required data is included before submitting the Class I "Recall Termination Recommendation" to the Center recall unit for concurrence. For Class II and III recalls, the division coordinator or other division personnel will prepare and submit, after coordinator review, the recall document to division management for concurrence. The name of the division manager approving the termination and the date of the approval is to be recorded in the recall record.

When the CRU concurs with the Class I recall termination recommendation in RES, notice of that concurrence will be electronically sent to the field coordinator and OSPOP/DE/ROB.

When the division obtains concurrence from division management for the termination of Class II and III recalls and so updates the RES recall record, the coordinator electronically notifies the CRU and OSPOP/DE/ROB of the termination.

Attachment D – Health Hazard Evaluation Worksheet

Note: The following Health Hazard Evaluation Worksheet has been developed by the agency. This worksheet, or an equivalent form, is to be used by all Center Health Hazard Committee personnel to record HHEs.

HEALTH HAZARD EVALUATION

1. PRODUCT/IDENTIFICATION NUMBER/USAGE (e.g. unit, lot, serial number, catalogue number, order number, etc.)
2. FIRM NAME, ADDRESS, IDENTIFICATION NUMBER(S)
3. NATURE OF PROBLEM

4. (a) Have any adverse reaction reports or other indication of injuries or diseases been reported relating to this problem?

☐ No

☐ Yes - Attach copies or explain

- (b) Have any adverse reaction reports or other indication of injuries or diseases been reported for similar situations?

☐ No

☐ Yes - Attach copies or explain

- (c) Is the problem easily identified by the user?

☐ No

☐ Yes

5. What is the risk to the general population?

- (a) For products not bearing dosage information, what is the normal consumption of the product by the general population and the population most at risk.

6. What segment(s) of the population is most at risk and why?
[e.g. entire population(animals/species), infants, children, elderly, pregnant women, women of child bearing age, nursing mothers, surgical patients, immune suppressed, clinical situations, food producing animals, non-food producing animals, other].

Is there any known/accepted off labeled use(s) that would increase or change the population at risk?

7. Within the population at risk, could individuals suffering from any particular conditions or diseases be more or less at risk and if so, why?
[e.g. Immune system debilities, diabetes, cardiac problem, concomitant medications, etc.]
8. What is the hazard associated with use of the product? Explain and cite literature references when applicable.

_____ Life-Threatening (death has or could occur)

_____ Results in permanent impairment of a body function or permanent damage to a body structure

_____ Necessitates medical or surgical intervention to preclude or reverse permanent damage to a body structure or permanent impairment of a body function

_____ Temporary or reversible (without medical intervention)

_____ -Limited (transient, minor impairment or complaints)

_____ No adverse Health Consequences

_____ Hazard cannot be assessed with the data currently available

Explanation: _____

9. What is the probability of an adverse event occurring?

_____ Every Time _____ Reasonable Probability _____ Remote

_____ Unlikely _____ Unknown

Explanation: _____

Signature _____

Date _____

Signature _____

Date _____

Signature _____

Date _____

Recall Product: _____

MARKET ASSESSMENT

Note: This market assessment is to be done by the Center's medical staff when requested to do so by the Center Recall Coordinator. This assessment should not impact on the health hazard. This assessment will only be used to alert agency personnel to potential drug shortage situations.

Would removal of this product(s) cause a major disruption relative to the treatment/prevention of disease? _____ No _____ Yes* _____ Not Applicable

* Please identify any alternative treatments/procedures that are available.

Center Recall Unit Assessment of Recall

Conclusion: the degree of seriousness of the hazard [real or potential] to the population at risk?

[] The product is violative and there is a reasonable probability that use of or exposure to the product will cause serious adverse health consequences or death. (Class I)

[] The product is violative and use of or exposure to the product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences (life threatening/death) is remote. (Class II)

[] The product is violative and use of or exposure to the product is not likely to cause any adverse health consequences. (Class III)

[] The product involves a minor violation or no violations. (Market Withdrawal)

Signature(s):

Date:

Attachment D1 – 21 CFR Part 7, Guidance to Health Hazard Evaluation Committees

The Food and Drug Administration's recall regulation (21 CFR Part 7) requires the conduct of an evaluation of the health hazard (actual or potential) presented by a product being recalled or considered for recall. The regulations (21 CFR 7.41(a)) specify the factors to be considered, among others, by the Health Hazard Evaluation Committee in making the health hazard evaluation. The purpose of the health hazard evaluation, in general, is to identify and document:

1. the population at risk,
2. conditions that may exacerbate or attenuate the risk of its occurrence,
3. the risk associated with the product under conditions of use (as labeled), and
4. the likelihood of the risk occurring in the future.

The purpose of these guidelines is to assist the Committee in the identification and documentation of the various factors listed in 21 CFR 7.41(a) that are to be considered in making the health hazard evaluation and to determine what additional data and information should be collected and evaluated during the recall either to confirm or revise the health hazard evaluation. The questions listed below are not all inclusive nor are they relevant to all recall situations. They are intended to focus attention on factors related to the significance of health hazards likely to be associated with a product being recalled or considered for recall.

21 CFR 7.41(a)(1) - Whether any disease or injuries have already occurred from the use of the product.

1. What is the name of the product (trade and generic) and what are its indications for use, where applicable?
2. What deaths, diseases, injuries, or other adverse reactions have already occurred in association with use of the product?
3. What documentation is there to support the association of the deaths, diseases, injuries, or other adverse reactions with the use of the product?
4. Was the product used in conformance with its labeled directions for use? (The Health Hazard Evaluation Committee should review product labeling for sufficiency in light of injuries). If not, did the deaths, diseases, injuries, or other specific adverse reactions result from product misuse?
5. If the product was used according to its labeled directions, were the associated diseases, injuries, deaths, or other specific adverse reactions due to a) product malfunction, b) product formulation, c) product quality (including potency, contamination, etc.), d) product design, e) inadequate directions for use, or f) other known or unknown causes? Specify.

21 CFR 7.41(a)(2) - Whether any existing conditions could contribute to a clinical situation that could expose humans or animals to a health hazard.

Any conclusion shall be supported as completely as possible by scientific documentation and/or statements that the conclusion is the opinion of the individual(s) making the health hazard determination.

1. Name the specific clinical conditions (e.g., diabetes, heart problems, etc.) which, if they exist, might render a person or animal more susceptible to experiencing a health hazard on exposure to the product.
2. How would these clinical conditions contribute to or change the risk of exposure to the products?
3. Could these clinical conditions mask or otherwise disguise the risk of exposure to the product?
4. What other products being used to treat these clinical conditions could contribute to or, conversely, lessen the risk of exposure to the product?

21 CFR 7.41(a)(3) - Assessment of hazard to various segments of the population, e.g., children, surgical patients, pets, livestock, etc., who are expected to be exposed to the product being considered, with attention paid to the hazard to those individuals who may be at greatest risk.

1. What is the universe of users by segment of population and what is the relative frequency of use of each, if known. For example, what percentage of the product is used by infants or children?
2. Which segment of the population exposed to the products is at greatest risk of health hazard?
3. Are any of the following high-risk groups likely to be exposed to the product?
 - a. Infants
 - b. Children
 - c. Elderly
 - d. Pregnant Women
 - e. Surgical patients
 - f. Others (specify)
4. For each of the high-risk groups identified, what is the anticipated frequency of exposure to the product?
5. In what setting is the product generally used (e.g., hospital, home, etc.)?
6. How frequently is the product used (e.g., daily, weekly, etc.) and what is the duration of use (e.g., one time only, for a month, over a lifetime, etc.)?

7. What percentage of the population at greatest risk is now under close medical supervision?

Could everyone in this population be easily brought under observation? In practice, would all users be brought under medical supervision if this is needed?

8. What actions or medical interventions could reasonably be expected to decrease the likelihood of occurrence of the health hazard? For example, could patient monitoring detect the product defect before it causes any untoward health consequences and could patient monitoring entirely prevent medical injury?

21 CFR 7.41(a)(4) Assessment of the degree of seriousness of the health hazard to which the population at risk would be exposed.

1. Are the health hazards likely to be acute (lasting several days to a few weeks) or chronic (lasting weeks to months)?

2. Describe the degree of seriousness of the health hazard if it did occur, and which specific segment of the population might be at risk? Express in terms of the following:

- a. Life threatening - death could occur
- b. Severe - permanent significant disability
- c. Moderate - transient but significant disability; permanent minor disability
- d. Limited - transient minor disability; annoying complaints
- e. None - no disability or physical complaints anticipated

21 CFR 7.41(a)(5) - Assessment of the likelihood of occurrence of the hazard.

1. How frequently have deaths, diseases, injuries, or other adverse reactions already occurred? How does the frequency of occurrence relate to the total extent of product exposure (e.g., number of devices implanted, number of prescriptions, etc.)? How has this frequency been documented?

2. If deaths, diseases, injuries, or other adverse reactions have not already occurred, estimate the likelihood of occurrence in each segment of the population at risk.

21 CFR 7.41(a)(6) - Assessment of the consequences (immediate or long range) of occurrence of the hazard.

- 1. What are the immediate consequences of the health hazard?
- 2. What are the long-range consequences of the health hazard?
- 3. If the product being recalled or considered for recall is used to treat a medical condition, are alternate forms of therapy available?

SUMMARY OF HEALTH HAZARD EVALUATION

On the basis of the answers to the questions listed above and any others that relate to the associated risk, state the likelihood of the health hazard occurring following exposure to the product being recalled or considered for recall and the likelihood of exposure to a defective product in all users of the product.

In addition, include in the recommendation specific data and information that should be collected, how and by whom these should be collected and evaluated, and how frequently the health hazard should be reevaluated.

Attachment E – Recalls Of Radiation Emitting Electronic Products Under Subchapter C - Electronic Product Radiation Control Of Chapter V Of The Federal Food, Drug, And Cosmetic Act (The Act), Formerly The Radiation Control For Health And Safety Act Of 1968 (RCHSA)

Recalls conducted under Subchapter C are different from recalls conducted under the Food, Drug, and Cosmetic Act in that Subchapter C has mandated recall provisions written into the Act (Sec. 535(a)). The law requires a manufacturer, when he learns that a product he manufactures is either defective or not in compliance with a published performance standard, to notify the Secretary of Health and Human Services (delegated to CDRH Director), and to notify the first purchaser (and known subsequent transferees) of the defect(s) or noncompliance(s). Subchapter C is specific as to the method of notification and procedure, and also contains "repair, replace or refund" provisions.

Differences may be encountered in dealing with recalls of radiation emitting versus non-radiation emitting medical devices. For medical devices, recall procedures for electrical and mechanical problems generally follow the pattern outlined in this chapter for general recalls. However, both medical and non-medical electronic products follow a different procedure when recalled under Subchapter C for radiation defects or deviations from a radiation safety standard. For example, consider a piece of diagnostic x-ray equipment that displays a mechanical problem not covered by Subchapter C (e.g., instability resulting in the unit falling over). The recall is conducted under the standard recall procedure of recommendation by the field, evaluation and classification by the Center and the usual recall notification, monitoring, and termination by the field. If that same equipment displays a radiation related defect or a noncompliance with the diagnostic x-ray standard (21 CFR 1020.30), the recall falls under Subchapter C, and follows the pattern outlined below:

(Note: The Health Hazard Evaluation Committee does not review recalls involving noncompliance with a standard because the significance of the hazard was considered when the standard was introduced).

Recalls conducted under Subchapter C of the Act

1. Center for Devices and Radiological Health (CDRH) Learns of Defect or Noncompliance

A manufacturer who discovers a radiation related defect or noncompliance is required by Subchapter C to immediately notify CDRH and submit a proposed corrective action plan (CAP). CDRH may also learn of defects or noncompliance from various other sources including establishment inspection, results from FDA field and laboratory testing, and review of reports required to be submitted by the manufacturer. CDRH will inform the manufacturer in writing of the defect or noncompliance and request the firm to propose a CAP as required by Subchapter C. In some cases, special field testing may be necessary in order to define the precise defect or noncompliance. These tests will be arranged by CDRH.

2. Opportunity to Refute Declaration or to Request Exemption from Notification Requirements

As provided by Subchapter C, a manufacturer has the opportunity to refute a defect or noncompliance declaration (Section 535(a)(2)). The manufacturer is usually given 14 days to refute the Center's declaration or to request exemption from notification based on evidence that the defect or noncompliance is not such as to create a significant risk of injury, including genetic injury, to any person. The burden of proof lies with the manufacturer. If the refutation is accepted, or if the exemption is granted, the manufacturer is then exempt from the notification requirements and is relieved of responsibility to "repair, replace or refund."

3. Proposal of Corrective Action Plan by Manufacturer

If no request for exemption has been filed or if the exemption request was denied, the manufacturer must then submit proposals to CDRH for user notification and correction of defective or noncompliant product(s). The notification to users is required to be by certified mail to the first purchaser (or subsequent transferees, if known) and must be mailed within 14 days after CDRH approval. CDRH requires that return receipts be maintained for recall audit purposes. Manufacturers are also required to provide CDRH with copies of all notices, bulletins, and other communications to dealers, distributors, purchasers, or other transferees which they have issued as required by Section 535(d). These notifications to users are required to contain instructions for interim safe operation of the product until such time as corrections can be made.

4. Correction Action Plan (CAP) Review

Upon receipt of the manufacturer's proposed CAP, the Center will review that document for thoroughness and technical accuracy. The following are elements of a typical approved CAP:

- A. Product description (including all model and serial numbers used) and the total number of units of this product that are involved.
- B. Consignee list (foreign and domestic).
- C. Description of the defect (including all reports, documents, memos, etc., of meetings, technical reviews, etc., which pertain to the analysis of the problem and the development of a "fix").
- D. Proposed steps to be taken to correct the product in the field and steps taken to prevent future occurrences.
- E. Proposed effectiveness checks to be conducted.
- F. Proposed date of completion and appropriate interim dates for design, fabrication, and implementation of the correction.
- G. Any and all injury/death investigations or reports. h. Pertinent complaints on file.

Some additional requirements may be included in a CAP if necessary. For example, a CAP may require that the recalling firm obtain a signed statement from their purchaser stating that corrections have been made or it may require that copies of service or work orders be held for FDA review.

In the event that the proposal is insufficient, the Center will request the additional data needed. When sufficient information has been submitted to the Center for review, the plan is evaluated and approved if it appears to be adequate.

5. Mechanics of Conducting Recall

CDRH will assign a recall number and issue a classification memo to the division and the Press Office when the corrective action plan (CAP) and an approval letter is signed and issued to the recalling firm. CDRH will send copies of the CAP approval letter, the corrective action plan and the letter of non-compliance with the classification memo. The home division will then promptly obtain from the firm by phone or a visit any other information required for the Enforcement Report and the Initial Recall Notification message to the field. This will not affect the way the division processes recalls for X-ray assemblers and suntan lamp recalls. The home district office or division will still continue to submit a Recommendation for Recall for cases generated in the field. The division s will approve the corrective action plans for these cases, and submit a copy of the division approval letter with the Recommendation for Recall to CDRH for issuance of a recall number.

The timeliness of audit check issuance will depend on the progress of the CAP and may be determined by recall status reports received from the firm. Audit checks should issue when the recall is approximately 25% complete and continue throughout the completion of the recall. At the point when the recalling firm indicates by way of their status reports to the division that they have completed the recall action at 25% of their consignees, the field will issue a request for a portion of the required audit checks to affected divisions. Upon receipt of the completed audit check reports from the divisions, the lead Recall Coordinator will evaluate the audit checks to determine if the recall is effectively on-going. If apparently effective, the balance of the audit checks need not be requested until the recall is complete, or nearly so. Center consultation is available, if needed, in determining the effectiveness of the recall at the 25% complete mark.

The recalling firm must, in its CAP, provide a target date for completing the recall. The time span is typically six months to one year. If the firm does not or is not likely to complete the recall within the specified time, a Warning Letter should be issued to the firm. The firm may request a time extension to complete the recall. All such requests must be approved by CDRH.

If a request for extension is denied, the home division will send the firm a warning letter when the target completion date expires.

The division will document unsatisfactory results of a CAP and/or other violations of Subchapter C by inspection and field testing. Bimonthly recall status reports will be sent to the Center recall unit and OSPOP/DE/ROB by the division.

At the conclusion of the recall, the division will conduct a termination ("close-out") inspection at the recalling firm, terminate the recall appropriately according to classification, and prepare a recall termination letter to the firm. (See Exhibit 7-10).

6. Time Frames

The timeframes associated with electronic products recalls are considerably different than for general FD&C recalls. At the time the Center identifies a problem, the manufacturer is often unaware that any problem exists. Opportunity is provided to the manufacturer to examine and possibly refute the agency's evidence, or to request exemption, or to locate all products and to formulate a CAP. The time between declaration of noncompliance and CDRH approval of the CAP varies widely depending upon the product, the nature of the problem, and the thoroughness of the proposed correction.

Attachment F – Recalls of Infant Formula

Due to the susceptible nature of the population affected by infant formulas, the recall of a violative infant formula is to receive the highest agency priority.

Normally, within five calendar days, infant formula manufacturers' notifications submitted to FDA in compliance with the Infant Formula Act will be evaluated by the Center, action memorandum prepared, and the recall approved by the ACRA.

Other than the above timeframe, recalls of infant formulas are to be handled under the same procedures as other recalls with two important additions:

1. Section 412(f)(3) of the Act requires that the manufacturer post written notice of the recall of an infant formula at each retail establishment where the infant formula is sold. The content of such notices should be reviewed by the agency prior to the posting, and the duration of posting should be part of the firm's recall strategy with agency concurrence. Audit checks should verify adequate posting.
2. Section 412(f)(1) of the Act requires that the manufacturer submit a report on the recall not later than 14 days after the initiation of the recall and at least every 14 days thereafter until the recall is terminated. The agency is to review these reports at least once every 15 days.

Attachment G – Recalls of Medical Devices, Section 518(e)

Guidance Regarding Mandatory Recalls under Section 518(e) of the Federal Food, Drug and Cosmetic Act.

1. BACKGROUND

On November 28, 1990, the President signed into law the Safe Medical Devices Act (SMDA), which was intended to improve the Medical Device Amendments of 1976. The new law includes provisions designed to expand and strengthen FDA's authority to ensure that devices entering the market are safe and effective. The SMDA, by streamlining procedures and augmenting FDA's authority, refines premarket controls and adds postmarketing controls relating to medical devices introduced into interstate commerce.

One of these provisions is section 518(e), the so-called mandatory recall authority. Section 518(e) requires a two-step process involving an order to a firm to immediately cease distribution of a defective device and notify users to cease using it; and either vacating the order or amending the order to require the product's recall. In the first step, if FDA finds there is a reasonable probability that a device intended for human use would cause serious, adverse health consequences or death, FDA shall order the manufacturer, importer, distributor, retailer, or any appropriate person to immediately cease distribution of the device and to immediately notify health professionals and device user facilities of FDA's order, and to instruct such professionals and facilities to cease use of the device.

"Reasonable probability" means that it is more likely than not that an event will occur.

"Serious adverse health consequence" means any significant adverse consequence, including those which may be either life-threatening or involve permanent or long-term injury, but excluding non-life-threatening injuries that are temporary and reasonably reversible. Injuries attributable to a device that are treatable and reversible by standard medical techniques, proximate in time to the injury, meet this latter definition.

After giving the party subject to the order in step 1, an opportunity for an informal hearing, FDA shall either vacate the order or amend it to include a recall of the device. The opportunity for an informal hearing is contained in the order in step 1. The hearing must be held not later than 10 days after the date of issuance of the order, in accordance with the procedures set out in section 201(y) of the Act and 21 CFR Part 16. Failure to request a hearing will generally result in an amended order requiring recall. The party subject to the order may also request, by written submission, review of an order without an informal hearing.

2. PROCEDURES:

These procedures are final publication of regulations implementing section 518(e). Actions under section 518(e) may be initiated by the Center or recommended by the field.

A. Factors to be considered when deciding to recommend a 518(e) recommendation are:

- Does the hazard meet the criteria for a Class I recall situation, i.e., there is a strong likelihood that the use of, or exposure to, a violative product will cause serious, adverse health consequences or death?
- Are other administrative or enforcement actions more appropriate to address the problem?
- Seizure or detention may be a lesser agency burden and may address the health risk situation more effectively.
- GMP issues alone will not support the contention that use of the device will cause serious adverse health consequences.

If the division office believes this threshold has been met, a recommendation should be submitted to CDRH Office of Compliance (OC). Before the division submits a 518(e) recommendation, the firm should be fully apprised of our concern and have been given an opportunity to initiate corrective action.

B. Content and Format

The 518(e) recommendation should be in an organized Recall Recommendation format, and be flagged, "Recommendation for 518(e) Action". It should include the following:

1. The product labeling, and product advertising and/or newsletters to consumers, if pertinent.
2. The basis for determining that 518(e) criteria have been met, such as:

Any sample analysis that documents that the device does, or may, present a serious health hazard.

Any testing done which substantiates device failure, e.g., firm's in-house and/or FDA testing, independent studies, etc.

The number of known injuries and/or deaths as documented in the firm's files.

Complete documentation of those events should be provided to support the 518(e) criteria. The firm's complaint, litigation and service files are valuable in obtaining this information.

A summary of complaints and description of those complaints such as 20 complaints of electrical shortage, 15 complaints of shock, 13 complaints due to over-infusion, 30 complaints of under-infusion. To say that there are 300 complaints may indicate a problem, but does not necessarily indicate a serious health issue. Provide copies of significant or representative medical device complaints or service

records, if available, and any significant correspondence with customers.

The EIR, if inspectional findings support the problem, especially if testing is inadequate.

f. Any pertinent manufacturing or recall history.

Date of the last visit to the firm, the reason for the visit, and any subsequent correspondence or communications. Is a limited update inspection needed or some other mechanism available to determine whether the hazard condition still exists? Be clear on the firm's regulatory history, conditions of approval of the device, etc., so the firm will not later argue that it did not have advance notice of the problems. It presents problems in demonstrating the case as a serious health risk if the case review has taken months.

Any other pertinent information to document that the device presents a hazard consistent with 518(e) criteria.

3. Because a hearing may take place quickly, include one extra copy of ALL information for the Office of Chief Counsel (OCC). All written materials which FDA will rely on for support at the hearing (for example, the EIR) must be turned over to the opposing side at least one day before the informal hearing.

Do not delay other regulatory actions (e.g., seizure) pending the 518(e) review. In addition, do not stop collecting data, as the issue can still potentially result in a trial, seizure, Congressional hearing, etc.

OC will convene a Health Hazard Evaluation Committee (HHE) to evaluate the information in the recommendation. If the HHE concludes that a 518(e) action is warranted, OC, with Chief Counsel concurrence, will prepare the order for signature of the Director, OC. The order will be faxed to the firm and the division. If the firm cannot receive facsimile transmissions, the order will be hand delivered by the division. In either situation, the division should seek an immediate determination from the firm as to its actions. If the order is not complied with, any product encountered should be administratively detained in accordance with the instructions in [RPM Chapter 5 - Administrative Actions](#), Section 5-4, "Administrative Detention of Devices", and appropriate regulations found in 21 CFR 800.55.

The firm is to provide periodic status reports to the division. The frequency of such reports will be specified in the order. Communications developed by the firm to implement the order must be submitted to CDRH for review and approval prior to distribution. The Center will work with the division and firm so that users comply with the order in a medically safe manner. The firm may need to immediately replace defective devices with equivalent devices, including those of a competitor. The Center will review all "emergency" or "urgent need" requests to permit continued use of the device on a

case-by-case basis. We have found that there may be unique medical conditions for which there is no alternative to the device subject to the order.

In those cases, we have permitted continued use of the device provided certain safety precautions are followed.

3. INFORMAL HEARING

The person receiving the order may, within the timeframe specified in the order, submit a written request to FDA for a regulatory hearing. The request must be addressed to the agency employee identified in the order. Ordinarily, FDA will require that the person named in the order submit the hearing request within 3 days of receipt of the order. When necessary, however, FDA may require that the hearing request be submitted in less than 3 days.

The informal hearing will be conducted as a regulatory hearing under 21 CFR Part 16. Following the hearing, the Hearing Officer will issue a decision to vacate the original "cease and desist" order, modify such order, or amend the order to require recall of the product. An ordered recall should begin on the date of the amended order to recall and, generally, should be at mid-stage in six weeks, and completed no later than three months from the recall's initiation.

CDRH OC will make arrangements for the informal hearing including a conference room and stenographer. The hearing will be held in the Washington area. The Center will identify a hearing officer. The hearing will be held not later than 10 days after issuance of the order, unless both the person named in the order and FDA agrees that the hearing will be held at a later date. Such an agreement is unlikely because of the hazard presented by the device.

As soon as OC determines that a 518(e) action is appropriate, the field fact witnesses should immediately prepare for possible testimony in anticipation of the informal hearing. Each should prepare a narrative memo of findings of facts pertaining to the device, i.e., inspectional findings, analytical findings, etc. The Office of Chief Counsel will need the narrative memo three (3) days before the hearing, and will follow-up with a telephone call to the CSO involved. The Center will also be gathering documentary support and locating expert witnesses to testify at the hearing. Expert identification and preparation is a difficult and time-consuming process. The field office should be alert to potential experts and provide their names to CDRH. A pre-meeting of FDA participants and CC will be held 1-2 days prior to the informal hearing, to discuss the issues and prepare our strategy for the hearing.

If a hearing is to be public, it will be announced on the public calendar. If FDA wants the hearing to be closed to the public, it must state one of the reasons contained in 21 CFR 16.60. If the company wants the hearing to be closed to the public, the company must state its reason under 21 CFR 16.60 in its request for a hearing. The Hearing Officer will make the final determination as to whether a hearing is to be open to the public or closed.

If the person named in the order does not request a hearing within the timeframe specified in the order, the right to a hearing will be deemed waived. In such cases, FDA is free to amend the order to require a recall as it deems appropriate.

The person named in an order may, in lieu of requesting a hearing, submit a written request to FDA asking that the order be modified or vacated. The written request must be addressed to the agency employee identified in the order and must be submitted within the timeframe specified in the order. The agency official who issued the cease distribution and notification order will provide the requestor written notification of the agency decision to affirm, modify, or vacate the order within a reasonable time after completing the review of the request.

If the person named in a cease distribution and notification order does not request a regulatory hearing or submit a request for agency review of the order, or if after conducting a regulatory hearing or completing agency review of a cease distribution and notification order, FDA determines that the order should be amended to include a mandatory recall of the device with respect to which the order was issued, FDA will amend the order. The amended order will contain the requirements of the mandatory recall and the form of patient notification, if required.

The statute does not permit FDA to require the recall of devices in the possession of patients or individuals. However, FDA may require the firm to notify patients, if necessary. Patient notification should be used only where the device is in a home health care setting and notification to doctors would not be sufficient. Patient notification should be evaluated on a case-by-case basis, depending on the type of product being recalled. If a significant number of individuals at risk cannot be identified, FDA may use any technique at its disposal to notify such individuals, i.e., publicity section 705(b) of the Act.

Similarly, an amended order cannot include recall of a device from user facilities if FDA determines that the risk of recalling it from the facilities presents a greater health risk than the health risk of not recalling the device, unless the device can be replaced with an equivalent device by the recalling firm (including a competitor's product equivalent to the device).

Attachment H – Methods for Conducting Recall Effectiveness Checks

1. INTRODUCTION

In the Federal Register of June 16, 1978, (43 FR 26202), The Food and Drug Administration (FDA) issued as a final rule, Recalls (Including Product Corrections) - Guidelines on Policy, Procedures, and Industry Responsibilities. Section 7.42 of these guidelines states that the recalling firm will ordinarily be responsible for conducting recall effectiveness checks. Such checks are for the purpose of verifying that the recalling firm's consignees have received notification about the recall and have taken appropriate action.

To assist the recalling firm in carrying out this responsibility and in accordance with section 7.42(b)(3) of the FDA recall guidelines, the following may be used as a guide on how to use different methods for conducting recall effectiveness checks. The methods described include mail, telephone calls, personal visits, and combinations of these alternatives.

2. METHODS

A. General

All the methods for conducting effectiveness checks have several common aspects: a consignee list, a common identifier, a questionnaire, and a procedure for recording responses.

A consignee list is to be prepared when a recall is initiated by a firm. Each of the consignees notified of the recall is a candidate for a recall effectiveness check. However, if there is suitable documentation that a consignee has been notified and has either made the proper disposition of the recalled product or has submitted a negative report on having the product, it may not be necessary to perform a recall effectiveness check at the consignee.

In order to facilitate the correlation of responses from consignees, each consignee could be assigned a unique number which would serve as an identifier. The consignee's zip code could be used as part of the number. The identifier would be put on any return mail card and provided on any telephone or personal visit list used for effectiveness checks. The number would provide easy match with the consignee list and the reconciliation of the consignee contacts and recall effectiveness.

Reconciliation of the effectiveness checks may be handled in numerous ways. It may be by computer or by a system as simple as preparing pressure sensitive labels for each consignee which contain the name, address, and identifying number assigned to that consignee. The number of labels required for each consignee will vary according to the recall method used, i.e. five labels for mailings (if two mailings are used), and two labels for telephone calls and personal visits. For all methods, one of the labels is to be placed on a 3 X 5 card to be used as the control. The second label is to be used for the consignee questionnaire.

As a questionnaire is returned and/or completed, it is placed with the control file card for the consignee for “logging in” purposes.

B. Mail

There are four elements to the use of mail:

- a. a letter to the consignee,
- b. an envelope prominently inscribed with “IMPORTANT RECALL INFORMATION INSIDE”,
- c. a questionnaire, and
- d. a self-addressed, stamped envelope for the consignee to return the completed questionnaire.

The letter to the consignee should state exactly state the reason for the recall, a complete description of the product being recalled or corrected, instructions regarding the disposition of the recalled product, and a request for cooperation in completing and returning the questionnaire. [Exhibit 7-1](#) provides an example of the type letter that can be used. [Exhibit 7-2](#) provides an example of the questionnaire to accompany the effectiveness check letter. It should be noted that the exhibit questionnaires are only examples and that actual circumstances may necessitate changes in the questionnaire wording. Some pretesting of the questionnaire prior to mass mailing is suggested.

In conducting a recall effectiveness check, there are certain basic questions that need to be asked. The purpose of these questions is to determine whether: the recall notification was received; the product involved was handled as instructed in the recall notification; the product was further distributed by the consignee before receipt of the recall notification; and, if so, were the additional consignees notified. Other questions may need to be asked depending upon the nature of the recall. Also, the design and format of the questionnaire may vary depending upon the method of contact to be used.

Attachment I – Mandatory Recall of Tobacco Products**BACKGROUND**

On June 22, 2009, President Obama signed the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) into law. The Tobacco Control Act amended the Federal Food, Drug, and Cosmetic Act (FDCA) (21 U.S.C. 301 et seq.) to give FDA important new authority to regulate the manufacture, marketing and distribution of tobacco products to protect the public health generally and to reduce tobacco use by minors.

The Tobacco Control Act provides for recalls for violations of FDCA requirements that relate to tobacco products under Sections 908(a) and 908(c) of the TCA.

Section 908 reads as follows:

(a) NOTIFICATION- If the Secretary determines that--

(1) a tobacco product which is introduced or delivered for introduction into interstate commerce for commercial distribution presents an unreasonable risk of substantial harm to the public health and

(2) notification under this subsection is necessary to eliminate the unreasonable risk of such harm and no more practicable means is available under the provisions of this chapter (other than this section) to eliminate such risk, the Secretary may issue such order as may be necessary to assure that adequate notification is provided in an appropriate form, by the persons and means best suited under the circumstances involved, to all person who should properly receive such notification in order to eliminate such risk. The Secretary may order notification by any appropriate means, including public service announcements. Before issuing an order under this subsection, the Secretary shall consult with the persons who are to give notice under the order.

(b) No Exemption from Other Liability-Compliance with an order issued under this section shall not relieve any person from liability under Federal or State law. In awarding damages for economic loss in an action brought for the enforcement of any such liability, the value to the plaintiff in such action of any remedy provided under such order shall be taken into account.

(c) RECALL AUTHORITY.-(1) IN GENERAL.-If the Secretary finds that there is a reasonable probability that a tobacco product contains a manufacturing or other defect not ordinarily contained in tobacco products on the market that would cause serious, adverse health consequences or death, the Secretary shall issue an order requiring the appropriate person (including the manufacturers, importers, distributors, or retailers of the tobacco product) to immediately cease distribution of such tobacco product. The order shall provide the person subject to the order with an opportunity for an informal hearing, to be held not later than 10 days after the date of the issuance of the order, on the actions required by the order and on whether the order should be amended to

require a recall of such tobacco product. If, after providing an opportunity for such a hearing, the Secretary determines that inadequate grounds exist to support the actions required by the order, the Secretary shall vacate the order.

(2) AMENDMENT OF ORDER TO REQUIRE RECALL.- (A) IN GENERAL.-If, after providing an opportunity for an informal hearing under paragraph (1), the Secretary determines that the order should be amended to include a recall of the tobacco product with respect to which the order was issued, the Secretary shall, except as provided in subparagraph (B), amend the order to require a recall. The Secretary shall specify a timetable in which the tobacco product recall will occur and shall require periodic reports to the Secretary describing the progress of the recall.”

Attachment J – Mandatory Recall Authority for Foods

PURPOSE

This attachment provides procedures and defines responsibilities for various operations related to the Mandatory Recall of Food under Section 423 of the Act, as amended by section 206 of the Food Safety Modernization Act (FSMA). Use of our mandatory recall tool does not prevent us from using other regulatory tools available to us. At any point during the mandatory recall process the agency may discuss and/or pursue another action as needed.

BACKGROUND

On January 4, 2011, the FDA Food Safety Modernization Act (FSMA) was signed into law. Section 423 of the Federal, Food Drug, and Cosmetic Act (the Act) (21 U.S.C. 350l) as amended by section 206 of FSMA, gives FDA the authority, to order the recall of an article food² (other than infant formula) if FDA concludes that there is a reasonable probability that the article of food is adulterated under section 402 or misbranded under section 403(w) and there is a reasonable probability that use of or exposure to the food article will cause serious adverse health consequences or death to humans or animals (SAHCODHA). The Agency will initiate use of its mandatory recall authority within 24 hour of making the determination that the legal standard has been met and the firm is not willing to voluntarily conduct a recall.

PROCEDURES

See Attachment J10 – Process Flow Chart

Step 1: Basis for Mandatory Recall

A. FDA may exercise its authority to order the recall of an article of food based on information developed internally or from outside sources, including states and other agencies, or gathered through any other means. When considering the need to order a food recall, the recommending organization (the FDA Center or Division) shall notify the Office of Strategic Planning and Operational Policy (OSPOP) and create a Work Activity in the Compliance Management System (CMS) as a Preliminary Assessment. The recommending organization will schedule a conference call for representatives of the team to assess the need for mandatory recall. Additional calls may be necessary if more information is needed to reach a conclusion. For human food mandatory recalls, CFSAN should brief SCORE (Strategic Coordinated Oversight of Recall Execution)

² The term “article of food,” as it is used in this document, refers to any article of food for humans or animals, other than infant formula. Infant formula recalls are conducted under separate authority in section 412 of the Act.

following the conference call, and their involvement may be requested at this time or at any subsequent time. FDA may concurrently pursue other actions including, but not limited to, a public warning, administrative detention, food facility registration suspension, seizure or injunction.

B. The recommending organization will prepare and upload into CMS a recommendation memorandum (**See Attachment J1 - Recommendation Memorandum**), a draft 423(a) letter (**See Attachment J2 - Notification of Opportunity to Initiate a Voluntary Recall**) and supporting evidence. Supporting evidence may include distribution information and the Division should attempt to obtain a complete distribution list of all shipments of the suspect lot(s), including foreign distribution. See Attachment B.

Any FDA office that acquires relevant documentation, including correspondence, concerning the matter is responsible for uploading that documentation into the CMS Work Activity, so that it may be reviewed concurrently by OSPOP, the associated Division(s), the appropriate Center compliance staff, the Office of Chief Counsel (OCC), and, if there is an associated human food-borne outbreak, the Coordinated Outbreak Response and Evaluation Network (CORE), or an outbreak involving animal food, the CVM Complaint Emergency Recall Team (CERT), collectively “the team.” OSPOP will be responsible for coordinating the process flow and document cohesiveness throughout the mandatory recall case processing. If a more than one Center (CFSAN and CVM) is involved, the centers will determine the lead center for the action.

Center compliance staff will ensure a health hazard evaluation (HHE) is completed prior to making a determination whether or not to proceed with mandatory recall. The HHE may be updated at any point in the process if/when necessary. The HHE to support invoking mandatory recall authority must conclude that there is a reasonable probability of SAHCODHA. This conclusion should be clear in the HHE. The HHE must be done before the 423(a) letter is sent. The HHE will be attached as an exhibit to the 423(a) letter. The HHE can satisfy the need for the administrative record to address the SAHCODHA conclusion, on two conditions: 1) it must be thorough and contain sufficient explanation to make FDA’s basis and conclusions clear and 2) the subject matter expert(s) who signs the HHE is committed to being available to provide their view in real time (at least by phone) during a hearing, should a hearing be necessary. If the HHE fails to meet either of these requirements (e.g., it is cursory and will not be revised, or the expert cannot be available to testify at a hearing), the Center will prepare a separate expert memo regarding the SAHCODHA conclusion, which must meet all the same requirements as the expert memo on adulteration/misbranding. The Center will upload both the HHE and SAHCODHA memorandum into CMS.

Additionally, the Center will begin to prepare an expert memo regarding reasonable probability of adulteration or 403(w) misbranding. This expert memo must be prepared and should be final, signed, and uploaded into CMS before the 423(a) letter is sent. Moreover, the expert who prepares and signs this memo should be isolated from the matter when possible and be made aware of the possible timeframe in which the 423

process will play out and must commit to being available to provide their view in real time (at least by phone) during a hearing, should a hearing be necessary.

The center will prepare a written record of FDA's conclusion that the firm is required to register under section 415 of the FD&C Act, as well as the basis for that conclusion. This may be informal in nature (e.g., an email) if there are no significant issues, but the analysis must be complete and uploaded to CMS before the 423(a) letter can be sent. The Center should also check the database to see if they have in fact registered and make a record of the result of that search, which should also be uploaded to CMS before the 423(a) letter is sent.

If there are any issues specific to the case (e.g., jurisdiction is challenging such that firm may argue product is not a food; or facility is such that it has a reasonable argument that it is not required to register), all of the following must be prepared, finalized, signed, and uploaded to CMS before the 423(a) letter is sent:

- a. a record memo laying out the legal and factual basis for FDA's position (e.g., the legal argument as to why the products at issue are foods, which for example might rely in part on information on product labels);
- b. a sworn affidavit laying the foundation for any evidence upon which the record memo analysis relies (e.g., investigator declaration that the product labels cited in the record memo are true and accurate copies of the labels collected during inspection of the firm); and
- c. all evidence referenced in the affidavit/memo (e.g., copies of the product labels).

OSPOP will send a request for OCC involvement to the OC OCC FSMA Mailbox and designate the request as "URGENT": Possible Mandatory Recall" in the subject line. OSPOP will notify the FDA Office of Media Affairs and keep them involved as necessary in the process. The OSPOP will keep a chronology of events, including documenting when any letters or order are sent to and received by the responsible party.

OSPOP will identify an appropriate person to serve as a Presiding Officer (PO) if needed. This person must not have been previously involved in decision-making for the matter (including, for example, SCORE calls discussing the matter) and should be advised to maintain separation of functions from the ORA personnel who are working with the OFVM/CFSAN/CVM/ORA team. OSPOP will determine the availability of the PO and ensure the PO is in contact with OC attorney(s) available to them.

The Center will identify a subject matter expert who has not previously worked on the matter and can advise the PO/Commissioner's Team as needed with respect to the specific types of evidence that form the basis of FDA's case. This person must also be available at the time that will be critical: the day of anticipated issuance of the 423(b) order and at least the next two calendar days (and up to a week) immediately after issuance of the 423(b) order. This person should be advised to maintain separation of functions from the CFSAN/CVM subject matter experts who are working with the OFVM/CFSAN/CVM/ORA team.

C. Once a decision is made to move forward with the mandatory recall the team will immediately begin reviewing the recommendation memo, draft 423(a) letter, supporting evidence, and once completed, the HHE and SAHCODHA Memorandum, to determine whether there is a reasonable probability that an article of food is adulterated under section 402 of the Act or misbranded under section 403(w) of the Act, and whether there is a reasonable probability that the use of or exposure to such article of food will cause SAHCODHA.

D. When and if the team determines that there is a reasonable probability that the article(s) of food is adulterated under section 402 of the Act or misbranded under section 403(w) of the Act and there is a reasonable probability that the use of or exposure to the article(s) of food will cause SAHCODHA, the recommending office or organization (usually the division) will change the Work Activity in CMS to a case (FSMA – Opportunity to Cease Distribution and Conduct Voluntary Recall: 423(a)) and proceed to Step 2.

Step 2: Notification of Opportunity to Initiate a Voluntary Recall – Section 423(a)

A. The team will concurrently review and recommend necessary changes to the recommending organization's draft 423(a) letter, Notification of Opportunity to Initiate a Voluntary Recall. OSPOP will coordinate with all parties to ensure recommended changes are incorporated into a final draft for review and clearance by OCC. During this time, recommending organization will prepare a draft 423(b) letter (**See Attachment J3 – Prehearing Order to Cease Distribution and Give Notice**) to be finalized in the event the responsible party chooses not to recall voluntarily in accordance with the 423(a) letter.

All of the following steps must be taken before OCC can clear the 423(a) letter:

- Lab test results on which the agency plans to rely must be final and accepted by FDA. If they are preliminary in some form, that must be clearly stated when the results are referenced in other documents (until they become final). Summaries and analytical worksheets need to be uploaded into CMS as soon as they are available.
- If FDA intends to rely on lab work done by a non-FDA-lab as evidence in the matter, an appropriate person at FDA must review the documentation and sign a brief memo regarding the validity of the non-FDA lab's analysis. If FDA experts are not prepared to say that the non-FDA lab's work can be relied upon to show what it purports to show, FDA cannot use that evidence. FDA only needs one such memo. The Center and ORA will decide who is responsible for this analysis so there will be no duplication/conflict.
- Firm websites, if used as evidence in the matter, need to be captured by screen shot and uploaded into CMS as PDFs.
- The HHE, expert memos, memo supporting the violation, documentation supporting the registration requirement, and memos addressing potential challenges to the case must be complete and uploaded into CMS.

- The 423(a) letter must clearly state and support (with attachments including relevant factual evidence such as lab test results, and the HHE) the complete basis for FDA's conclusions of reasonable probability of adulteration/misbranding and reasonable probability of SAHCODHA.

B. After all recommended changes are captured and the above list of steps completed, OSPOP will forward the 423(a) letter final draft to OCC for final review and clearance. Once cleared, OCC will provide a copy of the cleared document to OSPOP. OSPOP will prepare the letter for signature, with accompanying supporting evidence, and provide the package to the Deputy Commissioner of Food Policy and Response (or designee, if appropriate delegations exist). OSPOP will issue the letter to the responsible party by overnight delivery (with delivery confirmation). If transmitted in a manner other than overnight delivery, e.g., by electronic mail, request a delivery and read receipt. Additionally, a copy of the letter will be sent using the most expeditious method that is available to the responsible party (e.g., by electronic mail or facsimile). OSPOP will email the letter to the team and upload a copy into CMS. When possible, the Program [Division] Director shall also contact the responsible party to convey the information contained in the letter orally.

All communications with the responsible party will be documented in CMS. The two working day timeframe for initiating the voluntary recall, as indicated in the letter, will begin once the Division Office (DO) confirms the responsible party has received the letter.

C. If the responsible party initiates a voluntary recall and ceases distribution of the article of food within 2 working days and in any manner prescribed by FDA, the DO will immediately notify the team. The oversight, processing and tracking of the recall action will follow the procedures for Class I recalls in the RPM, Chapter 7 – Recall Procedures. The recall will be documented in RES. The DRC will select the recall type from the voluntary drop down list, "Voluntary-423(a)" on the "Edit Start Recall" screen. In the Public Reason for Recall, include the statement: "[FIRM] received a 423(a), Notification of Opportunity to Initiate a Voluntary Recall, letter from FDA and is recalling [Product] because [Reason]."

D. If the responsible party refuses to or does not voluntarily cease distribution and recall such article within two working days and in the manner prescribed by FDA, the DO will notify the team and the action shall proceed to Step 3, Prehearing Order to Cease Distribution and Give Notice – Section 423(b).

The team may reconvene at any time to discuss further regulatory action needed to mitigate public health risks. If at any point the process appears to be slowing or stagnating, the team will escalate the issue to senior ORA/Center officials and/or SCORE.

Step 3: Prehearing Order to Cease Distribution and Give Notice – Section 423(b)

A. The team will concurrently review and make necessary changes to the recommending organization's draft 423(b) letter - Prehearing Order to Cease Distribution and Give Notice, informing the responsible party that it must cease distribution and immediately notify all persons manufacturing, processing, packing, transporting, distributing, receiving, holding or importing and selling the article of food, and to which such food has been distributed, transported, or sold, to immediately cease distribution of the article. The order will also advise the responsible party that it has the opportunity for an informal hearing, and provide the responsible party instructions on how to request a hearing.

Once all parties have had the opportunity to recommend changes, OSPOP will forward the final 423(b) letter to OCC for final clearance.

B. Once OCC provides final clearance of the 423(b) letter and it is signed by the Deputy Commissioner of Food Policy and Response (or designee, if appropriate delegations exist), OSPOP will issue the order to the responsible party with delivery confirmation. FDA should make every effort to issue the 423(b) order EARLY IN THE DAY ON THE DAY IT IS ISSUED (the earlier the better, no later than 12:00 pm Eastern, aiming for an ideal closer to 9:00 am Eastern), with a plan for all of the deadlines that follow. If the 423(b) can't be issued early on the desired day, move issuance to the next day. A copy of the order will be sent using the most expeditious method that is available to the responsible party (e.g., by electronic mail or facsimile). When possible, the Program or Division Director shall also contact the responsible party to convey the information contained in the order orally. Further, the recommending organization will change the action in CMS to FSMA – Prehearing Order to Cease Distribution and Give Notice.

C. The division will attempt to determine whether the responsible party ceased distribution and gave notice.

D. The contact person must be CONSTANTLY monitoring their email/phone during the 24 hours provided to the firm for the hearing request. If the responsible party requests an informal hearing, the request will be forwarded immediately to the PO team and Center team so that all are aware and can begin working on the request and related tasks.

Step 4: Decision to Grant an Informal Hearing– Section 423(c)

A. If the responsible party does not request an informal hearing, the team will proceed to Step 9 (**Amend or Modify the Prehearing Order to Cease Distribution and Give Notice without Holding an Informal Hearing**).

B. If the responsible party requests an informal hearing, the request will be reviewed by the PO team in accordance with the procedures set out in 21 CFR Part 16 (to the extent

that those procedures do not conflict with procedures required under section 423 of the Act) to determine whether a hearing should be granted.

The PO needs to decide whether a genuine issue of material fact has been presented:

1. For most types of hearing requests, PO can decide with no opposition brief from Center team.
2. If requesting opposition brief from OFVM/CFSAN/ORR Team (e.g., jurisdictional challenge), PO team should give Center team a deadline, default 3 hours from receipt of hearing request. For example, hearing request received Day 5 at 9:00 am. Center and PO team immediately review request, PO team takes 0.5 hour to determine they need an opposition from Center team because challenge is jurisdictional (Center team will also be looking during this time and should anticipate same so can begin work immediately). At 9:30 am PO team tells Center Team they have until 12:00 pm to submit opposition if they want to oppose the request.
3. Target for PO decision issuance on hearing request (regardless of outcome): COB Day 5. If PO decides to grant hearing request, issue decision ASAP and include start time for hearing (must be on Day 6, likely in PM), along with room/call-in details/statement of the specific issue(s) on which hearing is being granted. Also include request to both parties for witness lists – default could be for these to be submitted by Day 6, 12:00 pm.

If it is determined that a hearing should be granted, proceed to Step 5 (**Informal Hearing Procedures**).

If it is determined that a hearing should not be granted, the responsible party shall be notified by the presiding officer of this decision by overnight delivery (with delivery confirmation) and by fax or electronic mail. **See Attachment J4 (Denial of Hearing Request)**. The Center/Division/OSPOP/OCC team will be immediately notified of this decision. If the team believes that the removal from commerce of the food subject to the original (i.e. unmodified) order is necessary, or that the Commissioner should modify the prehearing order to cease distribution and give notice and that the removal of the article of food that is the subject of such order is necessary, proceed to Step 9 (**Amend or Modify the Prehearing Order to Cease Distribution and Give Notice Without Holding an Informal Hearing**).

Whether a hearing is granted or denied, documentation of the PO's decision will be captured in CMS.

Step 5: Informal Hearing Procedures

A. FDA will conduct the hearing consistent with section 201(x) of the Act and 21 CFR Part 16 (to the extent that Part 16 is not in conflict with section 423 of the Act).

B. PO team has until COB Day 6 to commence hearing if it is granted. Hearing need not finish on Day 6.

1. FDA prefers to conduct the hearing in person or via video conference, but teleconference is also an option. The hearing will be conducted in a designated hearing room.

2. At the hearing, the parties will have the right to hear a full and complete statement of the action that is the subject of the hearing together with the information and reasons supporting such action, to conduct reasonable questioning, and to present any oral or written information relevant to such action.

3. If credibility is a material issue, the presiding officer will assess the credibility of witnesses.

4. OSPOP will contract with third party services for recording and transcription of the hearing. A copy of the recording/transcript will be uploaded into CMS.

C. The presiding officer will write a hearing report. **See Attachment J6 (Hearing Report).** PO team should immediately begin work on post-hearing report, using notes and recording of hearing until transcript is available. The final hearing report must be uploaded into CMS.

D. If the presiding officer determines following the informal hearing that adequate grounds do not exist to continue the actions required by the prehearing order proceed to Step 6 (**Vacate the Prehearing Order to Cease Distribution and Give Notice Following the Informal Hearing**). If the presiding officer determines that removal of the article from commerce is necessary, proceed to Step 7 (**Amend or Modify the Prehearing Order to Cease Distribution and Give Notice Following the Informal Hearing**).

Step 6: Vacate the Prehearing Order to Cease Distribution and Give Notice Following the Informal Hearing

A. If the presiding officer determines that adequate grounds do not exist to continue the actions required by the order, the presiding officer will draft an order vacating the prehearing order within 24 hours of the informal hearing. **See Attachment J7 (Vacated Order).**

B. The presiding officer will send the proposed final vacated order and the administrative record of the hearing to the Office of the Commissioner (OC) by electronic mail.

C. As soon as practicable thereafter, the Commissioner will be advised by a designee in the OC on the matter. If the Commissioner approves the vacated order, the Commissioner will sign the vacated order, or revise and sign the order as appropriate, and the OC will send the signed order to the presiding officer. The Commissioner's decision should be made within 24 hours of receipt of the administrative record of the hearing from the PO.

D. The presiding officer will draft a hearing report cover letter. **See Attachment J5 (Hearing Report Cover Letter).**

E. The presiding officer will issue and send the vacated order with a cover letter and the hearing report to the responsible party by overnight delivery (with delivery confirmation). A copy of the vacated order will be sent using the most expeditious method to the responsible party, e.g., by electronic mail or facsimile. When possible, the presiding officer will also contact the responsible party to convey the information contained in the vacated order orally. Additionally, the presiding officer will send the vacated order with the cover letter and the hearing report to the FDA hearing participants by electronic mail or facsimile. A copy of the vacated order will be uploaded into CMS by either the division or OSPOP.

Step 7: Amend or Modify the Prehearing Order to Cease Distribution and Give Notice Following the Informal Hearing - Section 423(d)

A. If an informal hearing is conducted and the presiding officer determines that it is not necessary to modify the actions of the prehearing order, and that the removal of the article of food that is the subject of the unmodified order from commerce is necessary, the presiding officer will immediately (within 24 hours) draft an amended order that, as appropriate (1) amends the prehearing order to require recall of such article or other appropriate action; (2) specifies a timetable in which the recall shall occur; (3) requires periodic reports describing the progress of the recall; and (4) requires notice be provided to consignees and consumers to whom such article was or may have been distributed. **See Attachment J8 (Amended Order).** Similarly, if, after an informal hearing is conducted, the presiding officer determines that certain actions in the prehearing order should be modified and that the removal of the article of food that is the subject of that modified prehearing order from commerce is necessary, the presiding officer will immediately (within 24 hours) draft a modified order that, as appropriate (1) amends the prehearing order to require recall of such article or other appropriate action; (2) specifies a timetable in which the recall shall occur; (3) requires periodic reports describing the progress of the recall; and (4) requires notice be provided to consignees and consumers to whom such article was or may have been distributed. **See Attachment J9 (Modified Order).**

B. The presiding officer will send the proposed final amended order, or modified order as applicable, and the administrative record of the hearing to the OC by electronic mail.

C. As soon as practicable thereafter, the Commissioner will be advised by a designee in OC on the matter. If the Commissioner approves the amended order, or modified order as applicable, the Commissioner will sign the order or revise and sign the order as appropriate, and the OC will send the signed order to the presiding officer. The Commissioner's decision should be made within 24 hours of receipt of the administrative record of the hearing from the PO.

D. The presiding office will draft a hearing report cover letter. **See Attachment J5 (Hearing Report Cover Letter).**

E. Following the Commissioner's decision, the presiding officer will immediately issue and send the amended order or modified order, as applicable, with a cover letter and the hearing report to the responsible party by overnight delivery (with delivery confirmation). Additionally, a copy of the order will be sent using the most expeditious method to the responsible party, e.g., by electronic mail or facsimile. When possible, the presiding officer will also contact the responsible party to convey the information contained in the order orally. Additionally, the presiding officer will send the amended order, or modified order, with the cover letter and hearing report to the FDA hearing participants by electronic mail. **Proceed to Step 10 (Manage the Recall).**

Step 8: Vacate the Prehearing Order to Cease Distribution and Give Notice without Holding an Informal Hearing

A. If at any time after providing opportunity for an informal hearing it is determined that adequate grounds do not exist to continue the actions required by the original (i.e. unmodified and not amended) order to cease distribution and give notice, and that the order should not be modified, the OSPOP will draft an order vacating the order to cease distribution and give notice. **See Attachment J7 (Vacated Order).**

B. The OSPOP will send a proposed final vacated order to the OC by electronic mail.

C. As soon as practicable thereafter, the Commissioner will be advised by a designee in OC on the matter. If the Commissioner approves the vacated order, the Commissioner will sign the vacated order, or revise and sign as appropriate, and the OC will send the signed order to the OSPOP.

D. The OSPOP will issue and send the vacated order with a cover letter to the responsible party by overnight delivery (with delivery confirmation). A copy of the vacated order will be sent using the most expeditious method to the responsible party, e.g., by electronic mail or facsimile with delivery confirmation. When possible, the Director of the OSPOP will also contact the responsible party to convey the information contained in the vacated order orally.

Step 9: Amend or Modify the Prehearing Order to Cease Distribution and Give Notice Without Holding an Informal Hearing – Section 423(d)

A. If the responsible party does not request an informal hearing or one is not granted, and the OSPOP determines that it is not necessary to modify the actions of the prehearing order, and that the removal of the article of food that is the subject of the unmodified order is necessary, the OSPOP will immediately (within 24 hours) draft an amended order that, as appropriate (1) amends the order to require recall of such article or other appropriate action; (2) specifies a timetable in which the recall shall occur; (3) requires periodic reports describing the progress of the recall; and (4) requires notice be provided to consignees and consumers to whom such article was or may have been distributed. **See Attachment J8 (Amended Order).** Similarly, if the responsible party does not request an informal hearing or one is not granted, and the OSPOP determines that certain actions in the prehearing order to cease distribution and give notice should

be modified and that the removal of the article of food that is the subject of that modified prehearing order from commerce is necessary, the OSPOP will immediately (within 24 hours) draft an amended order that, as appropriate (1) amends the order to require recall of such article or other appropriate action; (2) specifies a timetable in which the recall shall occur; (3) requires periodic reports describing the progress of the recall; and (4) requires notice be provided to consignees and consumers to whom such article was or may have been distributed. **See Attachment J9 (Modified Order).**

B. OSPOP will send the proposed final amended order, or modified order as applicable, to the OC by electronic mail.

C. As soon as practicable thereafter, the Commissioner will be advised by a designee in the OC on the matter. If the Commissioner approves the proposed amended order, or modified order as applicable, the Commissioner will sign the order, or revise and sign the order as appropriate, and the OC will send the signed order to the Director of the OSPOP. The Commissioner's decision should be made within 24 hours of receipt of the proposed amended order or modified order as applicable from OSPOP.

D. The OSPOP will issue the amended order, or modified order as applicable, to the responsible party by overnight delivery (with delivery confirmation). Additionally, a copy of the order will be sent using the most expeditious method to the responsible party (e.g., by electronic mail or facsimile). When possible, the Director of the OSPOP will also contact the responsible party to convey the information contained in the amended or modified order orally. Proceed to Step 10 (**Manage the Recall**).

Step 10: Manage the Recall

A. The O-SPOP will ensure that FDA provides public notification of the recall to consumers and retailers to whom such article was, or may have been, distributed, in accordance with section 423(g) of the Act.

B. The oversight, processing and tracking of the recall action will follow the procedures for recalls in the RPM, Chapter 7 – Recall Procedures. The recall will be documented in RES. The DRC will select the recall type from the mandatory drop down list, "FDA Ordered-423(d)" on the "Edit Start Recall" screen. In the Public Reason for Recall, include the statement: "[Firm] is recalling [Product] because [Reason], consistent with an FDA Order for FSMA Mandatory Recall of Food under Section 423(d) of the Act."

C. The OSPOP will ensure that FDA indicates the status of the recall (such as whether a recall is ongoing or has been completed) on its website.

D. In accordance with section 423(j) of the Act, the OSPOP will establish an incident command operation or a similar operation that will operate not later than 24 hours after the initiation of a mandatory recall, or the voluntary ceased distribution and recall of an article of food for which there is a reasonable probability that use of, or exposure to, such article will cause serious adverse health consequences or death to humans or animals.

Step 11: Vacate the Amended or Modified Order

A. If after providing opportunity for an informal hearing the Division, applicable Center(s), or OSPOP, or the Commissioner on his/her own initiative, determines that adequate grounds do not exist to continue the actions required by an order made under Step 7 or 9 (**Amend or Modify the Prehearing Order to Cease Distribution and Give Notice Following the Informal Hearing OR Amend or Modify the Prehearing Order to Cease Distribution and Give Notice Without Holding and Informal Hearing**), the OSPOP will draft, at the Commissioner's direction as applicable, an order vacating the order made under Step 7 or 9. **See Attachment J7 (Vacated Order).**

B. The OSPOP will send a proposed final vacated order to the OC by electronic mail.

C. As soon as practicable thereafter, the OSPOP will advise the Commissioner on the matter. If the Commissioner approves the vacated order, the Commissioner will sign the vacated order, or revise and sign the order as appropriate, and the OC will send the signed order to the OSPOP.

D. The OSPOP will issue and send the vacated order with a cover letter to the responsible party by overnight delivery (with delivery confirmation). A copy of the vacated order will be sent using the most expeditious method to the responsible party (e.g., by electronic mail or facsimile). When possible, the Director of the OSPOP will also contact the responsible party to convey the information contained in the vacated order orally.

Attachment J1 – Recommendation Memorandum

To: Office of Commissioner

From:

Date:

Subject: Formal Recommendation Regarding Whether to Provide [responsible party name and address] With an Opportunity to Cease Distribution and Recall [article of food]

Responsible Party and Contact Information:

Firm Identification #(s):

Description of Article:

Article Identification #(s):

Background:

Evidence:

District Office's Recommendation - [person's name]:

Center's Recommendation - [person's name]:

OCC's Recommendation - [person's name]:

OSPOP's Recommendation - [person's name]:

Determination:

Determination Date:

Attachment J2 – Notification of Opportunity to Initiate a Voluntary Recall

[Date]

[Responsible Party Name]

[Firm Name]

[Street]

[City, State Zip]

Dear [Name]:

Pursuant to section 423 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 3501), as amended by the FDA Food Safety Modernization Act, the U.S. Food and Drug Administration (FDA) is providing your firm [firm name], with an opportunity to voluntarily cease distribution and conduct a recall of the below referenced products. Section 423(a) of the FD&C Act provides in relevant part that if FDA “determines...that there is a reasonable probability that an article of food (other than infant formula) is adulterated under section 402 of the Act or misbranded under section 403(w) of the Act and the use of or exposure to [article of food] will cause serious adverse health consequences or death to humans or animals,” before taking further action under section 423 of the FD&C Act, FDA must offer the responsible party the opportunity to voluntarily cease distribution and recall such articles (21 U.S.C. 3501(a)).

[Identify the specific product(s) and code(s) that should be recalled and the basis for FDA’s determination that there is a reasonable probability that the product(s) are adulterated under 402 or misbranded under 403(w) and the reasonable probability that use of or exposure to the product(s) may result in serious adverse health consequences or death to humans or animals. If there are violative samples, inspectional evidence, adverse events, or other compelling information that the FDA’s determination is based on, they should be included.]

In accordance with section 423(a) of the FD&C Act, we are providing you with an opportunity to voluntarily cease distribution and conduct a recall of the [referenced product(s)]. If you elect to voluntarily cease distribution and conduct a recall of these products, you should do so in the following time and manner:

- Within 2 working days of your receipt of this letter, cease distribution and initiate a recall of the following product(s): [product(s)]
Notify all direct consignees and request that those who further distributed these products conduct a sub-recall to the consumer level.

- Conduct your recall of these products in coordination with the FDA [] Division Recall Coordinator and in accordance with the manner prescribed by FDA.
- Follow the procedures for recalls found in FDA's regulations at 21 CFR Part 7 to the extent that it doesn't conflict with the time and manner prescribed in this letter. A copy of these regulations is enclosed.

If you do not voluntarily cease distribution and conduct a recall within 2 working days and in the manner described in this letter, FDA may, by order require you to immediately cease distribution of [article of food]. Additionally, FDA may, by order require you to immediately notify all persons manufacturing, processing, packing, transporting, distributing, receiving, holding, or importing and selling [article of food] to immediately cease distribution of such article; and to immediately notify all persons to which such article has been distributed, transported, or sold, to immediately cease distribution of [article of food].

Please respond to this letter by contacting [Program [Division] Director Name, Telephone Number and Electronic mail Address] as soon as possible. If a response is not received from you by [deadline], FDA may by order require you to immediately cease distribution and notify applicable parties, as explained above.

Sincerely,

[Deputy Commissioner of Food Policy and Response]

Enclosure: 21 CFR Part 7

Attachment J3 – Prehearing Order to Cease Distribution and Give Notice

[Date]

[Responsible Party Name]

[Firm Name]

[Street]

[City, State Zip]

Dear [Name]:

Pursuant to section 423 of the Federal Food, Drug, and Cosmetic Act (the Act), as amended by the FDA Food Safety Modernization Act, FDA has determined that there is a reasonable probability that [responsible party name]'s [article of food and identifying information] is adulterated under section 402 of the Act or misbranded under section 403(w) of the Act and the use of or exposure to [article of food] will cause serious adverse health consequences or death to humans or animals. FDA notified you of its determination and provided you with the opportunity to voluntarily cease distribution and conduct a recall. At present, you have not [responded to or taken all the actions specified in] FDA's request. Accordingly, FDA is now ordering you to immediately cease distribution of [article of food], and to immediately notify (1) all persons manufacturing, processing, packing, transporting, distributing, receiving, holding, or importing and selling such article; and (2) all persons to which such article has been distributed, transported, or sold to immediately cease distribution of [article of food]. You are further required to give any warehouse-based third party logistics provider that may be in possession of [article of food] sufficient information to identify the article of food covered by this order.

You have the right to request that an informal hearing be held at which, if granted, you would have the opportunity to address the actions required by this order and why the article that is the subject of this order should not be recalled. If you would like to request an informal hearing please send a written request to [Program [Division] Director Name, Address, Telephone Number and Electronic mail Address] within 24 hours of receipt of this order. Please submit [describe information to be submitted in the request]. If you request a hearing, you must follow-up your written request with a phone call to [Program [Division] Director Name] to confirm receipt of the hearing request. If you do not request a hearing in writing within [number of days or hours] you will waive your right to a hearing. Enclosed are the regulations covering FDA's informal hearing procedures in 21 CFR Part 16. Please also refer to 21 CFR Part 10, subpart C for information describing FDA's policies and procedures applicable to electronic media coverage of agency public administrative hearings.

Please note that a request for a hearing may not be granted if FDA determines that no genuine or substantial issue of fact has been raised by the material submitted. If you do not submit a timely written request for a hearing, or if your request for a hearing is

denied, you may be required to recall [article of food] within a specified timetable, provide periodic reports on the status of the recall, notify consumers of the recall, and other appropriate action. Moreover, if you do not comply with such a recall order, you will be charged user fees to cover food recall activities associated with such order.

Sincerely,

[Deputy Commissioner of Food Policy and Response]

Attachment J4 – Denial of Hearing Request

[Date]

[Responsible Party Name]

[Firm Name]

[Street]

[City, State Zip]

Dear [Name]:

On [date], pursuant to section 423 of the Federal Food, Drug, and Cosmetic Act, as amended by the FDA Food Safety Modernization Act, FDA sent you a prehearing order to cease distribution and give notice. FDA also informed you that you had the opportunity to request an informal hearing to address the actions required by that order and why the article that is subject to that order should not be recalled.

FDA has reviewed your request for a hearing and has determined [reason for denying the hearing]. [Summary of material submitted and any further explanation for denial.] Therefore, your request for a hearing is hereby denied.

Sincerely,

[Presiding Officer]

Attachment J5 – Hearing Report Cover Letter

[Date]

[Hearing Party's Name]

[Street]

[City, State Zip]

Dear [Name]:

On [date], an informal hearing was held on [the actions required by the order to cease distribution and give notice, and on whether the article of food that is the subject of the order should not be recalled]. Enclosed, please find the [vacated, modified, or amended] order that resulted from that hearing, along with a copy of the hearing report.

Sincerely,

[Presiding Officer]

Attachment J6 – Hearing Report

On [date], I served as the presiding officer in an informal hearing that was attended by [names of parties and titles in relation to the responsible party or FDA]. The hearing was held [on the actions required by the order to cease distribution and give notice, and on whether the article of food that is the subject of the order should not be recalled].

Prior to the hearing, on [date], FDA provided formal notice to [the responsible party name] that it had the opportunity to cease distribution and conduct a voluntary recall of [article of food]. [Responsible party name] did not [recall or cease distribution of the article of food in the time and manner prescribed, if so prescribed]. Subsequently, on [date] FDA sent [by registered mail, facsimile, and/or electronic mail] [responsible party name] a prehearing order to cease distribution and give notice.

At the hearing, I considered the actions required by the prehearing order to cease distribution and give notice and the evidence and testimony presented at the hearing. I was provided with [list of documents and summary of any pertinent information].

[Option: If credibility is at issue, include a finding on the credibility of witnesses (other than expert witnesses) and explain why the finding was made.]

Based on this information, I have determined [choose from options below]

[Option 1: that adequate grounds do not exist to continue the actions required by the order and have decided to vacate the order.]

[Option 2: that the removal of [article of food] from commerce is necessary. The prehearing order to cease distribution and give notice should be amended to, [as appropriate (1) require [responsible party name] to recall [article of food and identifying information] or [take other appropriate action]; (2) [specify a timetable in which the recall shall occur]; (3) require [periodic reports] describing the progress of the recall; and (4) require that notice be provided to consignees and consumers to whom such article was or may have been distributed.]

[Option 3: that the prehearing cease distribution and give notice order should be modified [because], and that the removal of [article of food] subject to the modified order from commerce is necessary. The modified prehearing order to cease distribution and give notice should be modified to, [as appropriate (1) require [responsible party name] to recall [article of food and identifying information] or [take other appropriate action]; (2) [specify a timetable in which the recall shall occur]; (3) require [periodic reports] describing the progress of the recall; and (4) require that notice be provided to consignees and consumers to whom such article was or may have been distributed.]

[Presiding Officer]

Attachment J7 – Vacated Order

[Date]

[Responsible Party Name]

[Firm Name]

[Street]

[City, State Zip]

Dear [Name]:

On [date] you were ordered to immediately cease distribution of [article of food], and to immediately notify (1) all persons manufacturing, processing, packing, transporting, distributing, receiving, holding, or importing and selling such article; and (2) all persons to which such article has been distributed, transported, or sold to immediately cease distribution of [article of food]. You were also ordered to give any warehouse-based third party logistics provider that may be in possession of [article of food] sufficient information to identify the article of food covered by the order. [As applicable, [Furthermore, the [date] order was [amended or modified] on [date] to [describe requirements of the amended or modified order]]].

At this time, adequate grounds do not exist to continue the actions required by the [date] order. [Insert any additional information regarding the decision to vacate the order, as desired]. Accordingly, the [date] order is hereby vacated.

Sincerely,

Commissioner, Food and Drugs

Attachment J8 – Amended Order

[Date]

[Responsible Party Name]

[Firm Name]

[Street]

[City, State Zip]

Dear [Name]:

On [date], you were ordered to immediately cease distribution of [article of food], and to immediately notify (1) all persons manufacturing, processing, packing, transporting, distributing, receiving, holding, or importing and selling such article; and (2) all persons to which such article has been distributed, transported, or sold to immediately cease distribution of [article of food]. Furthermore, you were ordered to give any warehouse-based third party logistics provider that may be in possession of [article of food] sufficient information to identify the article of food covered by the order.

At this time, the removal of [article of food] from commerce is necessary. Therefore, the [date] order is hereby amended, and you are ordered to [as applicable, recall [article of food] or take other appropriate action [within timetable]; provide [periodic] reports to [designee] describing the progress of the recall; and immediately notify consumers to whom such article was, or may have been, distributed].

Please note that if you do not comply with this order, FDA may impose a civil penalty or pursue other actions, as appropriate. This order is effective immediately. If you have questions regarding this order, you may contact Program [Division] Director Name, Telephone Number and Electronic mail Address.

Sincerely,

Commissioner, Food and Drugs

Attachment J9 – Modified Order

[Date]

[Responsible Party Name]

[Firm Name]

[Street]

[City, State Zip]

Dear [Name]:

On [date], you were ordered to immediately cease distribution of [article of food], and to immediately notify (1) all persons manufacturing, processing, packing, transporting, distributing, receiving, holding, or importing and selling such article; and (2) all persons to which such article has been distributed, transported, or sold to immediately cease distribution of [article of food]. Furthermore, you were ordered to give any warehouse-based third party logistics provider that may be in possession of [article of food] sufficient information to identify the article of food covered by this order.

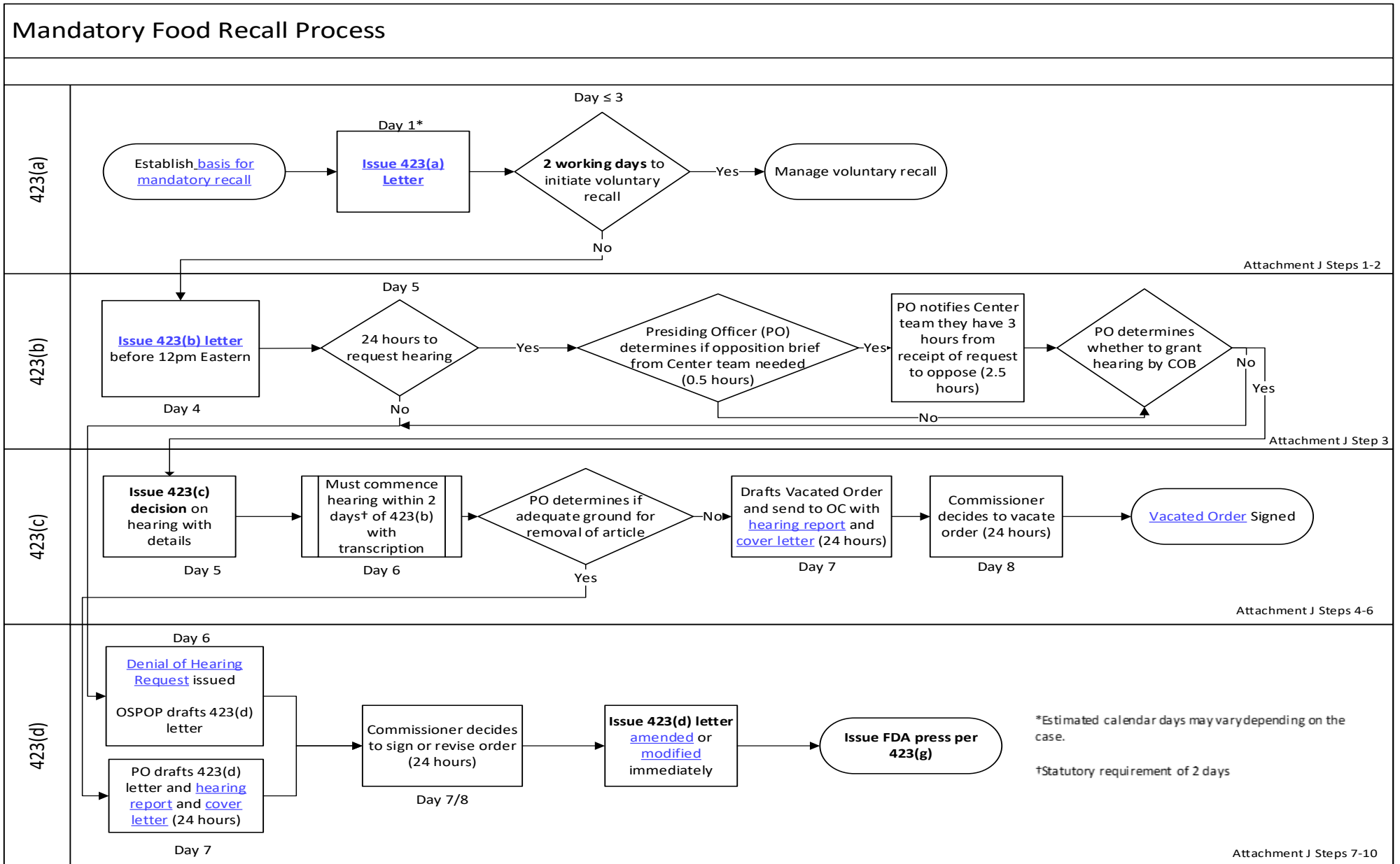
At this time, the [date] order is modified [insert any specific modifications, e.g. the scope of coverage in terms of articles of food or persons who must be notified]. Additionally, at this time the removal of [article of food] from commerce is necessary. Therefore, you are hereby ordered to [as applicable, recall [article of food] or take other appropriate action [within timetable]; provide [periodic] reports to [designee] describing the progress of the recall; and immediately notify consumers to whom such article was, or may have been, distributed.]

Please note that if you do not comply with this order, FDA may impose a civil penalty or pursue other actions, as appropriate. This order is effective immediately. If you have questions regarding this order, you may contact Program [Division] Director Name, Telephone Number and Electronic mail Address.

Sincerely,

Commissioner, Food and Drugs

Attachment J10 – Mandatory Food Recall Process Flow Chart



Attachment K – Notification, Nondistribution, and Recall of Controlled Substances for Human or Animal Use

PURPOSE

This attachment provides procedures and defines responsibilities for various operations related to the issuance of an order of nondistribution and the mandatory recall of controlled substances under Section 569D of the Act [21 U.S.C. 360bbb-8d], as amended by section 3012 of the Substance Use-Disorder Prevention That Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act). Use of this mandatory recall tool does not prevent the agency from using other available regulatory tools. At any point during the notification, nondistribution and recall process, the agency may discuss and/or pursue another action as needed.

BACKGROUND

Section 3012 of the SUPPORT Act, Notification, Nondistribution, and Recall of Controlled Substances, adds section 569D to the Federal Food, Drug, and Cosmetic Act (FD&C Act) and grants authority for FDA to order a firm to cease distribution of controlled substances in situations where the agency determines there is a reasonable probability that the controlled substance would cause serious adverse health consequences or death in humans or animals. Before the order of nondistribution can be issued, the appropriate person must be given an opportunity to consult with the agency. Following the issuance of an order of nondistribution, the appropriate person may request a hearing. Following a hearing or a failure to request a hearing within the prescribed timeframes, FDA, through the official designated by the Secretary can resolve an order of nondistribution in any of the following ways:

- A. Vacate the order of nondistribution.
- B. Continue the order of nondistribution requiring the appropriate person to cease distribution of the controlled substance until a date specified in such continued order.
- C. Amend the order of nondistribution to require a recall of the controlled substance, including any requirements to notify appropriate persons, a timetable for the recall to occur, and a schedule for updates to be provided to FDA regarding such recall.

According to section 569D(c), “an official may not be so designated under this section unless the official is the Director of the Center for Drug Evaluation and Research or an official senior to such Director.”

PROCEDURES***Step 1: Preparing for the Issuance of the Order of Nondistribution:***

- A. FDA may exercise its authority to issue an order of nondistribution (see Attachment K1), which may be followed by a recall of a controlled substance, based on information developed internally or from outside sources, including states and other agencies, or gathered through any other means. When considering the need to issue the order, and once concurrence is obtained from the Center Deputy Director to move forward with providing the appropriate person the opportunity to consult, the FDA Center shall notify the Office of Regulatory Affairs (ORA) Program Division and request the ORA Program Division set up an internal meeting with the Center, the Office of Chief Counsel (OCC), the ORA Division of Enforcement (DE), and all other interested parties for awareness before the firm is contacted to set up an opportunity to consult meeting. The FDA Center will create a case in the Compliance Management System (CMS) as a Compliance Action: Order of Non-Distribution - Support Act.
- B. The FDA Center will prepare and upload into CMS, as appropriate, an order of nondistribution and recall action memo, the health hazard evaluation (HHE), the draft order of nondistribution, and any other supporting memos or evidence.

Any FDA Office that acquires relevant documentation, including correspondence concerning the matter, is responsible for uploading that documentation into the CMS case, so that it may be reviewed concurrently by the ORA Program Division, OSPOP/DE, the appropriate Center compliance staff, and OCC; collectively “the team.” The team reporting to the Center Deputy Director that is involved with the opportunity to consult and possible issuance of the nondistribution order, should not be involved in assisting the Center Director, or delegated authority senior to the Center Director, for order resolution.

The ORA Program Division will be responsible for coordinating the process flow and document cohesiveness throughout the order issuance and mandatory recall case processing. If more than one Center (i.e. CDER and CVM) is involved, the centers will determine the lead center for the action.

Center compliance staff will ensure an HHE is completed prior to deciding whether to proceed with issuing a nondistribution order. The subject matter expert(s) who signs the HHE is committed to being available to testify (at least by phone) during a hearing, should a hearing be requested. If the expert cannot be available to testify at a hearing, the Center will prepare a separate expert memo regarding the determination that the controlled substance would cause serious adverse health consequences or death. The Center will upload both the HHE and, when needed, the serious adverse health consequences or death memorandum into CMS.

All the following must be prepared, finalized, signed, and uploaded to CMS by the appropriate organization (Center or Division) before the order of nondistribution is sent:

- 1) A record memo laying out the legal and factual basis for FDA's position (e.g., the legal argument as to why the products at issue are controlled substances, which for example might rely in part on information on product labels);
- 2) A sworn affidavit laying the foundation for any evidence upon which the record memo analysis relies (e.g., investigator declaration that the product labels cited in the record memo are true and accurate copies of the labels collected during inspection of the firm); and
- 3) All evidence referenced in the affidavit/memo (e.g., copies of the product labels).

The Center will contact OCC to clear the final order. OSPOP/DE will notify the FDA Office of Media Affairs and keep them involved as necessary in the process. OSPOP/DE will keep a chronology of events, including documenting when any communication, such as the order, is sent to and received by the appropriate person.

The OSPOP/DE will identify an appropriate person to serve as a Presiding Officer (PO) if a hearing is requested. This person must not have been previously involved in decision-making for the matter and should be advised to maintain separation of functions from personnel who are working with the team. The OSPOP/DE will determine the availability of the PO and ensure the PO is in contact with OCC attorney(s) available to them.

The Center will identify a subject matter expert who has not previously worked on the matter to advise the PO/Center Director, or delegated authority senior to the Center Director, as needed with respect to the specific types of evidence that form the basis of FDA's case. This person must be available the day of anticipated issuance of the order of nondistribution and at least the next ten calendar days immediately after issuance of the order. This person should be advised to maintain separation of functions from personnel who are working with the team involved in the opportunity to consult meeting and possible issuance of the order.

Step 2: Providing an Opportunity to Consult

The ORA Program Division will reach out to the appropriate person at the firm to set up a meeting to discuss the agency's concerns, give an opportunity to consult and inform the firm of the Agency's intent to issue an order of nondistribution, which may lead to an ordered recall. All Center representatives, OCC, and the ORA DE Recalls Branch will also be invited to this meeting.

- A. The conversation with the appropriate person will provide the agency's reasoning for pursuing the order of nondistribution.
- B. The agency will recommend that the firm voluntarily cease distribution, and as appropriate voluntarily recall the product.
- C. If the firm agrees to stop distribution and recall, ORA will follow normal recall procedures.
- D. If the firm disagrees, FDA will raise the potential for issuance of the order of nondistribution and note that such order may lead to an ordered recall.
- E. The firm will be given 24 hours to respond to the recommendation to stop distribution and recall.

Step 3: Issuance of the Order of Nondistribution

- A. The Center will coordinate with all parties to finalize the draft order for review and clearance by OCC. All the following steps must be taken before OCC can clear the order of nondistribution:
 - 1) Lab test results on which the agency plans to rely must be final and accepted by FDA. If they are preliminary in some form, that must be clearly stated when the results are referenced in other documents (until they become final). Summaries and analytical worksheets need to be uploaded into CMS as soon as they are available.
 - 2) If FDA intends to rely on lab work done by a non-FDA lab as evidence in the matter, an appropriate person at FDA must review the documentation and sign a brief memo regarding the validity of the non-FDA lab's analysis. If FDA experts are not prepared to say that the non-FDA lab's work can be relied upon to show what it purports to show, FDA cannot use that evidence. FDA only needs one such memo. The Center and ORA will decide who is responsible for this analysis so there will be no duplication or conflict.
 - 3) Firm websites, if used as evidence in the matter, need to be captured by a recent screen shot and uploaded into CMS as PDFs.
 - 4) The HHE, expert memos, and memos and affidavits, including referenced evidence, addressing potential challenges to the case must be complete and uploaded into CMS.
 - 5) The order of nondistribution must clearly state and support (with attachments, including relevant factual evidence, such as lab test results when needed, and the HHE) the complete basis for FDA's conclusion that

there is a reasonable probability that the controlled substance would cause serious adverse health consequences or death.

- B. After all recommended changes are captured and the above list of steps completed, the Center will forward the order of nondistribution final draft to OCC for final review and clearance. Once cleared, OCC will provide a copy of the cleared document to the Center who will then provide it to the Center Deputy Director, with a cc to the ORA Program Division and OSPOP/DE. Once signed, the Center will provide the signed order to the ORA Program Division. The ORA Program Division will send the order to the appropriate person by overnight delivery (with delivery confirmation). If transmitted in a manner other than overnight delivery, e.g., by electronic mail, request a delivery and read receipt. Additionally, a copy of the order will be sent using the most expeditious method that is available to the appropriate person (e.g., by electronic mail or facsimile). The ORA Program Division will email the order to the team and upload a copy into CMS. When possible, the ORA Program Division shall also contact the appropriate person to convey the information contained in the order orally.
- C. The order will advise the appropriate person that they have the opportunity for an informal hearing and will provide instructions on how to request a hearing. The hearing must be held not later than ten calendar days after the date of issuance of the order. To allow for the hearing to commence within 10 days of the issuance of an order of nondistribution, the order will inform the appropriate person that the request for the hearing must be made within three working days after the date of receipt of the order.
- D. The ORA Program Division will notify OSPOP/DE of the intended action so that a PO can be assigned in the event an informal hearing is requested and transcription services may be obtained.
- E. All communications with the appropriate person will be documented in CMS.
- F. The team may reconvene at any time to discuss further regulatory action needed to mitigate public health risks. If at any point the process appears to be slowing or stagnating, the team will escalate the issue to senior ORA/Center officials.

Step 4: Determination of Process for Order Resolution

- A. If the appropriate person does not request a hearing but ceases distribution and initiates a voluntary recall of the controlled substance within ten working days after the date of the issuance of the order, the ORA Program Division will immediately notify the team. The oversight, processing, and tracking of the recall action will follow the procedures for Class I recalls in the RPM, Chapter 7 – Recall Procedures. The recall will be documented in the Recall Enterprise System (RES). The Division Recall Coordinator (DCR) will select the recall type from the voluntary drop-down list, “FDA Ordered – 569D” on the “Edit Start Recall” screen. In the Public Reason for Recall, include the statement: “[FIRM] received an order

of Notice, Nondistribution and Mandatory Recall of Controlled Substance, from FDA and is recalling [Product] because [Reason]."

- B. If the appropriate person requests a hearing, within three working days after the date of issuance of the order, OSPOP/DE will ensure a PO is selected, and a hearing will be held as described in Step 5.
- C. If the appropriate person does not request a hearing within three working days after the date of issuance of the order, the ORA Program Division will alert the Center that the deadline has passed and the Center Director, or delegated authority senior to the Center Director, will be advised to determine order resolution.

Step 5: Informal Hearing

- A. FDA will conduct the hearing consistent with section 201(x) of the Act and 21 CFR Part 16 (to the extent that Part 16 is not in conflict with section 569D of the Act).
- B. The PO and individuals who assist with the hearing have no later than ten calendar days following the order issuance to commence a hearing. The hearing need not finish on Day 10.
- C. The PO will write a hearing report. See Attachment K3 (Hearing Report). The PO should immediately begin work on the hearing report, using notes and recording of the hearing until the transcript is available. The hearing report should include the PO's recommendation to the Center Director, or delegated authority senior to the Center Director, as to whether to vacate the order of nondistribution, continue the order of nondistribution until a specified date, or amend the order of nondistribution to include a recall. The hearing report should include a copy of the appropriate draft order using the corresponding template found in Attachments K4 – K6. The final hearing report and transcript must be uploaded into CMS by the ORA Program Division.
- D. If the PO concludes, following the informal hearing, that adequate grounds do not exist to continue the actions required by the order, proceed to Step 6 (Vacate the Order of Nondistribution). If the PO concludes that removal of the controlled substance from commerce is necessary, proceed to Step 7 (Amend the Order of Nondistribution to Include Recall). If the PO concludes that continued nondistribution is necessary, but a recall is not necessary, proceed to Step 8 (Continue the Order of Nondistribution).

Step 6: Vacate the Order of Nondistribution

- A. Following the informal hearing:
 - 1) If the PO concludes that adequate grounds do not exist to continue the actions required by the order, the PO will make a recommendation to vacate the order

and draft a vacated order within 24 hours of the informal hearing. See Attachment K4 (Vacated Order of Nondistribution).

- 2) The PO will send the proposed final vacated order and the administrative record of the hearing to the Center Director's office, or delegated authority senior to the Center Director, by electronic mail.
- 3) As soon as practicable thereafter, if the Center Director, or delegated authority senior to the Center Director, approves the vacated order, the Center Director, or delegated authority senior to the Center Director, signs the vacated order, or revises and signs the order as appropriate, and sends the signed order to the PO. The Center Director's, or delegated authority senior to the Center Director, decision should be made within 24 hours of receipt of the administrative record of the hearing from the PO.
- 4) The PO will draft a hearing report cover letter. See Attachment K2 (Hearing Report Cover Letter).
- 5) The PO will issue and send the vacated order with the hearing report cover letter and hearing report to the appropriate person by overnight delivery with delivery confirmation. A copy of the vacated order will be sent using the most expeditious method to the appropriate person, e.g., by electronic mail or facsimile. When possible, the PO will also contact the appropriate person to convey the information contained in the vacated order orally. Additionally, the PO will send the vacated order with the cover letter and the hearing report to the FDA hearing participants by electronic mail or facsimile. A copy of the vacated order will be uploaded into CMS by the ORA Program Division.

B. If an informal hearing is not requested:

- 1) In the event a hearing is not requested and the Center Director, or delegated authority senior to the Center Director, determines that the order should be vacated, the Center will draft, at the Center Director's, or delegated authority senior to the Center Director, direction, a vacated order, for Center Director, or delegated authority senior to the Center Director, signature. See Attachment K4 (Vacated Order of Nondistribution).
- 2) If the Center Director, or delegated authority senior to the Center Director, approves the vacated order, the Center Director, or delegated authority senior to the Center Director, will sign the vacated order, or revise and sign the order as appropriate, and the Center will send the signed order to the ORA Program Division.
- 3) The ORA Program Division will issue and send the vacated order with a cover letter to the appropriate person by overnight delivery with delivery confirmation. A copy of the vacated order will be sent using the most expeditious method to the appropriate person (e.g., by electronic mail or

facsimile). When possible, the ORA Program Division will also contact the appropriate person to convey the information contained in the vacated order orally. A copy of the vacated order will be uploaded into CMS by the ORA Program Division.

Step 7: Amend the Order of Nondistribution to Include Recall

A. Following an informal hearing:

- 1) If the PO concludes that it is necessary to amend the actions of the order, and that the removal of the controlled substance that is the subject of the order from commerce is necessary, the PO will draft an amended order within 24 hours of the informal hearing that amends the order to require recall of such controlled substance, specifies a timetable in which the recall shall occur, requires periodic reports describing the progress of the recall, and requires notice be provided to consignees and consumers to whom such controlled substance was or may have been distributed. See Attachment K6 (Amended Order to Include Recall).
- 2) The PO will send the proposed final amended order, and the administrative record of the hearing to the Center Director, or delegated authority senior to the Center Director, by electronic mail.
- 3) As soon as practical thereafter, if the Center Director, or delegated authority senior to the Center Director, approves the amended order, the Center Director, or delegated authority senior to the Center Director, signs the order or revises and signs the order as appropriate and sends the signed order to the PO. The Center Director's, or delegated authority senior to the Center Director, decision should be made within 24 hours of receipt of the administrative record of the hearing from the PO.
- 4) The PO will draft a hearing report cover letter. See Attachment K2 (Hearing Report Cover Letter).
- 5) Following the Center Director's, or delegated authority senior to the Center Director, decision, the PO will immediately send the amended order, hearing report cover letter and the hearing report to the appropriate person by overnight delivery (with delivery confirmation). Additionally, a copy of the order will be sent using the most expeditious method to the appropriate person, e.g., by electronic mail or facsimile. When possible, the PO will also contact the appropriate person to convey the information contained in the order orally. Additionally, the PO will send the amended order, with the cover letter and hearing report to the FDA hearing participants by electronic mail and upload into CMS a copy of the amended order, cover letter, and hearing report. Proceed to Step 9 (Manage the Recall).

B. If an informal hearing is not requested:

- 1) If the Center Director, or delegated authority senior to the Center Director, concludes that it is necessary to amend the actions of the order, and that the removal of the controlled substance that is the subject of the order, from commerce is necessary, the Center will draft, at the Center Director's, or delegated authority senior to the Center Director, direction, an amended order that amends the order to require recall of such controlled substance, specifies a timetable in which the recall shall occur, requires periodic reports describing the progress of the recall, and requires notice be provided to consignees and consumers to whom such controlled substance was or may have been distributed. See Attachment K6 (Amended Order to Include Recall).
- 2) If the Center Director, or delegated authority senior to the Center Director, approves the amended order ordering the recall, the Center Director, or delegated authority senior to the Center Director, will sign the amended order, or revise and sign the order as appropriate, and the Center will send the signed order to the ORA Program Division .
- 3) ORA Program Division will issue and send the amended order requiring the recall, with a cover letter to the appropriate person by overnight delivery (with delivery confirmation). A copy of the amended order will be sent using the most expeditious method to the appropriate person (e.g., by electronic mail or facsimile). When possible, the ORA Program Division will also contact the appropriate person to convey the information contained in the amended order orally and upload a copy of the amended order into CMS. Proceed to Step 9 (Manage the Recall).

Step 8: Continue the Order of Nondistribution

A. Following the informal hearing:

- 1) If the PO concludes that the continued nondistribution is necessary, but a recall is not necessary, the PO will make a recommendation within 24 hours of the informal hearing to continue the order of nondistribution until a specified date. See Attachment K5 (Continued Order of Nondistribution).
- 2) The PO will send the proposed final continued order and the administrative record of the hearing to the Center Director office, or delegated authority senior to the Center Director, by electronic mail.
- 3) As soon as practicable thereafter, if the Center Director, or delegated authority senior to the Center Director, approves the continued order, the Center Director, or delegated authority senior to the Center Director, signs the continued order or revises and signs the continued order, and sends the signed continued order to the PO. The Center Director's, or delegated authority senior to the Center Director, decision should be made within 24 hours of receipt of the administrative record of the hearing from the PO.

- 4) The PO will draft a hearing report cover letter. See Attachment K2 (Hearing Report Cover Letter).
- 5) The PO will issue and send the continued order with the hearing report cover letter and hearing report to the appropriate person by overnight delivery (with delivery confirmation). A copy of the continued order will be sent using the most expeditious method to the appropriate person, e.g., by electronic mail or facsimile. When possible, the PO will also contact the appropriate person to convey the information contained in the continued order orally. Additionally, the PO will send the continued order with the cover letter and the hearing report to the FDA hearing participants by electronic mail or facsimile. A copy of the continued order will be uploaded into CMS by the ORA Program Division.

B. If an informal hearing is not requested:

- 1) In the event a hearing is not requested and the Center Director, or delegated authority senior to the Center Director, determines that the order should be continued, the Center will draft, at the Center Director's, or delegated authority senior to the Center Director, direction, a continued order for Center Director, or delegated authority senior to the Center Director, signature. See Attachment K5 (Continued Order of Nondistribution).
- 2) If the Center Director, or delegated authority senior to the Center Director, approves the continued order, the Center Director, or delegated authority senior to the Center Director, will sign the continued order, or revise and sign the continued order as appropriate, and the Center will send the signed continued order to the ORA Program Division.
- 3) The ORA Program Division will issue the continued order to the appropriate person by overnight delivery (with delivery confirmation). A copy of the continued order will be sent using the most expeditious method to the appropriate person (e.g., by electronic mail or facsimile). When possible, the ORA Program Division will also contact the appropriate person to convey the information contained in the continued order orally. The ORA Program Division will upload a copy of the continued order into CMS.

Step 9: Manage the Recall

The oversight, processing, and tracking of the recall action will follow the procedures for recalls in the RPM, Chapter 7 – Recall Procedures.

Attachment K1 – Order of Nondistribution

[*Date*]

[*Appropriate Person Name*]

[*Firm Name*]

[*Street*]

[*City, State Zip*]

Dear [*Name*]:

Pursuant to section 569D of the Federal Food, Drug, and Cosmetic Act (the Act), as amended by section 3012 of the Substance Use-Disorder Prevention That Promotes Opioid Recovery and Treatment for Patients and Communities Act, FDA has determined that there is a reasonable probability that [*controlled substance(s) and identifying product information*] could cause serious adverse health consequences or death of [*humans and/or animals*]. The Agency provided you the opportunity to consult on [*date*,] during which, FDA discussed our concerns and recommended that you cease distribution and voluntarily recall the product. At present, you have not [*responded to or taken all the actions specified in*] FDA's recommendation. Accordingly, FDA is now ordering you to immediately cease distribution of [*controlled substance(s)*], and to immediately notify all manufacturers, importers, distributors, or pharmacists, who distribute such controlled substance to immediately cease distribution of such [*controlled substance(s)*].

You have the right to request that an informal hearing be held, at which you would have the opportunity to address the actions required by this order. If you would like to request an informal hearing, please send a written request to [*ORA Program Division Director Name, Address, Telephone Number and Electronic mail Address*]. Please submit [*describe information to be submitted in the request*]. If you request a hearing, you must follow-up your written request with a phone call to [*ORA Program Division Director Name*] to confirm receipt of the hearing request. If you do not request a hearing in writing within three working days after the date of issuance of this order, you will waive your right to a hearing. Enclosed are the regulations covering FDA's informal hearing procedures in 21 CFR Part 16. Please also refer to 21 CFR Part 10, subpart C for information describing FDA's policies and procedures applicable to electronic media coverage of agency public administrative hearings.

If you do not submit a timely written request for a hearing this order may be amended to continue this order until a date specified or require you to recall [*controlled substance(s)*], including any requirements to notify appropriate persons of the recall, a timetable for the recall to occur, and a schedule for updates to be provided to FDA regarding such recall.

Sincerely,

[*Center Deputy Director*]

Attachment K2 – Hearing Report Cover Letter

[*Date*]

[*Hearing Party's Name*]

[*Street*]

[*City, State Zip*]

Dear [*Name*]:

On [*date*], an informal hearing related to [*controlled substance(s) and identifying product information*] was held on [*the actions required by the order of nondistribution, and on whether the controlled substance(s) that is the subject of the order should not be recalled*]. Enclosed, please find the [*vacated or amended*] order that resulted from that hearing, along with a copy of the hearing report.

Sincerely,

[*Presiding Officer*]

Attachment K3 – Hearing Report

On **[date]**, I served as the Presiding Officer in an informal hearing related to **[controlled substance(s) and identifying product information]** that was attended by **[names of parties and titles in relation to the appropriate person or FDA]**. The hearing was held **[on the actions required by the order of nondistribution]**.

Prior to the hearing, on **[date]**, FDA provided to **[the appropriate person name]** the opportunity to consult. **[Appropriate person name]** did not **[cease distribution and/or recall the controlled substance(s)]**. Subsequently, on **[date]** FDA sent **[by registered mail, facsimile, and/or electronic mail]** **[appropriate person name]** an order of nondistribution.

At the hearing, I considered the actions required by the order of nondistribution and the evidence and testimony presented at the hearing. I was provided with **[list of documents and summary of any pertinent information]**.

[Option: If credibility is at issue, include a finding on the credibility of witnesses (other than expert witnesses) and explain why the finding was made.]

Based on this information, I recommend the following **[choose from options below]**

[Option 1: Adequate grounds do not exist to continue the actions required by the order and therefore I recommend vacating the order.] Specifically, **[list reasons to justify this recommendation.]**

[Option 2: The order of nondistribution of **[controlled substance(s)]** from commerce is necessary, but the removal of the **[controlled substance(s)]** from commerce is not necessary. Specifically, **[list reasons to justify this recommendation.]** I recommend the order of nondistribution be amended to continue until **[date]**.

[Option 3: The order of nondistribution should be amended to require recall of the **[controlled substance(s)]** (removal of the controlled substance from commerce) **[because]**. Specifically, **[list reasons to justify this recommendation.]** The order should be amended to, **[as appropriate (1) require [appropriate person name] to recall [controlled substance and identifying information]; (2) [specify a timetable in which the recall shall occur]; (3) require [periodic reports] describing the progress of the recall; and (4) require that notice be provided to consignees and consumers to whom such article was or may have been distributed.]**

[Presiding Officer]

Attachment K4 – Vacated Order of Nondistribution

[*Date*]

[*Appropriate Person Name*]

[*Firm Name*]

[*Street*]

[*City, State Zip*]

Dear [*Name*]:

On [*date*] you were ordered to cease distribution of [*controlled substance(s)*] and to immediately notify manufacturers, importers, distributors, or pharmacists who distribute such controlled substances, to immediately cease distribution of [*controlled substance(s)*]. [Furthermore, the [*date*] order was [*amended*] on [*date*] to [*describe requirements of the amended order*]].

At this time, adequate grounds do not exist to continue the actions required by the [*date*] order. [*Insert any additional information regarding the decision to vacate the order, as desired*]. Accordingly, the [*date*] order is hereby vacated.

Sincerely,

[*Center Director (or delegated authority senior to the Center Director)*]

Attachment K5 – Continued order of Nondistribution

[*Date*]

[*Appropriate Person Name*]

[*Firm Name*]

[*Street*]

[*City, State Zip*]

Dear [*Name*]:

On [*date*], FDA notified you that there is a reasonable probability that [*controlled substance(s) and identifying product information*] could cause serious adverse health consequences or death of [*humans and/or animals*] and you were ordered to immediately cease distribution of [*controlled substance(s)*] and to immediately notify manufacturers, importers, distributors, or pharmacists who distribute such controlled substance, to immediately cease distribution of [*controlled substance(s)*].

[*Based on the hearing held on date, if one was held*] continued nondistribution of [*controlled substance(s)*] is necessary. Therefore, the [*date*] order is hereby amended, and you are ordered to immediately notify manufacturers, importers, distributors, or pharmacists who distribute such controlled substance, to cease distribution of [*controlled substance(s)*] until [*date*].

Please note that if you do not comply with this order, FDA may pursue other actions, as appropriate. This order is effective immediately. If you have questions regarding this order, you may contact [*ORA Program Division Director Name, Telephone Number and Electronic mail Address*].

Sincerely,

[*Center Director (or delegated authority senior to the Center Director)*]

Attachment K6 – Amended Order to Include Recall

[*Date*]

[*Appropriate Person Name*]

[*Firm Name*]

[*Street*]

[*City, State Zip*]

Dear [*Name*]:

On [*date*], FDA notified you that there is a reasonable probability that [*controlled substance(s) and identifying product information*] could cause serious adverse health consequences or death of [*humans and/or animals*] and you were ordered to immediately cease distribution of [*controlled substance(s)*] and to immediately notify manufacturers, importers, distributors, or pharmacists who distribute such controlled substance, to immediately cease distribution of [*controlled substance(s)*].

At this time, the removal of [*controlled substance(s)*] from commerce is necessary. Therefore, the [*date*] order is hereby amended, and you are ordered to [*as applicable, recall [controlled substance(s) and scope] or take other appropriate action [within timetable]; provide [periodic] reports to [designee] describing the progress of the recall; and immediately notify consignees and consumers to whom such article was, or may have been, distributed.*]

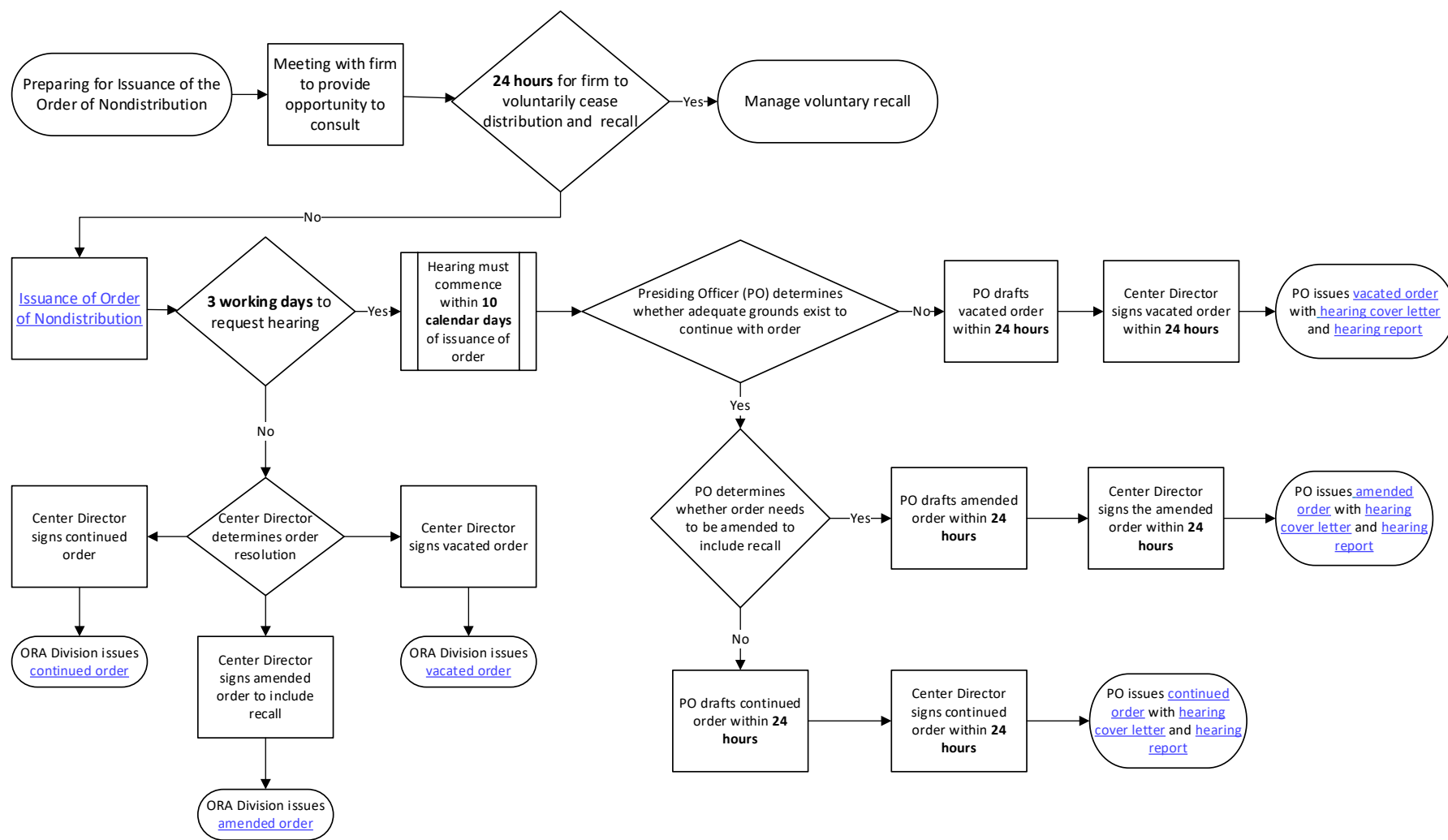
Please note that if you do not comply with this order, FDA may pursue other actions, as appropriate. This order is effective immediately. If you have questions regarding this order, you may contact [*ORA Program Division Director Name, Telephone Number and Electronic mail Address*].

Sincerely,

[*Center Director (or delegated authority senior to the Center Director)*]

Attachment K7 – Notification, Nondistribution, and Recall of Controlled Substances for Human or Animal Use Process Flow Chart

Notification, Nondistribution, and Recall of Controlled Substances for Human or Animal Use Process



Attachment L – Models for Standardized Recall Audit Check (RAC) Levels and Effectiveness of the Recall Notification System for Human Food Recalls

How Many RACS to Conduct

Based on the statistics described with each table, resources available to conduct RACs, and overall experience with monitoring recalls and related RACs, OSPOP ROB recommends the field use the following table to determine how many RACs should be assigned for a human food recall:

Table 1 - RAC Assignment Counts			
# of Direct Accounts	# of RACs		
	Potential Class II	Potential Class I/ Class II with Injury	Outbreak Related/ Class I with Injury
0	0	0	0
1	1	1	1
2-8	2	100%	100%
9-15	3	100%	100%
16-25	5	8	100%
26-50	8	13	20
51-90	13	20	32
91-150	20	32	50
151-280	32	50	80
281-500	50	80	125
501-1200	50*	80*	200*
1201-3200	50*	80*	200*

Table 1 - RAC Assignment Counts			
# of Direct Accounts	# of RACs		
	Potential Class II	Potential Class I/ Class II with Injury	Outbreak Related/ Class I with Injury
3201-10000	50*	80*	200*
10001-35000	50*	80*	200*
35001-150000	50*	80*	200*
150001-500000	50*	80*	200*
>500000	50*	80*	200*

This table was created using American National Standard Z1.4-2008, “Sampling Procedures and Tables for Inspection Attributes” for up to 500 direct accounts. General Inspection Level II was used for potential class II recalls. General Inspection Level III was used for potential class I recalls/class II recalls with injury. General Inspection Level III plus an additional sample size code letter was used for outbreak related/class I with injury.

*Because conducting RACs are unplanned work for the FTEs and as a result of the proof of process, recalls with more than 500 direct accounts will not have an increased amount of RACs recommended.

DRCs should read this model as, if you have between 91-150 direct accounts for your potentially class II recall, you will assign 20 RACs for that recall. For purposes of this table, “outbreak” is defined as an event that a Coordinated Outbreak Response and Evaluate (CORE) Response Team was involved in.

If the product was further distributed, the DRC will assign 3 or more RACs at sub-accounts for each distributor down to the recall depth (retail level, consumer level, etc.).

A higher number of RACs may be requested by the CRU or OSPOP ROB and those will be handled on a case by case basis. For example, if there is a recall of a product(s) suspected to be the cause of an outbreak, involves a death or an ingredient recall with an interest in what types of downstream consignees there are and if they are further manufacturing the recalled product, more RACs may be necessary. There are some instances when RAC's will not be assigned, for instance if all product was distributed outside of the United States. See RPM 7-8-2 for more instructions on when RAC assignments may not be appropriate.

Determining Recall Notification Effectiveness

After evaluating completed recall audit checks, DRCs will use the results of the RAC assignment and the following statistical model to determine if the recall notification system was effective or ineffective. This table is to be used for direct accounts only (the effectiveness of sub-account RACs is to determine the effectiveness of the sub-recall notification system, not as a measurement of the effectiveness of the recalling firm's notification system):

Table 2 - Acceptable Quality Levels for Completed RACs			
# of Direct Account RACs	Maximum Allowable "Ineffective – Notifying Firm" RACs		
	Outbreak Related/Class I with Injury	Potential Class I/Class II with Injury	Potential Class II
1	0	0	0
2	0	0	1
3-4	0	0	1
5-7	0	1	2
8-12	0	2	3
13-19	1	3	5
20-31	2	5	7
32-49	3	7	10
50-79	5	10	14

Table 2 - Acceptable Quality Levels for Completed RACs			
# of Direct Account RACs	Maximum Allowable “Ineffective – Notifying Firm” RACs		
	Outbreak Related/Class I with Injury	Potential Class I/ Class II with Injury	Potential Class II
80-124	7	14	21
125-199	10	21	21
200-314	14	21	21
315-499	21	21	21
500-799	21	21	21
800-1249	21	21	21
1250-1999	21	21	21
2000	21	21	21

This table was created using American National Standard Z1.4-2008, “Sampling Procedures and Tables for Inspection Attributes”, using an Acceptable Quality Limit of 6.0 for potential class II recalls, class I recalls, and class II recalls with injury. An Acceptable Quality Limit of 4.0 was used for recalls that are outbreak-related and class I with injury.

For purposes of this table, “outbreak” is defined as an event that a Coordinated Outbreak Response and Evaluate (CORE) Response Team was involved in.

Table 2 above identifies the maximum number of direct account RACs allowed to be endorsed as “Ineffective – Notifying Firm” before the entire notification system for that recall is determined to be ineffective. DRCs should read this model as, if 25 direct account RACs were completed for a class I recall (no outbreak), and 5 of them were confirmed by the DRC as being “Ineffective – Notifying Firm”, the notification system for the recall was effective. If 6 of them were “Ineffective – Notifying Firm”, the notification system was ineffective.

If the notification system is found to be ineffective using the table, the DRC will let the recalling firm know of the findings and discuss potential actions to improve the notifications, such as issuing additional notification letters or other updates to their recall strategy. The DRC will then issue an additional RAC assignment for 50% of the amount of RACs issued in the first assignment, and re-assess the effectiveness of the notification system. If the notification system is still ineffective after the second RAC assignment, or if the DRC believes there are mitigating factors which will cause the RACs to come back as ineffective – notifying firm, the DRC will request assistance from OSPOP ROB for next steps. All of this information should be documented in RES in the District Review section of the Summary and Termination screen.

If the notification system is found to be ineffective before the RAC assignment is completed, the DRC can suspend the RAC assignment. Once they have informed the recalling firm of the situation and additional actions have been taken to improve the notification system, the RAC assignment can be resumed. If 50% or less of the RACs in the original assignment have been completed, the RAC assignment will continue as originally assigned. If more than 50% of the RACs have been completed, the DRC will add enough RACs to reach 50% of the original amount assigned.

The DRC should include their analysis of the effectiveness of the notification system using Table 2, along with any additional information about the effectiveness of the recall, in the District Review section of the Summary and Termination screen in RES.

Attachment M – Medical Device Safety Alerts

This RPM Attachment covers medical device Safety Alerts exclusively and does not pertain to safety alerts designated by other Centers (e.g. CVM, CDER, CFSAN, CBER). A medical device Safety Alert is a notification to device users that, under certain circumstances, use of or exposure³ to the device may pose a risk of harm. CDRH will only consider a notification to be a Safety Alert if the device is not violative. The notification alerts users of the associated risk and steps to be taken to reduce or eliminate the risk. Safety Alerts will be entered in RES and processed accordingly.

Safety Alerts are reported by the firm to ORA Divisions who will work directly with that firm to obtain any information needed for review/evaluation. The ORA Divisions will enter the 24-Hour Alert and Recall Recommendation in RES. “N/A” will be entered for mandatory RES fields that are not applicable, then the action will be submitted to CDRH for review. After entering the Alert information in RES, the ORA Division will send an acknowledgement email to the firm.

CDRH will review and designate the action to be a Safety Alert, Market Withdrawal, or a Recall. If the action is designated to be a Safety Alert, CDRH will select “Safety Alert” in RES, and then inform the ORA Division if it is considered closed or additional information is needed prior to closure. If CDRH is considering the action to be a recall, they will request the additional information needed to classify the recall from the ORA Division. The ORA Division will follow the procedures for a recall and complete all applicable mandatory fields in RES. Alternately, upon reviewing an action initially submitted in RES as a potential recall, CDRH may designate it meets the definition of a Safety Alert. In that case, the ORA Division should continue processing the action as described in this attachment. NOTE: Status reports and termination request are not required for Safety Alerts.

Once the action has been determined to be a Safety Alert, the ORA Division will notify the firm of this designation. This notification will also inform the firm whether the action is considered closed or whether additional information is needed prior to closure.

Safety Alerts will be closed in RES upon the designation of Safety Alert or will be closed by the ORA Division once the additional information is received and reviewed. The ORA Division will send a closure letter to the firm. “N/A” will be entered for any mandatory fields that are not applicable and the action will be terminated by the ORA Division in RES.

³ The exposure mentioned in this definition excludes electronic product radiation exposure. See 21 CFR Subchapter J.

Exhibit 7-1 Model Effectiveness Check Letter (Industry)

Consignee
Name and Address

Date

(Pressure Sensitive Label)

Dear Sir:

On (date), you were notified by letter that John Doe Company, Someplace, Somewhere 12345, is recalling (product name), container size, code number. All products were manufactured by John Doe Company and distributed solely under the manufacturer's label.

Recall of the product was initiated following a change in their formulation which resulted in products in distribution channels having the same brand name but different ingredients. The old formulation contained X and there is concern that consumers may receive the old formula. Use of the old formulation by some consumers represents a potential health hazard.

The recall notice from John Doe Company requested consignees (wholesalers and retailers) to discontinue selling their existing stock of the old formulations and return existing inventories of the recalled formulations to John Doe Company.

In order to advise the Food and Drug Administration about the effectiveness of this John Doe Company recall, you are requested to complete and return the enclosed questionnaire promptly using the prepaid self-addressed envelope.

If you have any questions or problems with this request, please call (name and telephone number).

Thank you for your cooperation.

Sincerely,

NOTE: If this letter is sent to distributors who may have further sold the product to other distributors or to retail outlets, the third paragraph should include the fact that the recall notice requested the direct consignees to conduct sub-recalls by notifying their customers of the recall situation.

Exhibit 7-2 Model Effectiveness Check Response Format (Industry)

Consignee Name and Address

(Pressure Sensitive Label)

Recall Effectiveness
Checks-Mail Method

JOHN DOE PRODUCT RECALL

PLEASE READ EACH QUESTION AND CHECK THE PROPER ANSWER YOU HAVE CHOSEN. PLEASE CHECK WITH ANYONE WHO MAY HAVE RECEIVED THIS NOTIFICATION BEFORE ANSWERING.

DATE _____

1. Did your firm receive notification that the John Doe Company is recalling its (Name)_____ product?

YES__ NO__

2. Did your firm receive shipments of the product being recalled?
(If no, please sign and return).

YES__ NO__

3. Do you now have any of the recalled product on hand?
(Please check inventories before answering).

YES__ NO__

4. If the answer to question 3 is YES, do you intend to return the product to the John Doe Company as requested?

YES__ NO__

5. If the answer to question 4 is NO, please explain your intentions

6. Have you received any reports of illness or injury related to this product?

YES ____ NO ____

If yes, please provide details.

Name of person completing questionnaire:

Exhibit 7-3 Model Effectiveness Check Questionnaire for Telephone or Personal Visits (Industry)

Consignee Name and Address

(Pressure Sensitive Label)

JOHN DOE PRODUCT RECALL

After contacting the consignee and locating the person responsible for handling recall notifications and/or the product involved, an opening similar to the following may be used.

This is (Name of Interviewer). I am calling for (recalling firm) to check on the effectiveness of the company recall of (product description, including codes). On (date), (recalling firm) notified (how: letter, telephone, visit, mailgram, etc.), all firms which may have purchased (product) that all stock should be (returned, destroyed, modified, relabeled, etc.). I have the following questions to ask you about this recall:

DATE _____

1. Did your firm receive notification that (product name) products manufactured by John Doe Company are being recalled?

YES__ NO__

2. Did your firm receive shipments of the product being recalled?
(If no, terminate questioning and go to the closing).

YES__ NO__

3. Do you have any of the recalled product on hand?
(Please check inventories before answering).

YES__ NO__

4. If the answer to question 3 is YES, do you intend to return the product to the John Doe Company as requested?

YES__ NO__

5. If the answer to question 4 is NO, please explain your intentions.

6. Have you received any reports of illness or injury related to this product?

YES___ NO___

If yes, please provide details.

Thank you for your cooperation.

And your name is _____

And what is your title please? _____

Interviewer _____

Date _____

IF RESPONDENT HAS ANY FURTHER QUESTIONS, ASK HIM/HER TO CONTACT
THE JOHN DOE COMPANY, SOMEPLACE, SOMEWHERE 12345

Exhibit 7-4 Model Recall Letter (Generic, All Centers)

Company Letterhead

Date (Month, Day, Year)

URGENT

[Insert FOOD, DRUG, MEDICAL DEVICE, BIOLOGIC, COSMETIC, TOBACCO]

RECALL

[]

Contact Name or Department

Firm Name

Street Address

City, State, Zip Code

Dear [Insert Customer/Distributor/Manufacturer, etc.], This is to inform you of a product recall involving

[Insert: **PRODUCT NAME, BRAND NAME, DESCRIPTIONS, UPC CODES, LOT NUMBERS AND ETC.**]

See enclosed product label [for ease in identifying the product at retail/user level].

This recall has been identified due to [problem]. Use of [or consumption of] this product may [include any potential health hazard].

We began shipping this product on [date]. Use of [or consumption of] this product may [include any potential health hazard].

Immediately examine your inventory and quarantine product subject to recall. In addition, if you may have further distributed this product, please identify your customers and notify them at once of this product recall. Your notification to your customers may be enhanced by including a copy of this recall notification letter, or [Enclosed is a letter you should use in notifying your customers].

[Your notification must include instructions on what customers should do with the recalled product.]

This recall should be carried out to the [wholesale], [retail], [consumer], [user] level.

Your assistance is appreciated and necessary to prevent [i.e. consumer illness or patient harm].

Please complete and return the enclosed response form as soon as possible. If you have any questions, call [name and telephone number].

This recall is being made with the knowledge of the Food and Drug Administration.

Enclosures:

Name: (Print)

Signature:

Title:

Exhibit 7-5 Model Recall Return Response Form

[COMPANY LETTER HEAD]

Insert [Product] Insert [Lot numbers]

Please check ALL appropriate boxes.

☐ I have read and understand the recall instructions provided in the [date of] letter.☐ I have checked my stock and have quarantined inventory consisting of [] units or cases.☐ Indicate disposition of recalled product:

- ☐ returned (specify quantity, date and method)/held for return;
- ☐ destroyed (specify quantity, date and method);
- ☐ relabeled (specify quantity and date);
- ☐ quarantined pending correction (**specify quantity**);
- ☐ transfused - Blood or blood products (**specify quantity and date**);
- ☐ implanted (specify quantity and date)

Attached is a list of customers who received/ may have received this product. Please notify my customers.

Any adverse events associated with recalled/failed product? ☐ Yes ☐ No

If yes, please explain: _____

I have checked my stock and have performed the appropriate method of disposition to the inventory consisting of _____ [units, cases, etc.].

Please check the appropriate box(es) to describe the nature of your business:

☐ Wholesaler/distributor	☐ Food service/restaurant
☐ Grocery corporate headquarters	☐ Manufacturer
☐ Repacker	☐ Hospital/Medical facility
☐ Pharmacy-retail	☐ Medical laboratory
☐ Hospital pharmacies	
☐ Retailer	
☐ Other: _____	

Name/Title	
Telephone	
Email address	

Firm Name	
Address	
City/State	

PLEASE FAX COMPLETED RESPONSE FORM TO Tel. # [INSERT TELEPHONE NUMBER], ATTN: [INSERT NAME] OR MAIL TO: [INSERT FIRM NAME AND ADDRESS]

NOTE: This MODEL is intended to serve as guidance for recalling firms. It may not conform to your firm's recall strategy. Please make any appropriate modifications to the response form. IT IS ADVISABLE TO SUBMIT THE PROPOSED RECALL LETTER AND RESPONSE FORM TO YOUR LOCAL FDA RECALL COORDINATOR FOR REVIEW, PRIOR TO ISSUANCE.

Exhibit 7-6 Model Recall Envelope

FIRST CLASS MAIL

JOHN DOE
Somewhere, U.S.A. 12345

A. B. C. Pharmacy
Anywhere, U. S. A.

(red print) **URGENT: DRUG RECALL**

Exhibit 7-7 Model FDA Requested Recall Letter**FDA REQUESTED RECALL**

Responsible Official
Company
Address

Dear Responsible Official,

The U.S. Food and Drug Administration (FDA) requests that, in the interest of public health, you immediately initiate a recall of all [Product Name and Codes]. This request is based on [Evidence supporting violation].

[Products] that are produced at [Firm] are [adulterated/misbranded] within the meaning of section [Act/Regulation violation(s)].

During [inspection/sample] of your [facility/product] FDA investigators observed the following:

- [Inspectional Observations and support OR Sample Findings]

[If the firm has provided correspondence regarding the violation/observations/sample findings include acknowledgement of receipt and assessment of the firm's correspondence]

FDA has determined that due to [violation], these product(s) present a risk of illness or injury to consumers. To date, your firm has failed to initiate a recall of [products and codes]. FDA action is necessary to protect the public health and welfare.

FDA will classify this FDA Requested action as a [recall classification] recall. A [recall classification] recall is a situation in which [For Class I use: "a situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death" For Class II use: "use of or exposure to a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote"]. FDA recommends [Effectiveness Check Level and percent] effectiveness checks be performed to the [depth: user/retail] level.

FDA's recall policy and guidance is found in Title 21 Code of Federal Regulations (CFR), Part 7. [FDA Division Office] will provide guidance in implementing and assuring the effectiveness of your recall, including reviewing the proposed recall communication to your consignees. We are requesting that you work closely with the division and that you provide all necessary information regarding the recall in a timely manner. Title 21

CFR, Part 7 provides for, among other things, publishing your recall in an upcoming issue of the weekly FDA Enforcement Report.

Please respond to this letter within two working days of receipt. Your response to this letter should be directed to:

[Division Director Name and Address]

Due to the seriousness of this situation, FDA will issue a press release [date the PR will issue], advising consumers of the FDA Requested Recall letter and again warning consumers and retailers to discontinue use or sale of these products and of the health risk associated with the use of these products.

Failure to comply with this request may result in further regulatory action against you, your firm, and the adulterated products distributed by your firm.

Sincerely,

[ACRA Name]
Associate Commissioner for Regulatory Affairs

Exhibit 7-8 Model Acknowledgement (to be used when RES automated email request cannot be used due to the RES not functioning or the firm not having an email address)

Firm Recall Contact
Title
Company
Address

Dear (Firm Recall Contact):

This is to acknowledge your initial report of a removal or correction of (general product information). The Food and Drug Administration (FDA) will review information submitted by your firm and determine whether your action meets the definition of a recall ([21 CFR 7.3\(g\)](#)).

Your action has been assigned event number (insert RES number). Refer to this event number when corresponding with FDA.

FDA Recall Guidance and Policy can be found in [21 CFR 7](#) and recall resources can be found on the [FDA.gov website](#).

Industry Resources

- [Industry Guidance: Information on Recalls of FDA Regulated Products](#)
- [Public Warning and Notification of Recalls Under 21 CFR Part 7, Subpart C Guidance for Industry and FDA Staff](#)
- [Guidance for Industry: Product Recalls, Including Removals and Corrections](#)
- [Industry Notices and Guidance Documents](#)

If your action meets the definition of a recall ([21 CFR 7.3\(g\)](#)), it will be listed in the [FDA Enforcement Report](#). Note that for some recalls, FDA may first determine the action meets the definition of a recall and then classify ([21 CFR 7.3\(m\)](#)) and update the [Enforcement Report](#) with the classification. You will be notified in writing of FDA's recall determination and classification.

FDA requests the following:

Work with your Division Recall Coordinator to develop your recall strategy and to submit documentation for your recall.

Monitor the progress of your recall, including conducting [effectiveness checks](#). Such checks are for the purpose of verifying that the recalling firm's consignees have received notification about the recall and have taken appropriate action.

Submit periodic recall status reports per ([21 CFR 7.53](#)) to your FDA recall contact. Your firm's first status report is expected to be submitted within a month, and at monthly intervals thereafter unless otherwise requested by your FDA contact. The recall status reports should contain the following information:

1. Number of consignees notified of the recall, and date and method of notification.
2. Number of consignees responding to the recall communication and quantity of products on hand at the time it was received.
3. Number of consignees that did not respond (if needed, the identity of nonresponding consignees may be requested by the Food and Drug Administration).
4. Number of products returned or corrected by each consignee contacted and the quantity of products accounted for.
5. Number and results of [effectiveness checks](#) that were made.
6. Estimated time frame for completion of the recall. If the recall is complete, provide the date of completion

In addition, we may request the following prior to terminating this recall:

- Root cause of the recall.
- Corrective actions taken to prevent similar problems in the future.
- The final disposition of recalled products. If applicable, include a Destruction Memo or Certificate of Destruction containing the date, quantity, and method of destruction.

Prior to destroying or reconditioning returned product, notify your FDA recall contact. FDA may want to witness the products destruction or review proposed reconditioning. Please assure that all returned product is promptly inventoried, handled, and stored in such a manner as to assure its separation from acceptable materials so it will not be inadvertently used or shipped.

Submit a written request for recall termination to your FDA recall contact once all reasonable efforts have been made to remove or correct the product in accordance with the recall strategy, and when it is reasonable to assume that the product subject to the recall has been removed and proper disposition or correction has been made commensurate with the degree of hazard of the recalled product. FDA will notify you in writing when we concur with your termination request.

In the event FDA is not able to assess the progress and effectiveness of the recall, and consistent with our public health responsibilities, FDA may take further action, as appropriate, to remedy the underlying violation to address a product found to be in violation of the law, including, but not limited to, public warning to consumers, health practitioners, etc., seizure, or injunction.

Please address all correspondence for this event to (Division Recall Inbox or physical address).

FDA will remain in contact with your firm until this matter is resolved.

Sincerely,

Division Recall Coordinator
(Insert Division)

Exhibit 7-9 Model Notification of Classification Letter (FDA to Recalling Firm)

Mr. John Doe,
President J. D. Laboratories, Inc.
Somewhere, U. S. A.

Re: Recall No. D-000-9

Dear Mr. Doe:

We agree with your firm's decision to recall (Product), Code Nos. _____ due to (Reason for Recall).

We have reviewed your action and conclude that it meets the formal definition of a "Recall." This is significant, as your action is an alternative to a Food and Drug Administration legal action to remove your defective product from the market. This recall will be reported in an upcoming issue of the weekly FDA Enforcement Report.

It is suggested that you follow the FDA's "Enforcement Policy-Recalls (including Product Corrections) -- Guidelines on Policy, Procedures and Industry Responsibilities" in conducting your recall. Enclosed is a copy of this Enforcement Policy as well as a copy of the FDA's "Methods for Conducting Recall Effectiveness Checks."

This recall has been classified by the FDA as a Class _____ recall. This means (Insert Definition).

Our judgment regarding the effectiveness of your recall will largely be based upon your implementation of the enclosed recall guidelines. Please be advised that failure to conduct an effective recall could result in seizure of the violative product or other legal sanctions under the Federal Food, Drug, and Cosmetic Act (or other acts as appropriate).

Your cooperation in this matter is important for the protection of the general public.

Sincerely yours,

Program Division Director

_____Program

Enclosures

Exhibit 7-10 Model Recall Ineffective Recall Letter

Mr. John Doe, President
J. D. Laboratories, Inc.
Somewhere, U.S.A.

Dear Mr. Doe:

This confirms our telephone conversation/visit with you that our audit of your firm's class _____ recall of (Product) indicates that the recall is ineffective at the (Distributor, Wholesale, Retail, etc.) level. This determination is based on the fact that: (detail all audit findings, for example):

1. Review of your submitted recall status reports found that (number and type of consignees) have not responded to your recall communication.
2. Review of documentation at your firm found that sub-recall was not initiated by (number) wholesale distributors.
3. Audit checks conducted by FDA found that [explain].
4. Other [explain]:

It is therefore reasonable to assume that the defective product could still be in the hands of these consignees.

It is requested that you advise us in (*) days of the steps you plan to take to rectify this situation.

- (*) Two days for class I
 Five days for class II
 Ten days for class III

Sincerely,

Program Division Director

_____Program

Exhibit 7-11 Model Recall Termination Letter

Mr. John Doe, President
J. D. Laboratories, Inc.
Somewhere, U.S.A.

Dear Mr. Doe:

The Food and Drug Administration has completed the audit of your firm's actions concerning the recall of (Product), (Code Number) (s), (Recall No.)(s). We conclude that the recall has been completed and there has been proper disposition of the recalled articles. Therefore, FDA considers the recall terminated.

This letter is not intended to imply that the FDA will not recommend civil or criminal legal action related to this matter. It does not relieve you or your firm from the responsibility of taking all necessary steps to assure compliance with the Federal Food, Drug, and Cosmetic Act (or other acts as appropriate) in the future.

Sincerely,

Program Division Director

_____Program

Exhibit 7-12 Model Combined Recall Notification of Classification and Termination Letter

Re: Recall No. Z-000-5

Mr. John Doe
President
John Doe Enterprises, Inc.
4321 Enterprise Lane
Johnsontown, New York 12345-6789

Dear Mr. Doe:

This is to advise you that the Food and Drug Administration (FDA) agrees with your decision to (retrieve from the market to the retail, user, hospital, consumer, etc. level, or conduct a field correction of) (product), lot/code numbers due to (reason for action taken).

We have reviewed your action and conclude that it meets the FDA definition of a Class (I, II, or III) recall. This is a situation in which (quote appropriate classification definition from section 7.3(m) of Title 21 CFR). This recall has been posted on the FDA's recall web site. (When appropriate, a statement on the Center's suggested effectiveness check level and the firm's satisfactory completion of same may be added at this point.)

Information provided to FDA indicates that (the recall has been completed and there has been proper disposition of the recalled product, or your corrective action has been completed). Therefore, FDA considers the recall terminated.

This letter is not intended to imply that the FDA will not recommend civil or criminal legal action related to this matter. It does not relieve you or your firm from the responsibility of taking all necessary steps to assure compliance with the Federal Food, Drug, and Cosmetic Act (or other acts as appropriate) in the future.

Sincerely,

Program Division Director

_____Program

-Press Release

Exhibit 7-13 Model Recall Audit Check Memo Assignment

Date [Insert Date of Assignment]

From [Name, Title, and Division of Monitoring Division Recall Coordinator]

Subject Request to Conduct Audit Checks, Probable [Class I/II]

To Attention: Recall Coordinator: List Divisions Receiving Assignment

RES Event: [RES Event ID]

PAC: [PAC code for recall audit check]

Recalling Firm: [Recalling Firm name, address, and FEI]

1. Product/Codes(s): [List the names and coding for the recalled products]
2. Reason for Recall: [Include a short reason for recall]
3. Firm's Recall Strategy: [Detail the firm's recall strategy and include the recall notification instructions]
4. Audit Checks: [Discuss the FDA audit check strategy, including how many you are requesting, the type of audit checks, depth to which audit checks should be conducted, and any additional instructions. For example: "Please audit each of the attached consignees by visit. If the product was further distributed, please conduct checks at three subaccounts by visit or phone to the consumer level. Please return all 3177s electronically to (monitoring division email address). This audit check assignment is due on (10 days from issuance)."]
5. Attachments:
 - RES Event
 - Recall Notification Letter
 - Labeling
 - Distribution List

Exhibit 7-14 Initiating RAC by Mail or Email

The following script may be included in the RAC assignment memo when requesting divisions to initiate recall audit checks by mail or e-mail. The audit check itself should be done on the phone, but the mail/e-mail is to initiate contact between the consumer and FDA in a way that best protects the consumer's privacy.

Only complete FDA-3177s for the mail/e-mails which result in an audit check, not those that were sent and never responded to.

Dear Consumer,

We are writing to inform you of a voluntary recall of FDA-regulated products initiated in [Month, Year of recall initiation]. The firm may have sent you a recall notice via e-mail on or around [recall initiation date] and you may be affected by this recall.

The products are being recalled because they may be misbranded, adulterated, or contain unapproved new drug claims which have not been approved by the U.S. Food and Drug Administration.

We hope to verify your awareness of the product recall and to ensure no adverse experiences have occurred.

It is important you contact us at the [Name of Division performing the RAC] of the U.S. Food and Drug Administration.

Please call me back at my contact information.

Your full name

Title and Division Name

Contact Information

If you would like to verify this email is from the FDA and our contact information, please go to the FDA.gov website at this link <https://www.fda.gov/AboutFDA/ContactFDA/default.htm>, Find an FDA Staff Member (Search the HHS employee directory), click on the last name, call the number and ask to speak with the person listed above.

Exhibit 7-15 Weekly Class I Recall Status Report (Optional)

Divisions monitoring certain Class I certain recalls may be requested to submit a weekly status report by either the CRU or OSPOP /DE/ROB. (Weekly status reports may also be required for certain Class II recalls per the audit strategy.) When reports are requested, they should be prepared and submitted by close-of- business each Friday.

Data to be submitted may vary depending upon individual recall circumstances, but should usually contain the following points:

Subject: Status Report, Class I (or II), Recall No. _____

Product: Recalling Firm:

I. Summary of Firm's Activities

1. Number and type of consignees notified, date and method of notification.
2. Number of consignees responding to the recall communication.
3. Number of consignees not responding.
4. Number and results of effectiveness checks made.
5. Significant problems firm is experiencing in the recall.
6. Any additional steps the firm is taking to complete the recall.

II. Summary of FDA's Audit Activities

1. Date and No. of audit checks assigned.
2. Number of audit checks completed.
3. Number of audit checks finding the recall effective.
 - a. Direct Accounts
 - b. Sub-accounts
4. Number of audit checks finding the recall ineffective.
 - a. Direct Accounts
 - b. Sub-accounts
5. Significant problems encountered during the checks.

Provide any additional information pertinent to Center and OSPOP /DE/ROB evaluation of the recall's progress or effectiveness.

Exhibit 7-16 Recall Status Report Request Letter (to be used when RES automated email request cannot be used due to the RES not functioning or the firm not having an email address)

Firm Recall Contact

Title

Company

Address

Dear (Firm Recall Contact):

We are making this request because you have not sent a status report for your recall or you have not sent a status report within the requested frequency. Please send a recall status update per ([21 CFR 7.53](#)), with the following information:

1. Number of consignees notified of the recall, and date and method of notification.
2. Number of consignees responding to the recall communication and quantity of products on hand at the time it was received.
3. Number of consignees that did not respond (if needed, the identity of nonresponding consignees may be requested by the Food and Drug Administration).
4. Number of products returned or corrected by each consignee contacted and the quantity of products accounted for.
5. Number and results of [effectiveness checks](#) that were made. Such checks are for the purpose of verifying that the recalling firm's consignees have received notification about the recall and have taken appropriate action.
6. Estimated time frame for completion of the recall. If the recall is complete, provide the date of completion.

In addition, we may request the following prior to terminating this recall:

- Root cause of the recall.
- Corrective actions taken to prevent similar problems in the future.
- The final disposition of recalled products. If applicable, include a Destruction Memo or Certificate of Destruction containing the date, quantity, and method of destruction.

Prior to destroying or reconditioning affected product (returned or remaining on hand), notify your FDA recall contact. FDA may want to witness the products destruction or review proposed reconditioning. Please assure that all returned product is promptly inventoried, handled, and stored in such a manner as to assure its separation from acceptable materials so it will not be inadvertently used or shipped.

These status reports are expected to be submitted monthly, unless otherwise requested, to (Division Recall Inbox or physical address). Recall status reports are to be discontinued when the recall is terminated by the Food and Drug Administration.

In the event FDA is not able to assess the progress and effectiveness of the recall, and consistent with our public health responsibilities, FDA may take further action, as appropriate, to remedy the underlying violation to address a product found to be in violation of the law, including, but not limited to, public warning to consumers, health practitioners, etc., seizure, administrative detention, or injunction.

Sincerely,

Division Recall Coordinator
(Insert Division)

Exhibit 7-17 Model Reconditioning Proposal Template (FDA to Recalling Firm)

Firm Recall Contact

Title

Company

Address

Email address

Dear (Firm Recall Contact),

Your firm's reconditioning proposal should be submitted in writing to [insert division email address]. RES Number [XXXXX] should be referenced in the email subject line and in all correspondence related to this recall and reconditioning request. We will notify you in writing of FDA's decision regarding your firm's reconditioning proposal. Your proposal should include the following so that CFSAN can conduct their evaluation. All proposed reconditioning methods should be approved prior to implementation, and all products should be held intact until release is authorized.

Reconditioning Proposal Submitter name:

Contact (name and title)

Address

Phone

Email

Manufacturer and/or Importer of Record of the original product:

Contact (name and title)

Address

Phone

Email

Please provide the original product information. This should include the lot numbers, original intended use statement, original label.

Please provide the original violation. This should explain the background on the recall (or seizure) and the reason(s) the articles are considered adulterated for their originally intended food uses. Provide documentation of the levels, on a lot-by-lot basis, of any adulterant that may be present (e.g. lab report, lab worksheet). Also include the methodology used to determine the levels of the adulterant and the root cause if known.

Please provide detailed process to be used for reconditioning and how the product will be brought into compliance:

- What method will be used to recondition the affected product? How the product will be brought into compliance by reconditioning? Please provide detailed description.

- Where is the product currently on hold? Please provide firm name and address.
- Where will the reconditioning take place? Provide firm name and address.
- Who will perform the reconditioning?
- Will you assign the new lot number to the recondition product? Please provide the new lot number.
- **Product re-labeling method:**
 - If you are planning to bring the product into compliance by correcting the label, provide a copy of the original product labeling and proposed corrected labeling.
 - If you are planning to add a labeling sticker, provide a photo of the full product packaging with the new sticker and a detailed description of how the sticker will be affixed.
- **Additional guidance on other proposed methods:**
 - Describe each step of the reconditioning process, including all critical factors of the process parameters and pertinent Standard Operating Procedures (SOPs).
 - Include photos, diagrams, and flow charts, as appropriate, to assist in visualizing the specific reconditioning process
 - When necessary, provide literature that demonstrates the efficacy of proposed reconditioning process, particularly for a new process or an established process applied to a different food or with different parameters.
 - If applicable, provide sample collection protocols, including conditions/methods for storing and transporting article susceptible to spoilage.
 - Provide records or a description of the records that will be developed to demonstrate that the reconditioning process or operations were performed.
 - For products subject to HACCP regulations (juice and [Fish and Fishery Products](#)), a copy of the HACCP plan or food safety plan to be implemented.
 - For products which require specialized human testing or review (such as organoleptic testing), provide the CVs and qualifications of the individuals performing the testing.
 - For products with components subject to certification, such as color additives, provide certification information when the problem is related to the certification.
 - Any other documentations to support your proposal.

Describe how you will evaluate the reconditioning to determine if has been successful:

- Provide the laboratory name and address that will perform the testing.
- If testing, provide the methodology to be used and if the method has been validated. If the method has not been validated, provide confirmation of the method's reliability (e.g., spike positive control).
- Provide your post-process sample protocol. This should include a detailed sampling plan, including the location and number of samples that will be collected, schematics showing how the firm intends to sample the reconditioned product,

procedures to prevent recontamination of the product, and entity that will collect the samples.

Describe your product disposition plan if the reconditioning proposal is not approved:

- Describe how you will segregate and dispose of any rejected portions of the lot if the reconditioning is not approved or not successful. FDA may want to witness the product destruction.
- If you want to divert adulterated food to acceptable animal feed use, please submit a Diversion Proposal and include the requested information by CVM per the [Compliance Policy Guide \(CPG\) Section 675.200 Diversion of Adulterated Food to Acceptable Animal Feed](#)

Please assure that all affected product is promptly inventoried, handled, and stored in such a manner as to assure its separation from acceptable product so it will not be inadvertently used or shipped.

Following the reconditioning effort, FDA may collect and test reconditioned samples at our discretion. Please notify [insert division email address] upon completion of your reconditioning and submit the post-process sample test report.

Sincerely,

Division Recall Coordinator
(Insert Division)

Exhibit 7-18 Market Withdrawal Designation Template

Firm Recall Contact

Title

Company

Address

Email Subject: RES [#####] - Recalling Firm - Market Withdrawal Designation

Dear (Firm Recall Contact):

We have reviewed your firm's action regarding the [product(s)], [code(s)], [reason for removal or correction]. Based on the information provided, we conclude that your firm's action meets the definition of a Market Withdrawal. Per 21 CFR 7.3(j), Market Withdrawal means a firm's removal or correction of a distributed product which involves a minor violation that would not be subject to legal action by the Food and Drug Administration (FDA) or which involves no violation.

At this time, the FDA is requesting no additional communication from your firm related to this product action.

Sincerely,

Division Recall Coordinator
(Insert Division)

Exhibit 7-19 Market Withdrawal Designation – Additional Information Requested

Firm Recall Contact

Title

Company

Address

Email Subject: RES [#####] - Recalling Firm - Market Withdrawal Designation –
Additional Information Requested

Dear (Firm Recall Contact):

We have reviewed your actions regarding the [product(s)], [code(s)], [reason for removal or correction]. Based on the information provided, we conclude that your firm's action meets the definition of a Market Withdrawal. Per 21 CFR 7.3(j), Market Withdrawal means a firm's removal or correction of a distributed product which involves a minor violation that would not be subject to legal action by the Food and Drug Administration (FDA) or which involves no violation.

We request that you provide the following so we can continue to monitor this action.

[list requested information]

Please address all correspondence for this action to [division recall inbox]. Please reference RES# [#####] in all correspondence to FDA related to this action.

FDA will remain in contact with your firm until this matter is resolved.

Sincerely,

Division Recall Coordinator

(Insert Division)

Exhibit 7-20 Market Withdrawal Close Out to be Used when additional information was requested

Firm Recall Contact

Title

Company

Address

Email Subject: RES [#####] - Recalling Firm - Market Withdrawal Closeout

Dear (Firm Recall Contact):

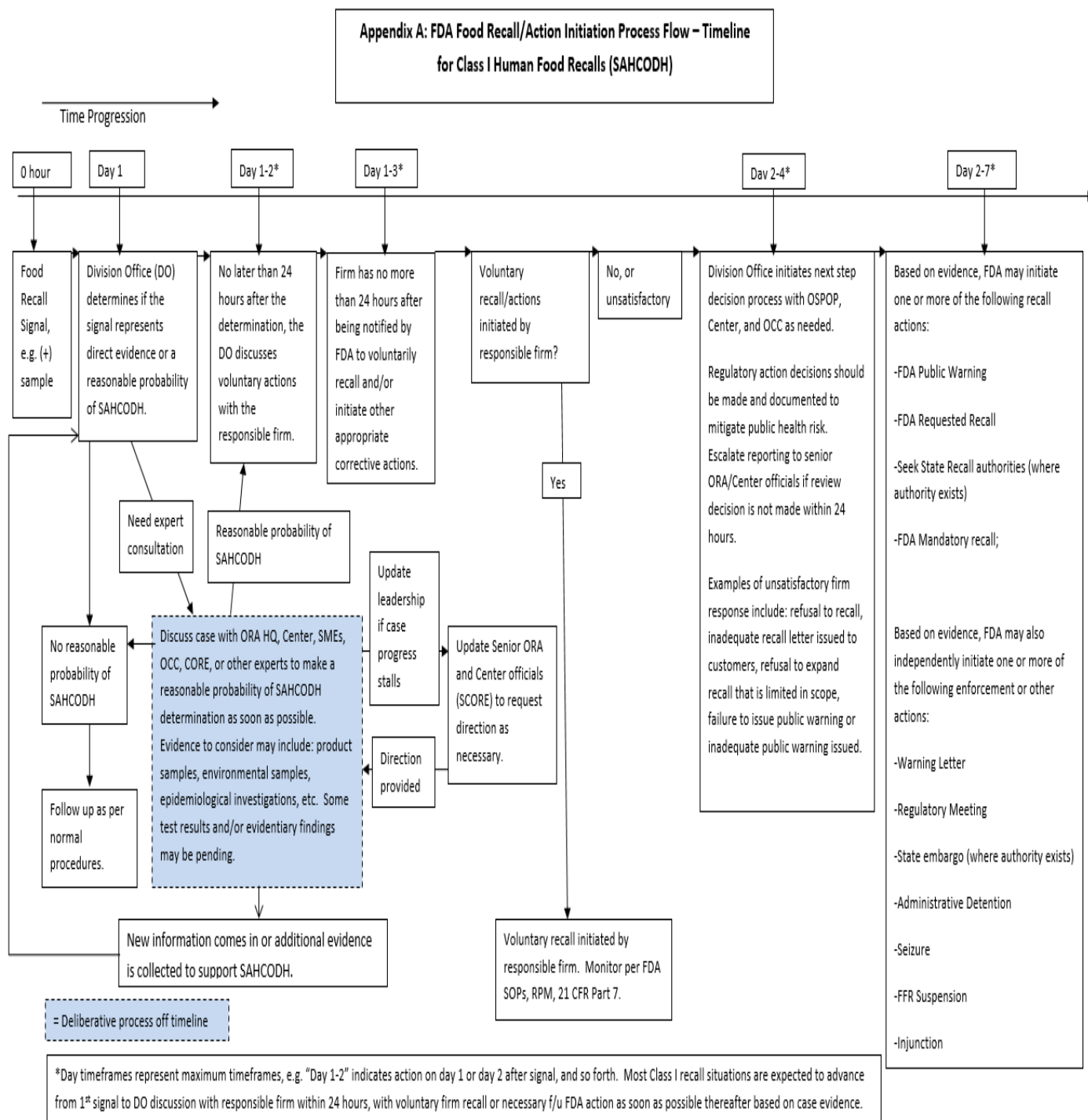
We have concluded our review of your firm's Market Withdrawal of [product(s)], [code(s)], [reason for removal or correction]. At this time, the FDA is requesting no additional communication from your firm related to this product action.

Sincerely,

Division Recall Coordinator

(Insert Division)

Appendix A FDA Food Recall/Action Initiation Process Flow/Timeline for Class I Human Food Recalls (SAHCODH)



Regulatory Procedures Manual

JULY 2018

CHAPTER 8 – Emergency Procedures

This chapter contains the following sections.

Section	Topic	Page
8-1	PURPOSE	2
8-2	INTRODUCTION	2
8-2-1	Procedures	2
8-3	RESPONSIBILITY	4
8-3-1	General	4
8-3-2	Declaring an Emergency	4
8-4	NOTIFICATION OF EMERGENCIES: TERMINOLOGY	4
8-4-1	Alert	5
8-4-2	Presumptive	5
8-4-3	Confirmed	5
8-5	TERMINATION OF EMERGENCY INVESTIGATION	5
8-6	OPERATING PROCEDURE	6
8-6-1	24-Hour Communications System	6
8-6-2	Emergency Alerts	6
8-6-3	Investigational Instructions	7
8-6-4	Emergency Management	7
8-6-5	Reporting	9
8-7	HEADQUARTERS OPERATING PROCEDURES	11
8-7-1	FDA Emergency Operations Center	11
8-7-2	Center Emergency Coordination Units	13
8-7-3	Office of Regulatory Affairs	13
8-7-4	Office of Partnerships (OP)	14
8-8	INTERAGENCY COORDINATION	15
8-8-1	Agencies FDA Cooperates With In Emergency Situations	15
8-8-2	Federal Agency Checklist	15

8-8-3 State and Local Agency Checklist.....	17
8-9 PRESS RELATIONS.....	17
8-9-1 Notification of the Office of Media Affairs (OMA).....	17
8-10 REFERENCES.....	18
8-10-1 General references.....	18
8-10-2 Specific references	18
8-11 Attachment A - Guidelines for Follow-up of Tampering	19

All questions pertaining to this chapter should be directed to the FDA [Office of Emergency Operations Office of Emergency Operations](#) (OEO), [Office of Emergency Management, Emergency Operations Center](#) (EOC), 866-300-4374 (24-hour number). See [SMG 1117.621](#) for more information on OEO.

FDA's Emergency Operations Plan is the detailed document that should be followed in an emergency. See [Emergency Preparedness > Emergency Response](#) on FDA.gov.

8-1 PURPOSE

To set forth emergency management procedures for the FDA's headquarters and personnel resulting from [Executive Order 12656](#), various Presidential Decision Documents, the [Stafford Disaster Relief and Emergency Assistance Act](#), and the [National Response Framework](#).

8-2 INTRODUCTION

8-2-1 Procedures

These procedures provide guidance for the Agency to act immediately to protect the public from contaminated or defective FDA-regulated products or in situations when FDA-regulated products need to be utilized or deployed. Prompt emergency actions are dependent upon the expeditious reporting and investigation of significant incidents or complaints relating to FDA-regulated products. Examples of such incidents include chemical and biological terrorism, chemical spills affecting food and animal feed supplies, natural disasters, radiological incidents, and food-borne illness outbreaks.

The emergency alert system, which is a part of this procedure, directs telephone notification to the [EOC, Office of Crisis Management, Office of the Commissioner](#). This alert system utilizes information from many internal FDA sources (e.g., systems to report consumer complaints, adverse reactions, product defects, radiological release, and other surveillance reporting systems). The EOC also receives information from outside sources, including other federal or state agencies, foreign health officials, industry and the press.

The FDA conducts response operations under the Incident Command System (ICS) of the [National Incident Management System Implementation](#). The EOC coordinates the FDA response to emergency situations by facilitating rapid and early information sharing as well as by providing real-time situational awareness to and from FDA headquarters, centers, and offices. The EOC is supported by a multi-level network of over 40 offices in FDA headquarters, centers, programs, and divisions.

A. Definition of Emergency

For the purpose of this procedure, the following definition of "emergency" shall apply:

An unforeseen occurrence or a combination of circumstances that poses a significant risk to public health, and that involves the safety, efficacy, and security of human and veterinary medicines, biological products, medical devices, food supply, cosmetics, products that emit radiation, or tobacco products, and that calls for immediate actions by FDA staff.

B. Scope of Incidents

This procedure was developed to provide guidance for planning, monitoring, coordinating, and directing FDA response to situations which include, but are not limited to:

1. National emergencies (e.g., civil disorders, major transportation and industrial strikes, acts of terrorism, refugee crises, etc.);
2. Natural disasters (e.g., hurricanes, floods, earthquakes, tornadoes, volcanic eruptions, etc.);
3. Man-made disasters (e.g., radiological incidents, chemical spills, toxic waste problems, air pollution problems, technological incidents and associated threats, etc.);
4. Injury and illness complaints or reports of tampering (e.g., foods, drugs, biologics, cosmetics, medical devices, and radiation emitting devices, veterinary products;
5. Epidemiological investigations (e.g., illness outbreaks associated with foodborne or other pathogens and adverse reactions, etc.); and,
6. Agency emergency preparedness (e.g., planning, development, implementation, and testing of emergency preparedness plans in response to attack).

C. Relationship to Recalls

Product recalls may occur during an emergency investigation; if so, procedures under Chapter 7 of the [Regulatory Procedures Manual](#) (RPM) should be followed as well. A recall that is for a defective product and that is progressing satisfactorily will not by itself activate this emergency procedure.

8-3 RESPONSIBILITY

8-3-1 General

Alerts to potential emergencies are nearly an everyday occurrence at FDA. The Agency's permanent organizational structure is designed, in part, to accommodate both large and small emergencies. In an emergency situation, it is important that individual assignments and responsibilities be consistent with normal functions and duties as outlined in unit functional statements and position descriptions.

The EOC is a focal point for the review of preliminary information about potential emergencies and the EOC assists in the early recognition of incidents, outbreaks and potential acts of terrorism. Primary responsibility for monitoring emergency alert information and coordinating investigations and scientific evaluations rests with the EOC. For any emergencies involving highly transmissible diseases such as Severe Acute Respiratory Syndrome (SARS), highly pathogenic avian influenza, West Nile Virus (WNV), malaria, etc., and for chemical, biological or radiological emergencies, staff should contact the EOC by email at Emergency.Operations@fda.hhs.gov or by phone at 866-300-4374.

8-3-2 Declaring an Emergency

This procedure includes mechanisms for monitoring investigations before making a determination that an emergency exists. It is expected that the involved centers and division offices will establish the coordination units discussed in this procedure during the course of an investigation as the situation warrants. In some instances, a formal declaration of an emergency may be required in order to activate the appropriate emergency coordinating units within the Agency. On other occasions, a formal declaration of an emergency may not be required because all coordination units are already functioning.

If there is disagreement among offices or if there is uncertainty regarding whether or not FDA should initiate emergency action under this procedure, the issue should immediately (by telephone) be referred to the Office of Crisis Management/EOC. See Chapter [8-6-3 Investigational Instructions](#). The Director, Office of Crisis Management along with the Associate Commissioner for Regulatory Affairs (ACRA) or designee, in consultation with ORA offices and the involved centers, will decide whether to implement the procedure and will notify the appropriate offices.

8-4 NOTIFICATION OF EMERGENCIES: TERMINOLOGY

The terms below (e.g., alert, case, suspect, preliminary, etc.) will be used in providing notification and describing the status of a sample analysis or the stage of an investigation. This consistent terminology can prevent confusion and misinterpretation in the identification and management of emergency situations.

8-4-1 Alert

Information without support: An alert should be made when the following type of information is received:

- A. An unconfirmed report of product related illness/injury or unanticipated adverse reaction;
- B. An unconfirmed report of the presence of a toxic (e.g., chemical, radioactive, or microbial) substance;
- C. A report of a man-made disaster (e.g., oil spill, radiological accident) or a natural disaster (e.g., hurricane, flood, tornado);
- D. Confirmation of a declaration of pandemic influenza (e.g., WHO Phases 4, 5, and 6; US Government Response Stages 2, 3, 4, and 5).

8-4-2 Presumptive

Information (analytical, inspectional, investigational, etc.) strongly suggests that a problem exists. Presumptive may be used to describe situations that include:

- A. Epidemiological data has provided a significant association between the illness, injury, or unanticipated adverse reactions and the product;
- B. An original analysis by a reliable laboratory has revealed a significant level of a toxic chemical, radioactive material, or microbial substance in a regulated product, but confirmation is not complete;
- C. An oil spill has drifted into fishing areas;
- D. A radiological incident has occurred and radioactive material has been released, but the extent is unknown;
- E. Floods have caused property damage in an area where regulated products are being held; or
- F. Confirmation of widespread outbreak of a novel strain of influenza in multiple locations overseas (e.g., WHO Phase 6; US Government Response Stage 3).

8-4-3 Confirmed

A problem has been confirmed through laboratory analyses, investigations, analysis of epidemiological data or a combination of these. Information received from another governmental agency or other source known to be reliable may be accepted for confirmation purposes. An example would be when the first human case of pandemic influenza in U.S. is confirmed (WHO Phase 6; US Government Response Stage 4).

8-5 TERMINATION OF EMERGENCY INVESTIGATION

When it is not possible to obtain information confirming that an emergency situation exists, emergency investigations may be terminated at the Alert

or the Presumptive stages. However, in all cases, the EOC will attempt to identify the source and scope of the problem, and the hazard involved.

The depth and extent of FDA activities, at the confirmation of an emergency situation, is based on factors such as:

- A. Interstate distribution of involved product, and,
- B. Other Federal, state, or local government efforts to control the problem.

When other Federal, state, or local agencies can deal more effectively with a problem, FDA will terminate its emergency investigation, at which time *ad hoc* emergency teams or units established under this procedure may be phased out by the EOC. The investigating agency should maintain contact with the EOC until a conclusion is reached. Likewise, following completion of an FDA emergency investigation, *ad hoc* emergency teams or units established under this procedure may be phased out after consultation with the EOC.

8-6 OPERATING PROCEDURE

8-6-1 24-Hour Communications System

Each program and division office will maintain a means by which headquarters can communicate emergency situations on a 24-hour, 7-days-a-week basis. Each designated contact, including an after hours phone number, should be identified to the EOC. Changes in contact points should be reported in a timely manner to the EOC. Each program and division will establish and maintain procedures for internal communications and will provide for appropriate liaison and notification systems to city, county, and state governments, and to local offices of Federal agencies.

8-6-2 Emergency Alerts

All reports of natural or man-made disasters and significant alleged or actual adverse effects associated with FDA-regulated products require prompt reporting to the EOC by phone, but e-mail, fax, text, or other available communication methods will be acceptable if telephones are not available. Confirmatory or summary reports may be forwarded by Email to Emergency.Operations@fda.hhs.gov.

- A. Report the nature and effect of the emergency including as much of the following information as is available:
 - 1. Product description, e.g., product name (proprietary and generic), dosage form (tablet, injectable, suspension, etc.), strength, expiration date, size and type of package, manufacturer, lot number, and product code;
 - 2. Probable or actual distribution pattern, e.g., state or nationwide;

3. Description of product-related illnesses or injuries, including symptoms, onset times, and duration; where applicable, include name, address, age, sex of affected parties, and identify hospital and medical personnel that are involved, including telephone numbers;
 4. Steps taken to coordinate FDA actions with state, local and other Federal officials; also, any independent actions taken by state and/or local officials; and
 5. Actions taken by firms to mitigate risk including corrective actions, recalls, public outreach or media coverage.
- B. In addition to the above, disasters related to fires, high winds, floods, wrecks, explosions, strikes, civil disorders, covert actions, pandemic influenza, radiological incidents, etc., also require the reporting of:
1. The magnitude of health hazards or other problems related to FDA activities; and
 2. The extent to which FDA facilities are or may be affected.

8-6-3 Investigational Instructions

Refer to [IOM](#), Chapter 8 — Investigations for detailed investigative procedures.

8-6-4 Emergency Management

A. Coordination with the EOC

The [EOC](#) will be the focal point for all emergency coordination between the division(s) involved, the center(s) involved, HQ offices, and other federal, state and local agencies. A member of the EOC staff will be designated to oversee each emergency situation. However, all EOC staff members are kept abreast of the situation and should be able to serve as a backup as necessary.

Other offices and agencies involved in an emergency situation will identify a contact for all communications.

B. Lead Office

As FDA conducts response operations under ICS, the office in which the emergency is occurring (e.g., where people are becoming ill or where a disaster has occurred) will assume the lead investigative role in determining the cause of the emergency, managing on-scene operations, and obtaining necessary information for the Agency to confirm the health hazard. This lead would generally be the division, but may be the program.

If it becomes apparent during the course of the investigation that a firm in another division is responsible for the product involved in the emergency, the lead division designation will be transferred to the home division of the responsible firm.

Any change in the designation of lead division should be concurred with by the EOC. In certain widespread emergencies involving more than one responsible firm, the EOC may assume the lead role without designation of a lead division.

The lead division will identify an ad hoc emergency management team to be headed by the division director or a designated division person and a coordinator. The exact number and mix of persons on the team will be determined by the division. Any recommendations for reallocation of staff between or among divisions during emergencies should be directed to the Office of Operations (OO).

C. Office Emergency Coordinator

A senior staff employee should be promptly named as coordinator of the emergency response activities. This person should generally be located at the lead division office to facilitate communication and review of records. In a widespread emergency, additional coordinators may be named by the involved division as necessary. The coordinator will be responsible for advising management of actions needed to follow-up on the emergency and for channeling all necessary communications.

D. Any or all of the following steps should be included:

1. Investigation/Analysis
2. Issuing assignments to division personnel to obtain the information necessary for Agency personnel to evaluate the health hazard of the situation;
3. Monitoring assignments to assure timely completion;
4. Arranging for continuing contact with investigators for flow of information;
5. Seeking technical guidance through the EOC relating to the investigation, samples needed, etc.;
6. Determining in consultation with the [Office of Regulatory Science](#), ORA the appropriate laboratory for submitting samples; and
7. Alerting that laboratory as soon as possible so that necessary preparations may be made.

E. Maintaining Communications

1. Keeping appropriate division and program management informed of investigational and analytical progress;
2. Preparing daily status reports;
3. Contacting the appropriate state and local authorities already involved with the investigation; and,

4. Serving as a local FDA press contact concerning the emergency, working with headquarters in preparing statements to the press.

NOTE: FDA employees may be asked by media or other outside organizations to respond to inquiries about ongoing investigations when the employees are not in a position to first seek guidance from the [Office of Media Affairs](#) (OMA). Such employees must assess these situations and the media requests on an individual basis and respond appropriately. When possible, media requests should be referred to first line supervisors or above. Unless specifically authorized to do so, only those employees whose position descriptions include communications with the press should provide statements to the press. See [8-9, Press Relations](#).

Care must be taken to ensure that timely, accurate, complete and authorized information is issued.

Significant emergency press coverage should be reported to the EOC promptly. The EOC will notify the Office of the Commissioner, [Office of Communications and Quality Program Management](#) (OCQPM), [Office of Partnerships](#) (OP), and other offices of the press coverage. Copies of local press releases by the state and/or the firm should be sent to EOC at Emergency.Operations@fda.hhs.gov as soon as possible.

F. Documentation

1. A chronology of the emergency situation should be kept, starting with the original alert. It should be updated frequently since this information is often needed on short notice by Agency or Department personnel.
2. Significant telephone conversations involving the emergency should be documented by the participants and forwarded to the EOC daily.
3. Statistical data such as numbers of samples analyzed, inspections made, injuries reported, farms quarantined, etc., should begin early in the process and should be maintained.

G. Command Post Location

The FDA lead division office facility should generally serve as the site of FDA's command post because of the available communications equipment. If the emergency is in a state without a well- equipped FDA office, consideration may be given to locating FDA's command post at the cooperating lead state agency.

8-6-5 Reporting

A. Status Report

During the height of an emergency, the division's emergency coordinator should forward daily status reports to the EOC by e-mail to Emergency.Operations@fda.hhs.gov, with a copy to the responsible

emergency coordination unit for the center(s). Copies of such reports should also be forwarded to the lead division(s) (see [8-6-3 Investigational Instructions](#)) by all investigating divisions. The EOC will specify when status reports are needed less frequently. Status reports should be in bullet format, highlighting significant information concerning the emergency (e.g., investigations, analyses, public affairs, cooperating agencies, scientific, and court matters).

The EOC will facilitate contact between divisions with the appropriate center coordinator.

B. Hard Copy Reports

The division's emergency coordinator should forward copies of all reports pertaining to the initial alert and subsequent investigation to the responsible center(s) and to the EOC. Each submission must include product name and product code to enable proper filing by the EOC. Copies of complaint reports, memos, collection reports, establishment inspection reports, reports of analyses, follow-up investigations, recommendations for regulatory action and recalls, when generated by an emergency, should be submitted. Unless a specific center office is identified to receive hard copy, hard copy reporting to the centers for emergencies is as follows:

1. Center for Food Safety and Applied Nutrition:

Center for Food Safety and Applied Nutrition
Office of Analytics and Outreach
Supervisor, Emergency Coordination and Response Team
5100 Paint Branch Parkway, Room 2B-014
College Park, MD 20740-3835

2. Center for Drug Evaluation and Research:

Counter-Terrorism & Emergency Coordination Staff (CTECS)
10001 New Hampshire Avenue, Room 2155
Silver Spring, MD 20993-1707

3. Center for Biologics Evaluation and Research:

Center for Biologics Evaluation and Research
Office of Compliance and Biologics Quality
Division of Inspections and Surveillance
10903 New Hampshire Avenue
Building 71, Room 5141
Silver Spring, MD 20993

4. Center for Devices and Radiological Health

For all reports:

Center for Devices and Radiological Health
Office of Compliance
10903 New Hampshire Avenue
Building 66, Room 2621
Silver Spring, MD 20993

For reports of incidents involving radiation or radioactive material releases:

Center for Devices and Radiological Health
Office of Communication, Education and Radiation Programs
Division of Mammography Quality and Radiation Programs
10903 New Hampshire Avenue
Building 66, Room 0609
Silver Spring, MD 20993

5. Center for Veterinary Medicine:

Center for Veterinary Medicine
Office of Compliance and Surveillance
Division of Compliance
Metro Park North 2, Building #4
7519 Standish Place
Rockville, MD 20855-7707

6. Center for Tobacco Products:

Center for Tobacco Products
Office of Compliance and Enforcement
Division of Enforcement and Manufacturing
10903 New Hampshire Avenue
Building 75, Room 7464
Silver Spring, MD 20993

7. Emergency Operations Center:

FDA Emergency Operations Center, OC/OCM
10903 New Hampshire Avenue
Building 32, Room 1359
Silver Spring, MD 20993

C. Final Reports

When the investigation of any emergency, (e.g., disaster, or civil disorder) has been terminated, the lead division will submit a final written summary to OC/OCM/EOC with a copy to the responsible center emergency coordination unit. This summary will be prepared using previous reports, records of meetings, chronologies, and reports from cooperating officials.

8-7 HEADQUARTERS OPERATING PROCEDURES

8-7-1 FDA Emergency Operations Center

The FDA [EOC](#) will monitor all emergency alerts/investigations and serve as the agency-wide and inter-agency focal point for 24-hour, 7-day communications concerning developing and active emergency situations.

A. Emergency Alerts

FDA headquarters units that receive initial emergency alerts from consumers and other sources outside FDA will report the information to the EOC. If potential danger to health is involved, the EOC will notify the affected program and district director(s) immediately at the telephone number listed in the “ORA Directory” in the [IOM](#). If an investigation is requested by another headquarters unit, the procedures established in [FMD 17, Field Assignment Issuances Guidelines for Headquarters Offices](#) allow requests to be issued directly to the action division or office with copies to the appropriate Program Director, ORA unit, and other center or office indicated. See also [8-4, Notification of Emergencies – Terminology](#).

B. EOC 24-Hour Telephone Contacts

After hours, or when the command center is not in operation, calls can be made to the 24-hour emergency number handled by the answering service. In the event that calls are designated as an emergency by the caller, the answering service will contact the late duty officer (LDO) or alternate LDO (ALDO) by cell phone or pager or both.

FDA Emergency Operations 24-hour telephone number is 866-300-4374.

C. Headquarters Coordination

The EOC will immediately advise the appropriate ORA offices, the center emergency coordination unit and ORA of significant emergency alerts or when any investigation reaches presumptive status. [OMA](#) will also be notified when public press coverage is ongoing or imminent. The [Office of Legislation](#) (OL) will be alerted when there is or may be congressional interest. The EOC will forward to OPOP copies of all reports from ORA offices pertaining to state and local activities, actions, and agreements; and any press releases issued, e.g., information required under [8-5, Termination of Emergency Investigation](#).

The EOC will prepare updated, periodic status reports on such alerts and investigations. These reports will be expedited to the Office of the Commissioner, the ACRA, and the ORA Office of Operations. Electronic mail will be used to distribute additional copies to other headquarters offices, responsible centers and to other appropriate units.

All reports required by the Department on disasters, civil disorders, or other emergencies will be prepared by the EOC for distribution within ORA Headquarters and the appropriate office within DHHS.

D. Interagency Liaison

The EOC will coordinate information concerning emergencies with headquarters offices of other Federal agencies in accordance with RPM Section [8-7, Interagency Coordination](#). When commerce with

Canada or Mexico is involved, coordination will be by the EOC in cooperation with the [Office of International Programs](#) (OIP). When other foreign governments are involved, the EOC will advise OIP so that office may establish and coordinate with the EOC the maintenance of communication channels.

8-7-2 Center Emergency Coordination Units

All centers will maintain an emergency coordination function that will serve as the focal point for intra-center communications with the EOC. Centers will be responsible for scientific evaluations and for policy decisions, in cooperation with ACRA, in their respective program areas. Centers will continue ongoing interagency liaison activities to the extent possible as emergency coordination with other agencies is managed pursuant to [8-7, Interagency Coordination](#).

Each center has identified the office listed in [8-6-5, Reporting](#), to serve as its coordination unit. These units facilitate any recall and case development activities that may be associated with an emergency.

A. Inter-Office Communications

Each center's emergency coordination unit will provide the EOC with a telephone number that will be the contact number for communications with the EOC during any stage of an emergency. The phone shall be suitable for conference calling.

B. After Hours Communication

Each center emergency coordination unit will provide the EOC with a call list that will provide 24-hour/7-days a week coverage. (A continuing effort will be made to evaluate various electronic communications systems to supplant the call lists.)

C. Reporting by Center and on-site emergency coordinators

Center emergency coordinators will maintain concise chronology of center activities similar to that which coordinators maintain (see [8-6-4, Emergency Management](#)). When the copy of the final report (see [8-6-5, Reporting](#)) is received from the lead division, the center will use its chronology during its review of the division report. The Center will then send any comments to the EOC before the EOC prepares a final report on the emergency.

8-7-3 Office of Regulatory Affairs

The [Office of Crisis Management/EOC](#) will serve as the focal point for emergency operations and communications within the [Office of the Commissioner](#). Any information received by ORA will be discussed as appropriate with the Office of Crisis Management, the Commissioner, the Deputy Commissioner for Operations, and with other Deputy Commissioners both during business and non-business hours.

This does not preclude the immediate reporting of significant emergency information to the Commissioner/Deputy Commissioner for Operations by

the Director of Office of Operations, the Center Directors, or the Director or Deputy Director, EOC.

D. Responsibility for Policy Statements

The [Office of Crisis Management](#) and the ACRA or the ACRA's designee, working with the responsible centers and ORA, will develop, issue, and approve any new or revised regulatory policy that is required by an emergency situation.

E. ORA Call List

The order in which EOC staff should call ORA personnel during non-business hours is:

1. [Associate Commissioner for Regulatory Affairs](#)
2. [Assistant Director for Management](#)
3. [Deputy Associate Commissioner for Regulatory Affairs](#)
4. [Director, Office of Enforcement and Import Operations](#)
5. [Director, Office of Partnerships and Operational Policy](#)

8-7-4 Office of Partnerships (OP)

The [Office of Partnerships](#) (OP), in cooperation with the programs or divisions, will coordinate Agency interaction with state and local agencies in emergency situations.

OP will maintain FDA's rapid communication system to state governments, major municipalities and poison control centers. OP will also continue the ORA OPOP/state association efforts to develop uniform emergency operational guidelines.

A. In emergency situations, OP will:

1. Ensure that the governors' offices have been notified of significant confirmed emergencies in their states;
2. Notify all states of confirmed emergencies involving two or more states.
3. Indicate potential or problem products entering commerce; and,
4. Prepare (or distribute) information requested by states for their emergency roles, and assure that states are fully advised as to what action the Agency can recommend to them under the circumstances of the specific emergency.

B. As routine functions, OPOP will:

Maintain a directory showing

1. the responsibilities of major state organizations;
2. names, telephone numbers, and addresses of key state personnel; and

3. other information needed to quickly enlist nation-wide state and local assistance to FDA's emergency operations.

8-8 INTERAGENCY COORDINATION

Liaison activities with responsible government agencies at the federal, state, and local levels must be effective during emergency situations to help ensure that resource allocations are efficient, that policy is understood, and that roles are well defined. Considering that federal agency responsibility varies from one emergency to another and that state and local government organizations differ from the federal model, the specific agencies that should cooperate in a given situation will depend on the problem and its location.

The EOC will coordinate all interagency liaison activities during emergencies and will establish communications with the headquarters office of the responsible federal agencies. The lead division will establish communications with offices of the responsible federal agencies. The EOC and the Division of Mammography Quality and Radiation Programs, CDRH, will share radiological emergency interagency liaison in accordance with attachment A.

Both the lead division and other investigating divisions will establish communications with responsible state agencies. State agencies often receive assistance from local agencies, universities, and other units in carrying out their responsibilities. Usually FDA will work through the state in coordinating efforts on the local level. Depending upon the state, it may be more appropriate for FDA division offices to work directly with such local units.

8-8-1 Agencies FDA Cooperates With In Emergency Situations

These agencies may be grouped under five broad areas of responsibility, as follows:

- A. Overall emergency management;
- B. Consumer products;
- C. The environment;
- D. Human health; and,
- E. Animal health.

8-8-2 Federal Agency Checklist

The following agencies and position titles should be considered for the appropriately relevant emergency:

- A. Overall Emergency Management

Federal Emergency Management Agency (FEMA)/Department of Homeland Security (DHS).

B. Consumer Products

1. Food Safety and Inspection Service (USDA/FSIS);
2. Consumer Product Safety Commission (CPSC);
3. National Oceanic and Atmosphere Administration (NOAA)
National Marine Fisheries Service (NOTE: The NOAA Seafood Inspection Program is often referred to as the U.S. Department of Commerce (USDC) Seafood Inspection Program and uses marks and documents bearing the USDC moniker);
4. Defense Logistics Agency (DLA);
5. Department of Defense (DOD);
6. Contract Compliance Service, Veterans Administration (VA);
7. Environmental Protection Agency (EPA), Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Products; and,
8. Federal Bureau of Investigation (FBI).
9. The Environment
10. Environmental Protection Agency (EPA);
11. National Oceanic and Atmospheric Administration (NOAA);
12. U.S. Coast Guard (USCG) (Oil Spills);
13. Nuclear Regulatory Commission (NRC);
14. Department of Energy (DOE); and,
15. Department of Transportation (DOT).

C. Human Health

1. Department of Health and Human Services – Secretary's Operations Center (SOC);
2. Centers for Disease Control and Prevention (CDC);
3. National Institutes of Health (NIH), National Institute of Environmental Health Sciences (NIEHS);
4. Occupational Safety & Health Administration (OSHA); and,
5. U.S. Department of Defense (DOD).

D. Animal Health

1. US Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS);
2. USDA National Animal Disease Laboratory (NADL);
3. US Department of the Interior, U.S. Fish & Wildlife Service; and,
4. Centers for Disease Control and Prevention (CDC).

8-8-3 State and Local Agency Checklist

- A. Overall Emergency Management
Governor's Office (or Governor's Designated Emergency Contact).
- B. Consumer Products
Appropriate state consumer protection counterpart.
- C. The Environment
Appropriate state environmental protection counterpart.
- D. Human Health
Appropriate state health counterpart.
- E. Animal Health
Appropriate state animal and agricultural counterpart.
- F. Agriculture
Appropriate state agricultural counterpart.

8-9 PRESS RELATIONS

The [Office of Media Affairs](#) (OMA) is responsible for issuing publicity and preparing answers to press inquiries about emergencies. OMA, in cooperation with the appropriate center and other Agency components, will:

- A. Prepare and approve all talk papers and press releases;
- B. Provide guidance to the lead and investigating divisions concerning the handling of local press inquiries;
- C. Notify the department of pending media coverage;
- D. Coordinate with the press operations of other agencies involved in an emergency;
- E. Counsel FDA management about necessary public statements; and
- F. Provide all Associated Press and United Press International wire copy about emergencies to EOC.

8-9-1 Notification of the Office of Media Affairs (OMA)

The OMA should be notified by any FDA unit that publicity has occurred relating to the emergency condition, as well as receipt of pending requests for information from the media or the public. The Director or any Deputy Director of OMA may communicate directly with the officials closest to the scene to ascertain what information needs to be released.

8-10 REFERENCES

8-10-1 General references

- A. FMD 17 – [Field Assignments from Headquarter Offices.](#)
- B. FMD 141 – [Infant and Toddler Products.](#)
- C. [IOM](#) CHAPTER 3 – Federal - State Cooperation [Subchapter 3.2 - Federal Agency Interaction](#)
- D. [IOM](#) CHAPTER 8 – Investigations
 - a. Subchapter 8.3 – [Investigation of Foodborne Outbreaks](#)
 - b. Subchapter 8.4 – [Investigation - Injury and Adverse Reactions.](#)
- E. Bovine Spongiform Encephalopathy (BSE) Response Plan, version 2.1, September 2002.
- F. FDA's Emergency Operations Plan (EOP) available on [Emergency Preparedness > Emergency Response](#) on FDA.gov. The current plan is FDA EOP, version 2.0, March 2014.

8-10-2 Specific references

- A. FMD 64 -- [Epidemiological Investigations Alert Reporting Procedures](#), June 1, 1995, revision.
- B. FMD 119 -- [Consumer Products Complaint System](#) March 5, 20122012 January 12, 1994, revision.
- C. FMD 141-- [Infant and Toddler Products](#), May 16,1995, revision.
- D. [Memorandum of Understanding between the Centers for Disease Control and the Food and Drug Administration](#), April 1, 1982.
- E. [MOU between the Centers for Disease Control and the Food and Drug Administration](#), 225-14-0017, 2014.
- F. [Multistate Foodborne Outbreak Investigations: Guidelines for Improving Coordination and Communication](#), National Food Safety System Project, Outbreak Coordination and Investigation Workgroup, February 2001.
- G. [Guide to Traceback of Fresh Fruits and Vegetables Implicated In Epidemiological Investigations](#), June 2006.
- H. [FDA's Coordinated Outbreak Response and Evaluation \(CORE\) Network.](#)
- I. [FDA Emergency Operations Plan](#), version 2.0, March 2014, Office of Crisis Management.
- J. [Office of Emergency Operations](#), [Office of Crisis Management](#), [Office of the Commissioner.](#)

8-11 Attachment A - Guidelines for Follow-up of Tampering

A. Introduction

The [Federal Anti-Tampering Act \(FATA\)](#) passed by Congress in 1983 makes it a Federal crime to tamper with certain consumer products and to commit certain other related acts. The Act provides specific statutory authority to the FDA to investigate tampering and alleged tampering of products that the agency regulates. There are five violations of the FATA:

1. Tampering, or attempted tampering, with a consumer product with reckless disregard for the risk of death or bodily injury.
2. Tainting a consumer product with intent to cause serious injury to the business of any person.
3. Knowingly communicating false information that a consumer product has been tainted.
4. Knowingly threatening to tamper with a consumer product.
5. Conspiracy to tamper with a consumer product.

A more detailed discussion of these violations can be found in the FATA (Title 18, United States Code, Section 1365).

B. Guidelines

1. The FDA [Emergency Operations Center](#) (EOC), 866-300-4374 (HFA-615), must be promptly alerted to all tampering/threat incidents. This is in addition to the prompt reporting of incidents outlined in the Emergency Procedures section of the RPM, Chapter 8.
2. Division and other ORA offices should immediately notify the appropriate Office of Criminal Investigations (OCI) office upon receiving information concerning a tampering/threat incident. This notification will enable the OCI office and the Division office to coordinate operations.
3. OCI offices have primary responsibility for liaison with law-enforcement agencies (i.e., FBI, state police, sheriff departments, and local police). In certain situations OCI may request ORA offices to maintain contact with and offer assistance to cooperating officials who investigate tampering incidents (i.e., FBI, USDA, state and local police, health department, coroner, and medical examiners).
4. The FBI expressed an interest in being notified in all tampering investigations involving extortion, serious injury or death, terrorism, and significant false reports. In all but critical circumstances such notifications will be done through the OCI office. In some situations the Division office may be asked by OCI to notify the FBI.

5. All requests for assistance from other law-enforcement agencies, including status briefings and notifications, regarding criminal investigations must be coordinated through OCI office.
 6. Complaints/reports concerning products subject to USDA regulations should be immediately referred to their local contact of USDA for their follow-up. The Division office should promptly notify the OCI office and EOC of all such referrals.
- C. When an alleged or suspected tampering incident is reported to FDA, the Agency must attempt to determine whether tampering has actually occurred or whether some other problem such as a manufacturing or distribution defect is involved. EOC and the centers are available to offer expert advice on possible manufacturing defects. The manufacturer can also provide information on defects. In addition, we should seek to determine where the tampering occurred (e.g., in the retail store, at the manufacturing site, etc.)
- D. The OCI office will have primary responsibility for all criminal investigations of tampering/threats incidents. In those incidents where OCI does not or cannot initiate a criminal investigation because of resource limitations, the Division offices must continue the investigation. Division offices must closely coordinate their efforts with OCI offices. In these special situations the Division office must keep the EOC and OCI office advised of their progress. Any referrals to law-enforcement agencies, other than OCI, may be made only after obtaining the concurrence of OCI office. The OCI Headquarters will provide details on tampering cases investigated by the OCI office to EOC for forwarding to the proper centers for their information and any action they may have to take.
- E. The Office of Chief Counsel/FDA (OCC) should be notified as soon as an FDA component determines that a case will be referred to a United States attorney in the following circumstances:
- F. Where there is a conspiracy.
- G. When an FDA regulated entity is included as a defendant.
- H. When Title 21 charges are contemplated.

In the absence of one of these three circumstances OCC need not be notified prior to referral to a United States attorney; however, OCC should be sent a copy of the charging document that is filed with the court.

Regulatory Procedures Manual

Chapter 9: IMPORT OPERATIONS AND ACTIONS

This chapter includes the following sections:

Section	Topic	Page
9-1	IMPORT PROCEDURES.....	6
9-1-1	SCOPE AND PURPOSE.....	6
9-1-2	DIVISION OF AUTHORITY	7
9-1-3	ENTRIES	8
9-1-4	SAMPLING	12
9-1-5	PROCEDURES WHEN VIOLATION IS FOUND FOR PRODUCTS THAT ARE NOT SUBJECT TO ADMINISTRATIVE DESTRUCTION.....	15
9-1-6	PAYMENT OF COSTS OF SUPERVISION OF RELABELING AND/OR OTHER ACTION	19
9-1-7	EXPORTATION OF MERCHANDISE REFUSED ADMISSION	20
9-1-8	BOND ACTION	20
9-2	COVERAGE OF PERSONAL IMPORTATIONS	21
9-2-1	PURPOSE.....	21
9-2-2	BACKGROUND	21
9-2-3	PERSONAL BAGGAGE.....	22
9-2-4	MAIL SHIPMENTS.....	22
9-2-5	GENERAL INSTRUCTIONS	23
9-3	“NOTICE OF FDA ACTION – DETAINED” FOR MAIL SHIPMENTS.....	25
9-3-1	PURPOSE.....	25
9-3-2	BACKGROUND	25
9-4	NOTICE OF REFUSAL OF ADMISSION AND ADMINISTRATIVE DESTRUCTION FOR MAIL SHIPMENTS OF DRUGS.....	29
9-4-1	PURPOSE.....	29
9-4-2	BACKGROUND	29
9-4-3	ISSUANCE OF NOTICES	29

9-5	IMPORTATION OF BIOLOGICAL PRODUCTS.....	31
9-6	FDA NATIONAL IMPORT PROCEDURE REGARDING WAREHOUSE ENTRIES.....	31
9-6-1	PURPOSE.....	31
9-6-2	BACKGROUND.....	31
9-6-3	INSTRUCTIONS.....	32
9-7	RELEASE NOTICES.....	32
9-7-1	PURPOSE.....	32
9-7-2	BACKGROUND.....	32
9-7-3	GENERAL COMMENTS.....	32
9-7-4	"STRAIGHT" RELEASE.....	33
9-7-5	RELEASE WITHOUT EXAMINATION.....	33
9-7-6	RELEASE WITH COMMENT.....	33
9-7-7	RELEASE AFTER DETENTION.....	35
9-8	DETENTION WITHOUT PHYSICAL EXAMINATION (DWPE).....	35
9-8-1	PURPOSE.....	35
9-8-2	AUTHORITY AND BACKGROUND.....	35
9-8-3	GENERAL PROCEDURES.....	36
9-8-4	RECOMMENDATIONS INVOLVING PESTICIDE RESIDUES.....	37
9-8-5	DIRECT REFERENCE AUTHORITY RECOMMENDATIONS.....	37
9-8-6	RECOMMENDATIONS BASED ON EIRs, OTHER GOVERNMENT AGENCIES, MOUs, ETC.....	37
9-8-7	DETENTION WITHOUT PHYSICAL EXAMINATION RECOMMENDATIONS.....	38
9-8-8	RECOMMENDATIONS BASED ON ONE VIOLATIVE SAMPLE.....	38
9-8-9	RECOMMENDATIONS BASED ON INFORMATION AND HISTORICAL DATA.....	39
9-8-10	RECOMMENDATION BASED ON MULTIPLE SAMPLES.....	40
9-8-11	DETENTION WITHOUT PHYSICAL EXAMINATION OF IMPORTERS ENTRIES.....	41
9-8-12	RECOMMENDATIONS BASED ON ESTABLISHMENT INSPECTION.....	42
9-8-13	OTHER SITUATIONS.....	42

9-8-14	PARTY NOTIFICATION OF DETENTION WITHOUT PHYSICAL EXAMINATION DECISION.....	42
9-8-15	REMOVAL FROM DETENTION WITHOUT PHYSICAL EXAMINATION..	43
9-8-16	REMOVAL OF PRODUCTS MANUFACTURERS/COUNTRIES EXCEPT FRESH PRODUCE.....	45
9-8-17	REMOVAL OF FRESH PRODUCE.....	46
9-8-18	REMOVAL OF IMPORTERS.....	47
9-8-19	REMOVAL BASED UPON AN ESTABLISHMENT INSPECTION.....	47
9-8-20	NOTIFICATION OF REMOVAL FROM DETENTION WITHOUT PHYSICAL EXAMINATION.....	48
9-9	NOTICE OF FDA ACTION - DETAINED FOR NON-MAIL SHIPMENTS.....	48
9-9-1	PURPOSE.....	48
9-9-2	BACKGROUND.....	48
9-9-3	EVIDENCE, ISSUANCE OF NOTICE, AND PREPARATION OF CHARGES.....	49
9-9-4	CUSTODY OF DETAINED SHIPMENTS.....	50
9-9-5	DETENTION OF VIOLATIVE PRODUCTS THAT ARE NOT PROPERLY IDENTIFIED FOR FURTHER PROCESSING AND EXPORTATION UNDER 801(D)(3) .	50
9-10	RESPONSE (HEARING) TO NOTICE OF FDA ACTION - DETAINED.....	51
9-10-1	PURPOSE.....	51
9-10-2	BACKGROUND.....	51
9-10-3	ELIGIBILITY OF RESPONDENTS	52
9-10-4	HEARINGS AND POSTPONEMENTS.....	53
9-10-5	CONDUCT OF HEARING: PERSONAL APPEARANCE OF RESPONDENT.....	53
9-10-6	CONDUCT OF HEARING: WRITTEN REPLY (MAIL, FAX, ETC.) FROM RESPONDENT.....	54
9-11	NOTICE OF FDA ACTION - REFUSAL OF ADMISSION.....	55
9-11-1	PURPOSE.....	55
9-11-2	BACKGROUND.....	55
9-11-3	INSTRUCTIONS.....	55
9-12	RECONDITIONING.....	58

9-12-1	PURPOSE	58
9-12-2	BACKGROUND	58
9-12-3	WHO MAY FILE AN APPLICATION	58
9-12-4	MECHANICS IN PROCESSING APPLICATION	58
9-12-5	AMENDED APPLICATIONS	60
9-12-6	REQUESTS FOR ADDITIONAL TIME TO COMPLETE RECONDITIONING.....	60
9-12-7	UNSUCCESSFUL RECONDITIONING OF ADULTERATED ARTICLES..	61
9-12-8	DISPOSITION OF LOTS NOT RECONDITIONED TO THE FDA'S SATISFACTION	61
9-12-9	RECONDITIONING OPERATIONS.....	61
9-13	SUPERVISORY CHARGES.....	63
9-13-1	PURPOSE	63
9-13-2	BACKGROUND	63
9-13-3	SUPERVISORY CHARGES.....	64
9-13-4	PREPARATION AND SUBMISSION OF CHARGE SHEET	66
9-13-5	PAYMENT OF SUPERVISORY CHARGES	67
9-14	BOND ACTIONS.....	67
9-14-1	PURPOSE	67
9-14-2	BACKGROUND	67
9-14-3	BOND VIOLATION	68
9-14-4	BOND ACTION PROCEDURES.....	69
9-14-5	RESPONSIBILITY UNDER THE BOND.....	70
9-14-6	PENALTY RECOMMENDATION.....	70
9-14-7	MITIGATION INSTRUCTIONS	71
9-14-8	TRACKING OF PENALTY ACTIONS.....	72
9-15	IMPORT INFORMATION DIRECTIVES	72
9-15-1	PURPOSE	72
9-15-2	BACKGROUND	72
9-15-3	APPROACH	73
9-15-4	IMPORT ALERTS	73

9-15-5	IMPORT BULLETINS (IB)	74
9-16	PRIORITY ENFORCEMENT STRATEGY FOR PROBLEM IMPORTERS.....	75
9-16-1	PURPOSE	75
9-16-2	BACKGROUND	75
9-16-3	APPROACH	76
9-17	IMPORT FOR EXPORT (IFE).....	83
9-17-1	PURPOSE	83
9-17-2	BACKGROUND	83
9-17-3	INSTRUCTIONS FOR INFORMATION SUBMISSION, ENTRY REVIEW AND DOMESTIC FOLLOW-UP.....	85
9-17-4	TIME FRAME FOR HOLDING IMPORTED PRODUCT	89
9-17-5	IMPORTED FOR FURTHER PROCESSING.....	89
9-17-6	PRODUCTS SUBJECT TO DETENTION WITHOUT PHYSICAL EXAMINATION.....	90
9-17-7	COMPLIANCE WITH RELEVANT EXPORT PROVISIONS	90
9-17-8	IMPORTATION OF FINISHED GOODS FOR STORAGE AND EXPORT WITHOUT FURTHER PROCESSING AND OTHER ARTICLES NOT INCLUDED UNDER SECTION 801(d)(3)	90
9-17-9	IMPORTATION OF VIOLATIVE COMPONENTS FOR FURTHER PROCESSING INTO OTHER COMPONENTS AND UNFINISHED PRODUCTS.....	91
9-17-10	IMPORT FOR EXPORT PROVISIONS FOR PRODUCTS MANUFACTURED IN FOREIGN TRADE ZONES.....	91
9-17-11	RECORDS AND INFORMATION TO BE PROVIDED TO FDA UPON REQUEST	91
9-17-12	AGENCY CONTACTS.....	92
9-18	IMPORTATIONS FOR TRADE SHOWS/FAIRS, EXHIBITS AND SPECIAL EVENTS.....	92
9-18-1	PURPOSE	92
9-18-2	BACKGROUND	92
9-18-3	CBP REQUIREMENTS	93
9-18-4	PROCEDURES FOR TRADE SHOWS, FAIRS, AND EXHIBITIONS	93
9-18-5	SPECIAL EVENTS	94
9-19	SECURED STORAGE (TEMPORARY REMOVAL DUE TO PENDING	

REVISION)	94
9-20 COMMUNICATION CONCERNING ASSESSMENT OF CIVIL MONETARY PENALTIES BY CBP IN CASES INVOLVING IMPORTED FOOD	94
9-20-1 PURPOSE.....	95
9-20-2 BACKGROUND.....	95
9-20-3 INSTRUCTIONS.....	95
9-21 NOTICE OF SAMPLING	96
9-21-1 PURPOSE.....	96
9-21-2 BACKGROUND.....	96
9-21-3 INSTRUCTIONS.....	96
9-22 GRANTING AND DENYING TRANSPORTATION AND EXPORTATION (T&E) ENTRIES	101
9-22-1 PURPOSE.....	101
9-22-2 BACKGROUND.....	101
9-22-3 INSTRUCTIONS.....	103
9-23 EXHIBITS	104
EXHIBIT 9-3	105
EXHIBIT 9-4	106
EXHIBIT 9-5	107
EXHIBIT 9-6	108
EXHIBIT 9-10	111
EXHIBIT 9-11	113

9-1 IMPORT PROCEDURES

Reminder: The statements in this chapter are intended only to provide operating procedures for FDA personnel and are not intended to create or confer any rights, privileges, or benefits on or for any private person.

9-1-1 SCOPE AND PURPOSE

The procedures outlined in this document cover imported merchandise subject to, but not limited to, the following Acts/Regulations:

- Federal Food, Drug, and Cosmetic Act as amended (FFDCA or the Act)
- Fair Packaging and Labeling Act
- Import Milk Act/Filled Milk Act
- Federal Caustic Poison Act
- Radiation Control for Health and Safety Act
- Public Health Service Act, Part F, Subpart 1, Biological Products
- Federal Cigarette Labeling and Advertising Act
- Comprehensive Smoking Tobacco Health and Education Act of 1986
- Title 21 CFR, especially Part 1, Subpart E - Imports and Exports
- Title 19 CFR Customs Duties, especially Part 141, et. seq. dealing with import procedures.

The purpose of this chapter is to provide an overview of import procedures for articles subject to the laws and regulations enforced by the Food and Drug Administration (FDA). The chapter also includes an overview of laws and regulations enforced by the United States Customs and Border Protection (CBP), as they relate to importation of articles regulated by FDA.

The statements in this chapter represent the Agency's current thinking on the application of the Import Procedures as identified by current law and regulation. It is intended only to provide operating procedures for FDA personnel and does not confer any rights on or for any private person and does not operate to bind FDA or the public.

9-1-2 DIVISION OF AUTHORITY

Primary responsibility for administering the nation's laws relating to import, export and the collection of duties is given to CBP, an agency within the Department of Homeland Security. FDA, however, is responsible for determining whether or not an article offered for importation is in compliance with or in violation of the acts enforced by FDA. This includes the responsibility of determining whether or not a violative article may be brought into compliance with the appropriate statute and/or regulations, and authorizing reconditioning in order to bring the article into compliance.

In order to fulfill their respective responsibilities, CBP and FDA must work in close cooperation. For example: the refusal of admission, and subsequent re-exportation, or destruction of merchandise found to be in violation of the FFDCA and other Acts enforced by FDA is generally carried out under the direction of CBP, except for drugs that are subject to administrative destruction, which are destroyed by FDA and not by CBP. Additionally, at some ports actual supervision of destruction of violative merchandise may be conducted by FDA pursuant to a local FDA/CBP agreement. In addition, supervision of reconditioning plans is exercised by either FDA or CBP as mutually arranged by FDA personnel. At ports in reasonably close proximity to an FDA office, such supervision is ordinarily exercised by FDA. At remote ports, such supervision is ordinarily exercised by CBP.

9-1-3 ENTRIES

Entry Processing

The responsible FDA office receives notification from CBP of all formal and informal entries of articles under FDA jurisdiction at ports of entry located in the office's responsibility. Through the use of CBP's Automated Commercial Environment/International Trade Data System (ACE/ITDS), currently the sole CBP-authorized Electronic Data Interchange (EDI) system for entries that contain FDA-regulated articles and FDA's ACE/Operational and Administrative System for Import Support (ACE/OASIS) some electronic entries may be forwarded to off-site offices for processing during certain periods of time, e.g., late night coverage of air carrier hubs. Automated Broker Interface (ABI) Filers using ACE for cargo release are required to provide FDA with information on entries submitted through ACE. The means of receiving notification for paper entries can be arranged through local CBP/FDA procedures.

The most satisfactory and efficient means for FDA to receive notification is through FDA's electronic entry system, the Operational and Administrative System for Import Support (OASIS). Entries processed through this system will be electronically screened against criteria developed by FDA.

Electronic entries include all required CBP entry information, including entry number, entry date, importer identification, port of entry, vessel/voyage information, filer identification, Harmonized Tariff Schedule (HTS) code(s) for product described in importing documents (tariff code), information on foreign shipper, country of origin quantity, and value. Through the screening process in ACE, CBP determines if the article is subject to FDA jurisdiction.

The CBP ACE uses specific codes within ACE to help it identify which articles are subject to which agency's jurisdiction. These codes are known as "other government agency" (OGA) flags. FDA flags are "FD0", "FD1" and "FD2". FD0 indicates that FDA has determined the article, even though subject to FDA's laws and regulations, is acceptable for CBP release without further presentation of entry information to FDA.

- For entries flagged FD1, the article may or may not be subject to FDA regulation. The filer may, based on information received from the importer regarding the intended use of the article, specify that the entry is not subject to FDA regulation and "Disclaim" the entry. Otherwise, information required by FDA laws and regulations must be submitted. FDA will periodically review "Disclaimed" entries to confirm the accuracy of the declaration.
- Entries covered by an FD2 flag are considered subject to FDA jurisdiction and must include information required by FDA laws and regulations.

Note: As of this update additional "other government agency" (OGA) flags have been added. If necessary, additional information on OGA flags can be obtained by contacting the Office of Import Operations (OIO).

FDA's electronic screening of the CBP ABI/ACE entry requires the filer to provide the following additional information:

- (1) FDA product code (FDA's product code is not the same as the HTS codes used for CBP screening purposes).
- (2) The MID code of the foreign manufacturer (MIDs are used by Customs as the "Manufacturer's Identification", and it has now been extended to cover all foreign firms). The MID includes, at a minimum, the two-letter identification of the foreign country, the name of the foreign firm (which is generally made up of the first three letters of the first and second names of the firm, where applicable), up to 4 numbers of the firm's address, if present in the address, and the first three letters of the city where the firm is located. This code is subsequently transmitted to FDA's screen as the un-coded name of the identified firm.
- (3) The MID information of the foreign shipper, including city and country, which may or may not be the same as the foreign manufacturer.
- (4) The country of origin (which may be different from the country of origin identified for CBP purposes).

FDA has also established Affirmation of Compliance (A of C) codes which provide FDA employees with information concerning the article offered for import (example: medical device listing number). Use of the A of C is voluntary, and may or may not provide for a more expeditious screening of the entry.

In OASIS, the FDA forms identified as "Notice of Sampling," "Release Notice," "Notice of Detention and Hearing," and "Notice of Refusal of Admission," are no longer issued as specific forms. OASIS will instead generate a "Notice of FDA Action," which will provide more specific information on the actions taken broken down by each entry line (e.g., "sample collected" or "intended for sampling", "detained", "released", or "refused"). As the status changes for a particular line, a new "Notice of FDA Action" will be issued to advise the appropriate individuals of the changes. For non-mail shipments, which includes parcels not received through the International Mail Facilities via the United States Postal Service, the use of the designation "Product Collected by FDA," "Detained," "Released," "Refused," or similar language on the "Notice of FDA Action," should be considered as satisfying the requirements of the law for "giving notice thereof to the owner or consignee." See 21 USC 381(a).

For drugs received through the International Mail Facilities that are subject to administrative destruction, the designation "Detained – Subjection to Refusal and Administrative Destruction," and "Refusal of Admission and Administrative Destruction," and the resultant issuance of a notice to the owner or consignee may also be used to satisfy the requirements of the law for "giving notice thereof to the owner or consignee." See 21 USC 381(a).

For articles received through the International Mail Facilities the use of the designation "Product Collected by FDA," "Detained – Subject to Refusal," "Released," "Refusal of Admission– Return to Sender," or similar language on the "Notice of FDA Action," and the resultant issuance of a notice to the owner or consignee should be considered as satisfying the requirements of the law for "giving notice thereof to the owner or consignee." See 21 USC 381(a).

An example of a "Notice of FDA Action" showing various decisions for products in an entry is attached to this chapter as [Exhibit 9-6](#).

Notices of FDA Action will usually be mailed to the addressees listed on the Notice. A copy of each notice is produced for the filer, importer of record, and consignee designated on the entry. (If the same firm fills one or more of those functions, only one copy is produced for the firm.) Notices are official documents communicating FDA decisions on entries. The distribution of the notices should be made by FDA, not the filer, to ensure proper notification to the parties involved (i.e., FAX, express pick-up services, postal service, etc.) The key is for FDA to distribute to the responsible firm directly without an intermediary.

Formal Entries

All articles offered for import into the U.S. (entries) that have a value greater than \$2500 (or such higher amount as the Secretary of the Treasury may set by regulation) are considered by CBP to be formal entries. Entry procedures for formal entries are set largely by statute, the most important requirement of which is a bond. Under the terms of a formal entry bond, imported articles may be unconditionally released to importers pending a determination of the admissibility and amount of duty to be paid on the articles. The bond requires importers to redeliver the articles to CBP, upon demand of CBP at any time; for example, to allow FDA sampling or for re-exportation following refusal of admission. If the importer fails to redeliver the goods, CBP, after consultation with FDA, may institute proceeding to collect the liquidated damages provided for in the bond. See 19 CFR 113.62 and 21 CFR 1.97.

Generally, importers notify CBP of an entry by the electronic submission of information to the CBP ACE/ITDS. The information is forwarded to FDA through ACE. FDA can then review the entry on screen to determine if further action is needed, or if additional paper documentation must be submitted. If FDA requires further documents for review, the filer (or importer, where appropriate) will provide FDA with copies of the CBP Entry documents (CBP 3461/33461ALT, or other CBP entry forms) and other documents, such as a copy of the invoice. If an entry is not filed electronically, the accompanying documents will be submitted directly to FDA at the time CBP entry is made in accordance with local port operations. Note: As of July 2016, all entries of FDA-regulated articles filed electronically are automatically forwarded to FDA through ACE

Note: the FD 700 set (Importers Entry Notice) and FD 720 set (Land Port Entry Notice) are no longer used for FDA notification. In lieu of these forms, CBP entry documents

(CBP 3461/3461ALT/7501 or alternate), along with appropriate commercial documents and/or other required documents, will be submitted to FDA.

CBP forms are available on the CBP site ([link](#)).

Informal Entries

Under current CBP procedures, entries with a value of \$2500 or less (or such higher amount as the Secretary of the Treasury may set by regulation) do not require posting a redelivery bond. All informal entries of articles under FDA jurisdiction that are entered by filers electronically will be forwarded to FDA through the CBP/FDA ACE interface. Informal entries not filed electronically will be processed by FDA for admissibility using the same criteria as non- electronic formal entries.

When informal entries that include articles under FDA jurisdiction are to be sampled, or FDA believes the articles may be in violation of FDA law, FDA may request CBP convert the informal entry into a formal entry, which requires the posting of a redelivery bond. "Section 321 entry" is a term CBP uses for those entries with a value of \$800 or less. These entries have a fair retail value of \$800 or less, as evidenced by the bill of lading (or other document filed as the entry). They pass free of duty and tax, and are imported by one person on one day. The use of the 321 entry process should not apply to multiple shipments covered by a single order or contract, sent separately for the express purpose of securing free entry, and avoiding compliance with pertinent laws or regulations.

Mail/Personal Baggage

In the case of articles imported by mail or in personal baggage, FDA offices should develop procedures with their local CBP International Mail Office or border crossing office to cover such products. The procedures should set out such information as who is responsible for coverage and when.

CBP is responsible in the first instance for examination of personal baggage. If, in the course of their examination of an individual's personal baggage, CBP determines the individual is entering a product subject to FDA review, the CBP officer will determine if the article should be brought to the attention of the local FDA office. Personal importations meeting the criteria of entry will be processed in accordance with procedures for non-electronic entries. Generally, since most personal importations are small in size and value, procedures have been developed for evaluating these importations. See RPM [subchapter 9-2 "Coverage of Personal Importations."](#)

Voluntary qualified Importer Program

FDA will work with CBP to expedite entry into the United States for Voluntary Qualified Importer Program (VQIP) foods. FDA sets screening in its Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting (PREDICT) import screening tool

to recognize shipments of food which are the subject of an approved VQIP application. PREDICT is designed to validate the VQIP supply chain information provided at the time of entry and recommend the shipment be may proceeded immediately after the receipt of entry information, unless examination and/or sampling are necessary for public health reasons. A “may proceed” recommendation from PREDICT will typically result in the line being may proceeded without going to a FDA reviewer for processing (referred to as "a system may proceed").

9-1-4 SAMPLING

Ports Covered by FDA

Most ports of entry into the U.S. are covered by FDA personnel, acting in cooperation with CBP. At these ports, where electronic entry submissions are filed, filers receiving a message indicating FDA review is required will provide appropriate additional entry information to the FDA office in whose territory the port of entry is located. For those entries submitted by paper, all appropriate entry documents should be included with the package sent to the local FDA office.

After the entry has been evaluated and a decision for additional documentation is made, FDA will take appropriate action. If FDA decides to collect a sample, it will provide the filer, importer, owner and/or consignee, where appropriate, with a Notice of Sampling and advise:

- (1) whether the entry is to be held intact for FDA examination or sampling; or,
- (2) specify only those items that need be held.

Generally, when FDA wishes to sample, it will be acting upon its authority in the Customs regulations (19 CFR 151.4) to collect its own samples for examination.

Ports not Covered by FDA

There are a number of ports where CBP does not maintain its ACE electronic entry process and FDA does not generally cover the port under its normal operating schedule. To cover these ports, the responsible FDA office will coordinate coverage with the responsible CBP Port manager to ensure FDA notification. If FDA decides to examine or sample articles offered for import through such a port, CBP, the importer, and broker will be notified.

Generally, for these entries, examination and/or sampling can take place at the point of destination. Under certain conditions, however, FDA may ask CBP to collect a sample at the point of entry and forward it to the FDA servicing laboratory. Appropriate information on the entry, sample requirement, and requirements for holding the entry will be provided to the CBP officials and importer by the responsible FDA office.

Entry Sampling

FDA may request an examination or sample of articles under its jurisdiction. If no examination or sample is requested, FDA will notify CBP and the filer, who is

responsible for notifying the importer or other designated parties. This is referred to as a "May Proceed Notice," and indicates that the shipment may proceed without further FDA examination. In the ACE/OASIS process this may occur as a result of the initial FDA/OASIS screening prior to the information being forwarded to the office representative, or after the responsible office performs an "On-Screen-Review" of the information provided.

Note: Should the article, at a later time, be found in violation of the law, FDA is not prevented from taking legal action (e.g., seizure, injunction) because it allowed admission of the article without examination at the time of importation.

If FDA requests an examination or sample, FDA will notify CBP and the broker or filer, importer, or other designated parties through the electronic entry system or other form of notification (e.g., Notice of FDA Action) of its intent to sample, requesting the relevant party to hold the entry. FDA will indicate the specific articles to be sampled.

Notice of Sampling

Whenever FDA intends to sample an article offered for import, it issues a Notice of Sampling to the importer of record, consignee, and filer of its intent to sample the article. Where an entry is manually processed, a copy of the Notice of Sampling may or may not be issued to CBP, depending on local FDA/CBP agreement. Where an entry is processed electronically and CBP collects the sample for FDA, the office will input the information of the entry/sample into OASIS and provide the Notice of Sampling to the importer of record, consignee, and filer specifying which articles were sampled.

For those entries where specific entry lines are not sampled or examined, the Notice of FDA Action will be amended to indicate which entry lines are "May Proceeded." See RPM [subchapter 9-21 "Notice of Sampling" for procedures](#).

Payment for Samples

The FDA will pay for all physically sampled articles found to be in compliance with the requirements of the Act and applicable regulations (21 CFR 1.91). In addition, FDA will pay for samples collected as FDA audits of private laboratory reports of analysis submitted to FDA in response to a detention when the article is found to be in compliance. FDA does not pay for samples taken in connection with the supervision of a reconditioning.

Where an owner or consignee seeks reimbursement it shall bill the FDA office responsible for the shipment was offered for import. FDA will not pay for a sample if the article is initially found to be in violation, even if the article is subsequently released.

Procedure When no Violation is Found

If the article is found to be in compliance after examination, the importer of record, consignee (where applicable), filer, and CBP are notified by a Notice of Release that the article may be admitted as far as FDA is concerned. See RPM 9-7 [subchapter 9-7 "Release Notices"](#) for procedures.

Procedure When Products Cannot Be Sampled or Examined

Under certain circumstances, FDA decides not to sample or examine articles offered for import. In these cases, if the entry is made through ACE/OASIS, the shipment should be "May Proceeded" through OASIS; if a manual (paper) entry, the shipment should be released by issuance of a paper "Notice of Release." The paper "Notice of Release" should be annotated to indicate that the article is "May Proceeded" and that FDA has made no determination as to the article's compliance with the Food, Drug, and Cosmetic Act, or other related acts or regulations.

In the OASIS system, if a notice is issued for the collection or examination of an article and the sample is not collected, or where an examination of the sampled article could not be accomplished, the filer will be so advised through a revised Notice of FDA Action indicating the article is "May Proceeded." The system will print a status of "May Proceeded" in the Line Summary and also print a detail section "Lines Which May Proceed." If the article FDA chose not to sample was part of a multi-line entry where other articles were collected for examination, the Notice of FDA Action automatically updates the status of the other articles not released.

In OASIS, the following are definitions used to describe "May Proceed" or "Release" actions:

May Proceed: "Product may proceed without FDA examination. FDA has made no determination the product complies with all provisions of the Food, Drug, and Cosmetic Act or other related acts. This message does not preclude action should the article later be found violative." (No compliance decision has been made.)

Release: "The product is released after FDA examination. This message does not constitute assurance the product complies with all provisions of the Food, Drug, and Cosmetic Act or other related acts and does not preclude action should the article later be found violative." (A compliance decision has been made.)

FDA offices will follow the appropriate instruction under each of the above procedures according to their import operations.

Voluntary qualified Importer Program

FDA will limit examination and/or sampling of VQIP food entries to “for cause” situations (i.e., when the food is or may be associated with a risk to the public health), to obtain statistically necessary risk-based microbiological samples, and to audit VQIP. In the examination and/or sampling circumstances identified, FDA will attempt, to the extent possible, to examine an entry and collect samples at the VQIP food destination or other location preferred by the VQIP importer. If exportation is warranted, FDA will assist in fulfilling an importer’s request to U.S. Customs and Border Protection (CBP) to export from the port preferred by the importer. FDA will expedite its laboratory analysis of “for cause” or audit samples of VQIP entries, to the extent possible in accordance with public health priorities.

Unless directed by assignment or specific sampling instructions from the VQIP Team, VQIP sample collection should occur in Domestic/Import (D/I) status.

9-1-5 PROCEDURES WHEN VIOLATION IS FOUND FOR PRODUCTS THAT ARE NOT SUBJECT TO ADMINISTRATIVE DESTRUCTION

For the procedures regarding administrative destruction of products determined to be drugs valued at \$2500 or less see sections [9-3 “Notice of FDA Action – Detained for Mail Shipments”](#) and [9-4 “Notice of Refusal of Admission and Administrative Destruction for Mail Shipments”](#).

"Notice of Detention & Hearing"

Examination or sampling of an article offered for import may indicate that the article appears to be in violation of the Act (e.g., section 801(a)), or may be subject to refusal of admission under acts and regulations enforced by FDA. If, after examination or sampling, detention is the chosen course of action, the filer, owner, and consignee where applicable are issued a "Notice of FDA Action - Detained" that shall specify the nature of the violation charged. The owner or consignee is entitled to appear before the FDA and have the right to introduce testimony in support of admissibility of the article in accordance with Section 801(a) of the FFDCA and FDA regulation 21 CFR 1.94. As a result, the "Notice of FDA Action - Detained" shall designate a place for the owner or consignee (or authorized representative) to provide testimony as to the admissibility of the article. Introduction of testimony by the owner or consignee for Agency review and consideration can be submitted via multiple forms including a telephone conversation, a facsimile, mail, or email, and does not have to be introduced in person. However, an in-person hearing will be scheduled if requested by the owner or consignee. It has generally been FDA's procedure to give the owner or consignee 10 working days from the date on the notice to provide FDA with testimony or evidence. However, if for some compelling reason the responsible FDA office determines that 10 working days is insufficient, such as inordinate mail delays due to holiday mailings, this time period may be extended. On the OASIS generated "Notice of FDA Action", this date is identified as the date to "Respond By". A copy of this Notice is also sent to CBP. See RPM

[subchapter 9-9 "Notice of FDA Action – Detained for Non-Mail Shipment"](#) for procedures.

Request for Authorization to Relabel or Perform Other Acts

In addition to presenting evidence as to the admissibility of the article, the importer may propose a manner in which an article, detained under section 801(a)(3), can be brought into compliance with the Act or be removed from coverage under the Act ("rendered other than a food, drug, device or cosmetic"). As provided for under 801(b) and 21 CFR 1.95, FDA may authorize relabeling or other action upon the timely submission of an ["Application for authorization to relabel or recondition non-compliant articles" Form FDA-766](#) ("Importer's Certificate"), and the execution of a good and sufficient bond ("CBP redeliver bond") by the owner or consignee (see 21 USC 381(b)). The redelivery bond remains on file with the District Director of CBP for the particular importation. The bond applies to any relabeling or other authorized action, and a new bond will not have to be filed.

After review of the application to relabel or recondition, FDA will notify the importer of its approval or disapproval. If approved (see 21 CFR 1.96 "Granting of authorization to relabel and recondition"), the conditions to be fulfilled, and the time limit within which to fulfill them will be noted. The original application will be sent to the applicant. Notification to other parties will be made where appropriate. A copy will be retained in the files of the FDA responsible office. See RPM [subchapter 9-10 "Response \(Hearing\) to Notice of FDA Action – Detained for Non-Mail Shipments"](#), and [RPM subchapter 9-12 "Reconditioning"](#) for procedures.

Inspection After Completion of Authorization to Bring Article into Compliance

After the relabeling or reconditioning operation has been completed, the applicant will submit the "Importer's Certificate" (page two of the [Form FDA-766](#)). At this point FDA may conduct a follow-up inspection and/or sampling to determine compliance with the terms of the authorization, or may accept the statement from the importer with no further follow-up. The follow-up inspection and/or sampling may be made by an officer of FDA or CBP, depending on the location of the reconditioning and agreements between the FDA responsible office and the local CBP office. The "Report of INVESTIGATOR/INSPECTOR" (page two of the [Form FDA-766](#)) shall be completed by the inspecting officer and forwarded to the appropriate FDA office.

Procedure When Conditions of Authorization Have Been Fulfilled

If the conditions of the authorization to relabel or recondition have been fulfilled, the FDA responsible office will notify the owner or consignee through a Notice of Release indicating that the admissible portion of the article is no longer subject to detention or refusal of admission. This notice is usually identified as "Originally Detained and Now Released." A copy of the Notice is also sent to CBP and the filer. Where there is a non-admissible portion of the article (rejects), the portion must be destroyed, or re-exported

under FDA or CBP supervision. A Notice of Refusal of Admission should be issued for the rejected portion, with copies distributed to the same parties receiving the Notice of Release. Normally, FDA will include in its approval of the reconditioning a provision for any non-admissible portions (rejects) of the reconditioned article be destroyed that should not be permitted to be exported.

Procedure When Conditions of Reconditioning Have Not Been Fulfilled.

If an importer's initial attempt at relabeling or reconditioning is not successful, FDA should not consider a request for authorization for a second relabeling or reconditioning unless the authorization includes a change or adjustment from the original authorized method, and the applicant provides reasonable assurance that the second attempt will be successful. If the importer fails to fulfill conditions of an authorization, FDA issues a "Notice of Refusal of Admission" to the importer, consignee, where applicable, and the filer, with a copy of the Notice to CBP.

Procedure After Hearing - "Notice of Release"

After the hearing on admissibility, the FDA responsible office may determine that the article does not appear to be in violation and should be released. In this situation, the importer of record and consignee are issued a "Notice of Release" for the detained article. The Notice will indicate that the detained article is no longer subject to detention or refusal of admission. The Notice will also be identified "Originally Detained and Now Released" and, where appropriate, explain the reason for the change of action. A copy of the Notice is sent to CBP, and all parties receiving the Notice of Sampling/Notice of Detention. See RPM [subchapter 9-7 "Release Notice"](#) for procedures.

Procedure After Hearing - "Refusal of Admission"

If, after consideration of all evidence, the FDA responsible office decides that the articles still appear to be in violation, the articles may be refused admission. In this situation, FDA notifies the importer, owner, and consignee, where applicable, by issuing a "Notice of Refusal of Admission." On this Notice, FDA states the charge(s) exactly as shown on the original (or amended) Notice of FDA Action - Detained. A copy of the Notice is also sent to CBP. See RPM [subchapter 9-11 "Notice of FDA Action - Refusal of Admission"](#) for procedures.

If an article is refused admission, such article must be destroyed or exported under CBP's supervision within 90 days of receiving the Notice of Refusal (see 21 USC 381), or within such additional time as specified by CBP. The FDA file for the import remains open until the FDA responsible office receives notification, usually from CBP, indicating that the article was either destroyed or exported.

Some local FDA and CBP offices have developed combination Notice of Refusal of Admission and Notice of Redelivery documents. At this time, use of the combined Notice of Refusal of Admission and Notice of Redelivery has not been approved for

national applications. Until the format of combined notices is authorized, FDA responsible offices should continue to follow local procedures as instituted. Under the OASIS procedures for issuing the Notice of Refusal of Admission, the notice will contain language which includes the reference to the requirement for redelivery. The notice will contain all the above required information concerning the product and charge(s) and will also include the following statements

"A request has been made to CBP to order redelivery for all the above product(s), in accordance with 19 CFR 141.113, which were conditionally released to you under terms of the entry bond. Failure to redeliver to CBP custody will result in a claim for liquidated damages under the provisions of the entry bond."

"These products must be exported or destroyed under CBP supervision within 90 days from the date of this notice, or within such additional time as the District Director of CBP specifies. Failure to do so may result in destruction of the products. Distribution of the products may result in their seizure and/or injunction or criminal prosecution of persons responsible for their distribution."

Voluntary qualified Importer Program

If exportation is warranted, FDA will assist in fulfilling an importer's request to U.S. Customs and Border Protection (CBP) to export from the port preferred by the VQIP importer.

Revocation of VQIP benefits:

- If FDA obtains credible evidence that the VQIP importer participated in smuggling or other fraudulent activities such as declaring an entry as a VQIP food when it is not, FDA will immediately revoke participation in VQIP. The Notice of Immediate Revocation will identify FDA's reason(s) for revoking participation in VQIP. If the VQIP importer believes revocation was in error, it may contact FDA upon receipt of this notice. VQIP participation and, thus, VQIP benefits will immediately cease for all VQIP foods on the day that FDA sends the Notice of Immediate Revocation. Unless it is determined based on a review of the evidence submitted by the VQIP importer that the revocation was enacted in error, FDA will not reinstate participation in VQIP for the remainder of the VQIP fiscal year. FDA will not approve VQIP applications for subsequent years, unless the VQIP importer provides sufficient evidence of affirmative steps to ensure that fraudulent activity does not occur again. Divisions should refer to section [9-16 Priority Enforcement Strategy for Problem Importers](#) when dealing with VQIP importers or other individuals who engage in business practices that appear designed to evade the lawful regulation of imports.
- If FDA finds deviations indicating the participant does not continue to meet one or more of the eligibility requirements to participate in VQIP, we will send an electronically generated Notice of Intent to Revoke participation in VQIP. The Notice of Intent to Revoke will identify FDA's reason(s) for intending to revoke participation

in VQIP and will indicate that the VQIP importer has 30 days to make and provide evidence of the corrections to the VQIP team. The VQIP team will be available via phone, email, or via the VQIP FURLS Portal. Benefits will continue for those 30 days unless FDA believes there is a risk to public health, in which case FDA will notify the VQIP importer via the Notice of Intent to Revoke.

If all corrections cannot be made within 30 days, the VQIP importer can submit a corrective action plan that includes detailed steps and a timeline for making corrections. FDA will verify the corrective actions by conducting an inspection or by reviewing documentation of the corrective actions, whichever is appropriate. If the VQIP importer does not respond or does not submit an adequate corrective action plan within 30 days, FDA will revoke participation in VQIP. Revocation of benefits will be effective on the date on which FDA sends the Notice of Revocation email.

If after revocation, the VQIP importer believes they have made corrections to support reinstatement, it may contact FDA. FDA will review the request to determine if corrective actions support reinstatement of benefits for the remainder of the VQIP fiscal year.

Note that revocation of VQIP participation does not prevent the Agency from taking additional enforcement actions against the indicated firm(s) or product(s), if warranted.

FDA follow up when VQIP importer self-reports a problem:

- The VQIP importer is responsible for promptly reporting all deviations that may impact their eligibility to participate in VQIP and their plans for correcting the deviations to FDA. The VQIP QAP should include procedures for taking prompt corrective actions, for updating procedures as necessary to prevent future occurrences of the problem, and for notifying FDA. When deviations occur in which a food(s) may be associated with a risk to public health, FDA may increase “for cause” or audit samples of VQIP entries. FDA will review the reported information from the VQIP Importer to determine if there is a risk to public health and/or if a revocation process needs to be initiated.

9-1-6 PAYMENT OF COSTS OF SUPERVISION OF RELABELING AND/OR OTHER ACTION

After completion of the authorized relabeling or other action, FDA will submit to CBP National Finance Center a detailed statement of expenses incurred by officers or employees of the FDA during the supervision of the authorized relabeling or other action. See 21 USC 381(c). Expenses include travel, per diem or subsistence, and supervisory charges [Form FDA-790 Charges for Supervision, Exhibit 9-12](#) (now IOM [Exhibit 6-3](#)).

The expenses shall be computed based on the following:

- Investigator's time
- Analyst's time
- Per diem allowance

- Travel other than by auto - actual cost of such travel
- Travel by auto (mileage, toll fees, etc.)
- Administrative support.

Charges for the above will be in accordance with existing regulations. See 21 CFR 1.99 and RPM [subchapter 9-13 "Supervisory Charges"](#) for procedures. CBP, upon receipt of the charges for supervision, will send a notice for payment to the identified importer of record. The expenses shall include charges of supervision of destruction of the article or rejects as provided for by the Tariff Act of 1911, as amended. See 19 U.S.C. 267. The owner or consignee shall remit payment to CBP. Payment of supervisory charges should not be accepted by FDA representatives.

9-1-7 EXPORTATION OF MERCHANDISE REFUSED ADMISSION

As provided under Section 801(a), CBP supervises exportation of refused articles in accordance with regulations which have been or may be prescribed by the Secretary of Treasury. However, if after a reasonable time, FDA has not received notification of exportation or destruction of articles refused admission, the FDA responsible office should investigate the status of disposition. The investigation should also consider, under certain conditions, verifying that the refused articles have been held intact pending exportation or destruction. Procedures on refusals to be verified may change based on the reason for detention.

9-1-8 BOND ACTION

Under the provisions of section 801(b) of the Act (21 USC 381(b)) and CBP regulations (19 CFR 113.62), a bond is required for all conditionally released articles offered for importation. This bond provides for relief to the government should the bond holder default on the conditions of the agreements identified by the CBP regulation. Default will result in the payment of liquidated damages in the amount specified in the bond order.

Bond actions are taken when an entry is distributed after the importer receives notification of FDA's intent to examine or sample the article, and the article is distributed and cannot be redelivered. Bond actions also are taken when an article has been detained and refused, and the article is not destroyed or exported in accordance with the requirements of the law.

If FDA has evidence that the entry, or any portion of an entry subject to FDA jurisdiction, was disposed of in violation of the terms of the appropriate act or its regulations, or of the terms of the bond (see 19 CFR 113.62(e)), it should immediately send such evidence to CBP.

If FDA receives evidence that a refused article was not exported or destroyed, it shall immediately investigate the matter and send a detailed statement to CBP. The statement will show the importer's liability under the redelivery bond or other applicable CBP bond. If the facts warrant, when the article was under detention, and the Notice of

Refusal of Admission has not been issued, FDA should immediately issue a Notice of Refusal to the owner or consignee, with a copy to CBP.

Upon the receipt of a bond holder's application for relief (appeal for Mitigation or Cancellation of Assessed Liquidated Damages) as provided under CBP regulations, CBP may cancel the liability for liquidated damages incurred under the bond. CBP will do so upon the payment of a lesser amount, or upon such other terms and conditions as shall be deemed appropriate under the law and in view of the circumstances. However, for assessment of liquidated damages involving FDA merchandise, CBP may not act unless the FDA office having jurisdiction at the port of entry is in full agreement with the action. See 21 CFR 1.97(b) and RPM [subchapter 9-14 "Bond Actions"](#) for procedures.

[Exhibit 9-6 of Notice of FDA Action](#) is a model and should not be considered all inclusive. The format and language in the actual Notice of FDA Action issued by FDA from the OASIS may also appear differently.

9-2 COVERAGE OF PERSONAL IMPORTATIONS

9-2-1 PURPOSE

To provide operating procedures for the coverage of personal-use quantities of FDA-regulated imported products in baggage and mail and to gain the greatest degree of public protection with allocated resources.

9-2-2 BACKGROUND

Because the amount of merchandise imported into the United States in personal shipments is normally small, both in size and value, comprehensive coverage of these imports is normally not justified. These procedures clarify how FDA may best protect consumers with a reasonable expenditure of resources.

There has always been a market in the United States for some foreign made products that are not available domestically. For example, individuals of differing ethnic backgrounds sometimes prefer products from their homeland or products labeled in their native language to products available in the United States. Other individuals seek medical treatments that are not available in this country. Drugs are sometimes mailed to this country in response to a prescription-like order to allow continuation of a therapy initiated abroad. With increasing international travel and world trade, we can anticipate that more people will purchase products abroad that may not be approved, may be health frauds or may be otherwise not legal for sale in the United States.

In addition, FDA must be alert to foreign and domestic businesses that promote or ship unapproved, fraudulent or otherwise illegal medical treatments into the United States or who encourage persons to order these products. Such treatments may be promoted to individuals who believe that treatments available abroad will be effective in the treatment of serious conditions such as AIDS or cancer. Because some countries do not regulate or restrict the exportation of products, people who mail order from these

businesses may not be afforded the protection of either foreign or U.S. laws. In view of the potential scale of such operations, FDA has focused its enforcement resources more on products that are shipped commercially, including small shipments solicited by mail-order promotions, and less on those products that are personally carried, shipped by a personal non-commercial representative of a consignee, or shipped from foreign medical facility where a person has undergone treatment.

9-2-3 PERSONAL BAGGAGE

FDA personnel are not to examine personal baggage. This responsibility rests with the CBP. It is expected that a CBP officer will notify their designated FDA representative when he or she has detected a shipment of an FDA-regulated article intended for commercial distribution (see [GENERAL INSTRUCTIONS](#) below) an article that FDA has specifically requested be detained, or an FDA regulated article that appears to represent a health fraud or an unknown risk to health.

When items in personal baggage are brought to FDA's attention, the designated office should use its discretion, on a case-by-case basis, in accordance with the instructions provided under [GENERAL INSTRUCTIONS](#) below, in deciding whether to request a sample, detain the article, or take other appropriate action.

9-2-4 MAIL SHIPMENTS

FDA personnel are responsible for monitoring mail importations. Mail importations are parcels received through the International Mail Facilities, via the United States Postal Service. It is expected that a CBP officer from the CBP Mail Division will examine a parcel and will set it aside if it appears to contain a drug, biologic, or device, an article that FDA has specifically requested be held, or an FDA-regulated article that appears to represent a health fraud or unknown risk to health.

FDA should audit those parcels set aside by CBP in accordance with the instructions provided under [GENERAL INSTRUCTIONS](#) below, using the following procedures:

- Prepare a Collection Report for each parcel sampled.
- Generally, a physical sample is not required on mail importations because a documentary sample (for example, labeling, labels and inserts) will be sufficient for most regulatory purposes.
- If a physical sample is needed, collect only the minimum necessary for analysis by the laboratory.
- The remaining portion should not be removed from the custody of the CBP Mail Division.

Importations detained in accordance with these procedures should be held by CBP until they are either released or refused entry. Attached as help are two specimen letters that may be sent with the Notice of FDA Action - Detained when a parcel is detained. See [Exhibit 9-3](#) for use in general mail importations and [Exhibit 9-4](#) for use in unapproved drug or device mail importations.

On occasion, products detained by FDA will be mixed with non-FDA-regulated products. When we refuse admission of the FDA-regulated portion, any request for the release of the non-FDA-regulated portion should be referred to the CBP Mail Division with a Notice of Refusal of Admission covering the detained article. Final disposition of all merchandise, including the destruction of detained merchandise, is the responsibility of CBP, except in the case of drugs that are subject to administrative destruction (e.g., drugs that are valued at \$2500 or less which have been refused admission, or have not met the Personal Importation Policy criteria as described in the subsection [9-2-5 General Instructions](#) section below). In these instances, the drugs will be destroyed by FDA.

9-2-5 GENERAL INSTRUCTIONS

FDA personnel may allow entry of shipments when the quantity and purpose are clearly for personal use, and the product does not present an unreasonable risk to the user. Even though all products that appear to be in violation of statutes administered by FDA are subject to refusal, FDA personnel may examine the background, risk, and purpose of the product before making a final decision. Although FDA may use discretion to allow admission of certain violative items, this should not be interpreted as a license to individuals to bring in such shipments.

Commercial or Promotional Shipments

Commercial and promotional shipments are not subject to these procedures. Whether or not a shipment is commercial or promotional may be determined by a number of factors including, for example, the type of product, accompanying literature, size, value, and/or destination of the shipment. FDA personnel may also consider whether an importation of drugs or medical devices is a commercial shipment by evaluating whether the article appears to have been purchased for personal use or whether the quantity suggests commercial distribution (i.e., the supply exceeds what one person might take in approximately three months). Commercial shipments generally include shipments other than those products that are personally carried, shipped by a personal non-commercial representative of a consignee, or shipped from a foreign medical facility where a person has undergone treatment.

Products Other than Drugs, Biologics, and Devices

Many products other than drugs, biologics, and devices that individuals seek to import in personal quantities do not pose a significant health risk although they appear to be violative and may be the subject of an import alert or detention without physical examination based on standards violations, filth, and/or labeling problems. When such items are brought to FDA's attention by CBP, it may be appropriate for FDA personnel to use their discretion to "Release with Comment" and advise the importer of the agency's concerns. FDA personnel should be alert to and should detain those products that do pose a significant health risk.

Drugs, Biologics, and Devices

When personal shipments of drugs, biologics, and devices that appear violative are brought to FDA's attention by CBP, FDA personnel will use their discretion to decide on a case by case basis whether to detain, refuse, or allow entry of the product. Generally, drugs, biologics, and devices subject to Import Alerts are not amenable to these procedures. Devices to be used by practitioners for treating patients should not be viewed as personal importations subject to this chapter.

Drugs subject to Drug Enforcement Administration (DEA) jurisdiction should be returned to CBP for handling.

In allowing personal shipments of drugs or devices, FDA personnel may consider a more permissive decision in the following situations:

1. When the intended use is appropriately identified, such use is not for treatment of a serious condition, and the product is not known to represent a significant health risk; or
2. When a) the intended use is unapproved and for a serious condition for which effective treatment may not be available domestically either through commercial or clinical means; b) there is no known commercialization or promotion to persons residing in the U.S. by those involved in the distribution of the product at issue; c) the product is considered not to represent an unreasonable risk; and d) the individual seeking to import the product affirms in writing that it is for the patient's own use (generally not more than 3 month supply) and provides the name and address of the doctor licensed in the U.S. responsible for his or her treatment with the product, or provides evidence that the product is for the continuation of a treatment begun in a foreign country.

If there are any questions about the application of these factors to any product, the product should be detained and FDA personnel should consult with the appropriate headquarters office.

When evaluating personal importations, FDA personnel may consider issuing a "Release with Comment" and, as appropriate, advise the recipient that

1. The drug (or device) that has been obtained for personal use appears to be unapproved in the United States;
2. The drug (or device) should be used under medical supervision;
3. FDA may detain future shipments of this product; and
4. The patient's physician should consider for example, enrolling the patient in an Investigational study or applying for Investigation New Drug (IND), Compassionate IND, or Treatment IND exemption.

IMPORT ALERTS

FDA personnel should recommend to OIO the issuance of an import alert if they encounter:

1. Personal importation of products that represent either a direct or indirect health risk; or
2. The promotion of unapproved foreign products for mail order shipment; or repeated importation of products that represent fraud*.

*See Compliance Policy Guides Manual (CPG), [120.500, "Health Fraud - Factors in Considering Regulatory Action."](#)

9-3 “NOTICE OF FDA ACTION – DETAINED” FOR MAIL SHIPMENTS

9-3-1 PURPOSE

To provide operating procedures for FDA personnel for:

1. The evidence to support a detention.
2. Preparation and issuance of the "Notice of FDA Action - Detained."
3. Charges under Section 801 or other Acts enforced by FDA, and, for administrative destruction, charges under other provisions of the FFDCA.
4. Hearing Process
5. Procedure after hearing

9-3-2 BACKGROUND

In developing FDA's automated import system, OASIS, the specific form "Notice of Detention and Hearing" has been replaced by the "Notice of FDA Action" with the description of the article sampled and the results of the examination indicating "Detained" for the specific article in the entry. For mail shipments, the use of the designation "DETAINED– Subject to Refusal", and for mail shipments containing drugs, "DETAINED – Subject to Refusal and Administrative Destruction," or similar wording may also be used to satisfy the requirements of the law for "giving notice thereof to the owner or consignee." See 21 USC 381(a).

The "Notice of FDA Action" gives notice of the right to a hearing on the detention for appearance of a violation, or for drugs subject to administrative destruction, a violation (21 CFR 1.94). In addition, the notice identifies charges that an import entry appears to violate, or violates the FFDCA, Public Health Service Act (PHS Act) or other acts enforced by FDA. Under the FFDCA section 801(a) an article subject to the FFDCA shall be refused admission if it appears from the examination or otherwise that

- (1) Such article has been manufactured, processed, or packed under insanitary conditions or, in the case of a device, the methods used in, or the facilities

- or controls used for, the manufacture, packing, storage, or installation of the device do not conform to the requirements of section 520(f), or
- (2) Such article is forbidden or restricted in sale in the country in which it was produced or from which it was exported, or
 - (3) Such article is adulterated, misbranded, or in violation of section 505. It also provides the owner or consignee with an opportunity to introduce testimony relative to the admissibility of the article.

Also, under the FFDCA section 801(a), as amended, FDA can destroy a drug that has been refused admission if the drug is valued at \$2500 or less (or such higher amount as the Secretary of the Treasury may set) and was not brought into compliance under Section 801(b). In addition, FDA intends to exercise its authority to destroy a drug that meets the statutory criteria for administrative destruction where the drug has also been determined to be adulterated, misbranded, or unapproved in violation of Section 505.

It should be noted that the Act does not provide specifically for the issuance of a notice charging that an entry of imported merchandise appears to be in violation. However, 21 CFR Section 1.94 provides that if it appears that an imported article may be subject to refusal of admission, the responsible FDA office shall give the owner or consignee a written notice to that effect.

Evidence Required for Detention

Every detention must be based upon evidence of a violation of the law(s) enforced by FDA. This does not mean that comprehensive examinations are required as a condition for detention, or that detention cannot be based upon very brief examinations if these are sufficient to furnish evidence creating the appearance of a violation, or a violation.

Furthermore, it is not essential that a detention invariably be based upon examination of a sample, as Section 801(a) of the FFDCA provides for refusal of admission if "it appears from the examination of such samples or otherwise" that the article is violative. However, in those cases in which detention is made without examination, there should be substantial evidence of a documentary type, (i.e., a violation in a previous shipment of the entered product from the same firm-see RPM subchapter 9-8 "Detention without Physical Examination" for additional procedures) to warrant a charge of violation.

FDA can destroy drugs refused admission, without the opportunity for export, that are valued at \$2500 or less and are adulterated, misbranded, or unapproved in violation of Section 505 of the FFDCA. The evidence supporting this determination must be collected and documented in OASIS by the Investigations Branch for review and evaluation by the Compliance Branch.

Issuance of Notice of FDA Action - Detained

The Notice of FDA Action - Detained provides a list of product being detained, and is addressed to the filer, the importer of record who is legally responsible for assuring

compliance with all laws and regulations affecting the importation of the merchandise in question, and consignee (if different from the importer of record). Copies should also be sent to whomever else was sent copies of the "Notice" for the sample collected. See RPM [subchapter 9-21 "Notice of Sampling"](#) for specific procedures on issuance of this notice.

Preparation of Charges

The statement of charges on the Notice of FDA Action - Detained issued for a detained product is the only information the importer has regarding the violation(s) or appearance of a violation(s) with which the importation is charged. It should be sufficiently informative and complete for the importer to understand clearly the apparent violation(s), or in the case of drugs subject to administrative destruction, the violation(s), so that the importer can prepare and introduce testimony.

A separate charge should be made for each apparent violation, or violation in the case of drugs subject to administrative destruction. See [Exhibit 9-5](#) to this chapter for charges used in OASIS. The charge should cite the section of the FFDC Act violated, quote the pertinent portion of that section, and make a brief statement of the specific way in which the product appears or has been determined to be in violation. Charges are drafted in accordance with Section 801 of the FFDC Act, stating "Examination of the following articles has been made and these articles are subject to refusal of admission into the United States because they do not appear to***" or for articles subject to administrative destruction "The article has been determined to be ***" (*** completed as appropriate for charge).

Under the OASIS procedure for issuing the Notice of FDA Action for a detained product, the individual responsible for the decision as to the compliance of the article will select the appropriate charge from the list of charges available in the OASIS system. The selected charge will be incorporated into the Notice of FDA Action, and the annotation required to specify the particular concern(s), where applicable, will be incorporated by the responsible FDA office. For example, if the article is being detained for the presence of a particular pesticide residue, FDA would annotate the charge provided by OASIS (using the narrative field) with the name of the specific pesticide residue found or alleged to be present.

See [Exhibit 9-6](#) example of the "Notice of FDA Action" issued under the OASIS which includes the identification of article(s) for detention.

Hearing Process for Mail Shipments

The owner or consignee is entitled to a hearing before FDA, in order to challenge the decision to refuse and/or destroy an article, as required by section 801(a) of the FFDC Act, or to provide testimony in support of admissibility of the article or to contest the administrative destruction of the article, as required by FDA regulation 21 CFR 1.94. It has generally been FDA's procedure to give the owner or consignee 10 working days following the date of detention shown on the notice (or longer if circumstances require a

longer time for response) to provide FDA with testimony or evidence. However, if for some compelling reason, the responsible FDA office determines that 10 working days is insufficient, such as inordinate mail delays due to holiday mailings, this time period may be extended. Introduction of testimony by the owner or consignee for Agency review and consideration can be submitted via multiple forms, including a telephone conversation, a facsimile, mail, email, or in person. Regardless of the way the testimony is introduced, the discussion and findings/outcome of the hearing should be sufficiently documented and stored by the Compliance Officer conducting the hearing. For example, the Compliance Officer should upload email correspondence or meeting minutes following a telephone conversation or in person interview into OASIS to support their final decision regarding the article's disposition.

For details on the eligibility of respondents see subsection [9-10-3](#); for hearings and postponements see [9-10-14](#); and for the conduct of a hearing, including personal appearance of respondent and written reply (mail, fax, etc.) from respondent, see subsections [9-10-5](#) and [9-10-6](#).

Procedure After Hearing for Mail Shipments "Refusal of Admission – Return to Sender" or "Refusal of Admission and Administrative Destruction"

If, after consideration of all evidence, the responsible FDA office determines that the articles are violative or appear to be violative, the articles may be refused admission. In this situation, FDA notifies the importer, owner, and consignee, where applicable, by issuing either a "Notice of Refusal of Admission – Return to Sender", or in the case of a drug valued at \$2500 or less a "Notice of Refusal of Admission and Administrative Destruction". On this Notice, FDA states the charge(s) exactly as shown on the original (or amended) Notice of FDA Action - Detained. (See RPM [subchapter 9-4 "Notice of Refusal of Admission and Administrative Destruction"](#) for procedures.)

After the article is refused admission, FDA has two options depending on the identity and value of the article. If the Compliance Officer has determined that the article 1) is a drug 2) is valued at \$2500 or less and 3) is adulterated, misbranded, or an unapproved new drug in violation of section 505 of the FFDCa, the refused product will be destroyed without providing the owner or consignee with the opportunity to export.

For all other articles, the refused article(s) are generally returned to sender. The FDA file for the import remains open until the article is either destroyed or exported.

Under the OASIS procedures for issuing the Notice of FDA Action - Refusal of Admission and Administrative Destruction, the notice will contain language...

Examination of the following articles has been made and you were given an opportunity to respond to a notice that the articles are subject to refusal of admission into the United States and subject to administrative destruction. FDA has determined that the articles are drugs that are not in compliance with the requirements of the law as indicated below. Further, FDA has determined that each article is valued at \$2500 or less. Because these drugs are not in compliance with

the requirements of the law and are valued at \$2500 or less, you are hereby notified that these articles will be destroyed by FDA in accordance with the FD&CA.

9-4 NOTICE OF REFUSAL OF ADMISSION AND ADMINISTRATIVE DESTRUCTION FOR MAIL SHIPMENTS OF DRUGS

9-4-1 PURPOSE

To provide operating procedures for issuing the Notice of Refusal of Admission and Administrative Destruction when refusing a drug valued at \$2500 or less.

At this time, FDA is using its destruction authority on those refused drugs valued at \$2,500 or less (or such higher amount as the Secretary of the Treasury may set by regulation) that are being imported via international mail. However, any refused drug that meets the criteria for administrative destruction may be destroyed regardless of the manner in which it is being imported or offered for import into the U.S. FDA management for the responsible office should be made aware if administrative destruction is appropriate for any such drug that is not being imported via international mail.

9-4-2 BACKGROUND

In 2012, Congress amended section 801(a) of the FFDCA (21 U.S.C. 381(a)) to provide FDA with the authority to destroy a refused drug valued at \$2,500 or less (or such higher amount as the Secretary of the Treasury may set by regulation) after providing the drug's owner or consignee with notice and an opportunity to present testimony to the Agency prior to the drug's destruction. This authority allows FDA to destroy such a drug without providing the owner or consignee with the opportunity to export the drug. The agency has decided to exercise this authority only after FDA makes a determination that a drug that has been refused admission is valued at \$2500 or less and is adulterated, misbranded, or unapproved in violation of Section 505 of the FD&CA, and was not brought into compliance as described in Section 801(b).

9-4-3 ISSUANCE OF NOTICES

Who Should Issue the Notice of Refusal of Admission and Administrative Destruction?

The language of the law places the responsibility for issuing the Notice of Refusal of Admission upon the Secretary of the Treasury who in turn has delegated this responsibility to the CBP. Traditionally, the Notice of Refusal of Admission is issued by the responsible FDA office over the facsimile signature of the Regional or District Director of CBP in accordance with local agreement. Each FDA office shall have the pertinent facsimile stamp of the signature of the Regional or District Director of CBP prepared for this purpose and supplied to the appropriate personnel, or have written delegation of authority from the District Director of CBP to issue the Notice of Refusal of

Admission under FDA personnel signature. A new stamp should be prepared each time there is a change of personnel in the Regional or District Director of CBP position.

When Should the Notice of Refusal of Admission and Administrative Destruction be Issued?

The Notice of Refusal of Admission and Administrative Destruction should be issued after an owner or consignee is given the opportunity to introduce testimony in response to a Notice of FDA Action – Detained and, after a hearing relative to the validity of the charges for detention, the hearing officer decides that the articles are in violation, or when no response to a Notice of FDA Action - Detained is received within the specified ten day time frame (excluding Saturdays, Sundays, and holidays) and an extension of time for responding has not been granted. Additional time may be noted due to circumstances affecting FDA operations.

A Notice of Refusal of Admission and Administrative Destruction should only be issued when:

- The product is a drug
- The product is valued at \$2,500 or less
- The product is adulterated, misbranded, or an unapproved new drug in violation of Section 505 of the FFDCA

AND

- A response to a Notice of FDA Action - Detained is not received within the specified 10 day time frame (excluding Saturdays, Sundays, and holidays) and an extension of time for responding has not been granted. (Additional time may be noted due to circumstances affecting FDA operations), or
- After a hearing relative to the validity of the charges for detention, the hearing officer decides that the articles are in violation.

Distribution of the Notice of Refusal of Admission and Administrative Destruction

The Notice of Refusal of Admission and Administrative Destruction is issued to the importer of record (who is the same person or firm who was issued the Notice of Sampling). All persons or firms who are sent copies of the Notice of Sampling and Notice of FDA Action - Detained must also be sent a copy of the Notice of Refusal of Admission and Administrative Destruction.

CBP and USPS will be periodically notified by FDA of all lines of drugs valued at \$2500 or less which are subject to refusal and destruction pursuant to section 801(a) of the Act, as amended. For additional procedures see the International Mail Facility (IMF) SOP, available on the OIO Program Resources International Mail Facilities intranet page.

Charges on the Notice of Refusal of Admission and Administrative Destruction

The individual violations on a Notice of Refusal of Admission and Administrative Destruction should be stated exactly as shown on the Notice of FDA Action - Detained. If it becomes necessary to include new or amended charges on a Notice of Refusal of Admission and Administrative Destruction, an amended Notice of FDA Action - Detained must first be issued providing another ten day period (excluding Saturdays, Sundays and holidays or additional time when appropriate) for an opportunity for hearing.

When to close the entry

After issuance of the Notice of Refusal of Admission and Administrative Destruction, the entry should be kept in an open status until the final disposition takes place at the IMF and the product is placed into a locked drum for destruction. The Drum ID # should be entered into OASIS before the entry is closed.

9-5 IMPORTATION OF BIOLOGICAL PRODUCTS

RPM subchapter 9-3, Importation of Biological Products was removed in January 2008 per CBER request. For procedures regarding the importation of biological products, FDA staff responsible for imports of biological products should contact OIO or refer to [Importing CBER-Regulated Products into the United States](#) for links to CBER's Import Compliance Programs (CPGM 7342.007 Imported CBER-Regulated Products; CPGM 7342.007 Addendum, Imported HCT/Ps).

9-6 FDA NATIONAL IMPORT PROCEDURE REGARDING WAREHOUSE ENTRIES

9-6-1 PURPOSE

To provide operating procedures regarding submission of entry notification to FDA by Customs for importers filing warehouse entries.

9-6-2 BACKGROUND

When a product is imported into the United States, the Importer of Record (Importer) must file entry paperwork with the U.S. CBP. The importer may choose to file a consumption entry, pay any applicable duty, and introduce the product into domestic commerce. Alternatively, the importer may file a warehouse entry, store the product in a bonded warehouse for up to five years, and pay duty only when the product is withdrawn for domestic commerce (withdrawal for consumption). If the importer exports the product while it is under bond, no duty is incurred.

There have been several instances where importers have questioned FDA's authority over, or right to see paperwork for, FDA regulated product covered by warehouse entries and intended for later export rather than domestic consumption.

Any product brought into the United States from a foreign country is "imported" and, therefore, subject to the import provisions set forth in section 801 of the FFDCA. Thus, all importers, including those filing warehouse entries, are subject to section 801 procedures, regardless of whether the intent is to later export the imported products. See also [Compliance Policy Guide \(CPG\) Sec. 110.200, "Export of FDA Regulated Products From U.S. Foreign Trade Zones."](#)

9-6-3 INSTRUCTIONS

To fulfill its obligation to ensure that regulated products comply with the requirements of the FFDCA, FDA should receive notification either electronically or by paper, no later than the time the warehouse entry is filed with CBP.

9-7 RELEASE NOTICES

9-7-1 PURPOSE

To provide operational procedures for releasing imported lots for which a Notice of Sampling has been issued.

9-7-2 BACKGROUND

The FFDCA, and its regulations directs that a notice (Notice of Sampling) shall be given to the owner or consignee of imported merchandise sampled or intended to be sampled under the authority of the Act. The regulations also require the issuance of a further notice to advise the owner or consignee of the result of examination of the sample, for which a Notice of Sampling has been issued [21 CFR and 1.90]. The Release Notice advises the owner or consignee that the merchandise need not be further held insofar as the FDA is concerned.

9-7-3 GENERAL COMMENTS

Release Notice Form, or computer generated notice from OASIS, is issued by FDA under the signature of the compliance officer or designated individual authorized by OIO to sign the notice, whenever FDA has no further interest in a lot for which a Notice of Sampling (or computer generated notice from OASIS) has been issued.

The Release Notice is routinely issued to the importer of record with a copy to CBP and the responsible FDA fiscal office and file. In accordance with local practices, copies may also be sent to the customhouse broker and the consignee when either is not named as the importer of record. In any case, all persons who are issued a Notice of Sampling should also be sent the Release Notice.

To meet the various circumstances surrounding a release, the following variations of the Release Notice are currently used:

- "Straight" Release
- Release without Examination
- Release with Comment
- Release after Detention

9-7-4 "STRAIGHT" RELEASE

This release form (or the computer generated notice from OASIS) is issued whenever it appears, from sample examination or otherwise, that merchandise, for which a Notice of Sampling has been issued, is in compliance with the law.

Examples of OASIS Release Notices will be provided at a later date.

9-7-5 RELEASE WITHOUT EXAMINATION

Whenever a sample cannot be examined, for which a Notice of FDA Action/Sampling has been issued; a Notice of FDA Action/Release Notice form as identified in [Exhibit 9-6](#) or the computer generated notice from OASIS is issued amended as follows:

"RELEASED WITHOUT EXAMINATION
MAY PROCEED WITHOUT FDA EXAMINATION ON THE RESPONSIBILITY
OF THE IMPORTER"

This statement is typed in caps following the blocked information on the notice. An example of the OASIS form will be provided at a later date.

9-7-6 RELEASE WITH COMMENT

Background

It had been the practice when an importation was encountered which did not fully comply with the requirements of the Act, but the violation was not of sufficient importance to warrant detention of the initial importation, to release the shipment with a "Release with Warning" that future similar violative importations might be denied entry. Although these "Releases with Warning" did not necessarily mean that the correction had to be made before the next importation, that frequently was the intent. The brevity of the warning often gave such notices an unintentional air of curtness.

Therefore, the "RELEASE WITH WARNING" and "RELEASE WITHOUT PREJUDICE" has been replaced with a "RELEASE WITH COMMENT" as a more flexible means of handling minor violations.

Approach

When an importation is encountered which does not fully comply with the requirements of the Acts which we enforce, but the violation(s) is (are) not sufficient to warrant detention on a first encountered basis, it may be "Released With Comment." The violation(s) must be minor, since a shipment with serious infraction(s) should be detained. For example, if an FPLA violation which is not considered subject to NLEA concerns is encountered in a product this shipment may be "Released With Comment." However, if the importer or country of origin has already received "notice" of our FPLA labeling requirements, the shipment may be detained.

A standard Release Notice is used with a notation "Release With Comment" prominently shown immediately following the blocked information on the notice. The comments may be placed directly on the Release Notice if sufficient space is available or, on an attached letter. If a letter is used, it should be stapled to the Release Notice and referred to in the body of the Form, i.e. "Release With Comment, See Attached Letter of (date)." An example of a "Release With Comment" is shown as [Exhibit 9-6](#) examples of OASIS Release With Comment notices will be provided at a later date.)

The violations on which the comments are based should be clearly covered by the Acts or regulations which we enforce. The comments should be stated in nonlegal language with reference to the specific sections of the Acts or regulations involved.

Generally, the Release With Comment should not be used if the problem is one commonly existing in domestic commerce and against which no FDA objection has been made. Center non-concurrence of detention recommendations that indicate non-agency support of similar domestic violation and past policy procedures with both domestic and imported products will serve as guide.

If the violation is clearly absent from similar domestic products, prompt correction should be requested by including the statement "Future shipments may be detained unless (nature of violation, i.e. misbranding) is corrected." By omitting this statement, the comments would serve as an information guide to provide a better understanding of the requirements of the law.

Before issuing a Release With Comment that includes a statement that future shipments may be detained we must be in a position to take action. However, other shipments that may be enroute at the time the comment issues or within a time frame established for correction to be completed may be allowed to proceed if otherwise in compliance.

A statement on the Release Notice should be included directing the importer to advise the foreign manufacturer/shipper of our comments when applicable. A copy of this letter should be requested for the FDA file.

9-7-7 RELEASE AFTER DETENTION

Release after detention is issued in the following situations:

1. After the issuance of the Notice of FDA Action - Detained (or computer generated notice from OASIS) the importer of record or other designated agent may present testimony which shows that the merchandise is in compliance.
2. In response to the Notice of FDA Action - Detained, the importer of record reconditions the merchandise to FDA's satisfaction pursuant to the terms of the Application for Authorization to Relabel or Recondition Non-Compliant Articles ([Form FDA-766](#)), or else causes it to be brought outside the jurisdiction of the Act. The latter situation can occur, for example, when an importer diverts insect-adulterated, food-grade starch to industrial uses (paper manufacturing, etc.).

Under these situations, a Release Notice is issued with a notation "ORIGINALLY DETAINED AND NOW RELEASED" prominently shown following the blocked information or as appropriately set from the computer generated notice. If the merchandise has been reconditioned, the fact of this reconditioning should also be shown on the notice including the loss (if any) during reconditioning, reject material, the disposition of reject material, and amount of acceptable material. If supervisory charges are also involved, the notice should also bear the statement "Subject to bond liability for charges in connection with reconditioning."

9-8 DETENTION WITHOUT PHYSICAL EXAMINATION (DWPE)

9-8-1 PURPOSE

To provide operating procedures regarding:

- Authority
- Criteria for recommending action
- Procedure for recommending action
- Criteria for recommending removal of action
- Procedure for notification of removal

9-8-2 AUTHORITY AND BACKGROUND

Section 801(a) of the FD&C Act states, "If it appears from the examination of such samples or otherwise that (1) such article has been manufactured, processed, or packed under insanitary conditions . . . or the facilities or controls used for the manufacture, packing, storage, or installation of the device do not conform to the requirements of Section 520(f), or (2) such article is forbidden or restricted in sale in the country in which it was produced or from which it was exported, or (3) such article is

adulterated, misbranded, or in violation of Section 505, then such article shall be refused admission."

Congress authorized FDA to refuse admission of regulated articles based on information, other than the results of examination of samples, that causes an article to appear to violate the FD&C Act.

Information such as an article's violative history, among other things, may cause an article to appear adulterated, misbranded, or otherwise in violation of the FD&C Act, as described in Section 801(a).

Section 801 of the FD&C Act explicitly authorizes FDA to refuse admission of articles that appear to violate the Act.

That section also provides the importer with the right to "introduce testimony bearing on the admissibility of the articles." To carry out the provisions of Section 801(a), FDA detains an article that appears violative and provides notice to the importer of the nature of the violation and the right to present testimony regarding the admissibility of the article (21 CFR 1.94). Depending on the information submitted by the importer, the article may either be admitted or refused entry into the United States.

Detention without physical examination (DWPE), first used by FDA in 1974, is appropriate when there exists a history of the importation of violative products, or products that may appear violative, or when other information indicates that future entries may appear violative. DWPE has the effect of reminding the importing community that FDA is a regulatory agency, not a quality control laboratory. Often, importers wait until the Agency has issued a Notice of FDA Action - Detained to determine whether the articles they are offering for import comply with the FD&C Act. DWPE properly places the responsibility for ensuring compliance with the law on the importer.

9-8-3 GENERAL PROCEDURES

Any FDA unit may recommend detention without physical examination or removal from detention without physical examination when it believes that such action is warranted. Such recommendations are submitted with supporting data and/or information to the OIO/DIO's Import Compliance Branch via FDA's Compliance Management Services (CMS) system.

Supporting information should include an analytical package, inspection report, or other supporting evidence, and documentation of center concurrence when no direct reference authority exists.

DWPE may also be recommended on the basis of analyses performed by state or local agencies where FDA has determined that the sampling and testing conducted by such agencies is accurate, acceptable and representative of the product on which the recommendation is based.

For analytical findings for which direct reference authority for addition to DWPE has been granted from a center to ORA, FDA import divisions have the discretion to consider placing future shipments coming through their ports from a particular packer, manufacturer or shipper, under detention where a recommendation for DWPE has been submitted for OIO/DIO concurrence, but has not yet been approved. Shipments of this nature do not require additional sampling.

9-8-4 RECOMMENDATIONS INVOLVING PESTICIDE RESIDUES

The Center for Food Safety and Applied Nutrition (CFSAN) will be responsible for review and concurrence of DWPE recommendations involving pesticide residues for which no tolerance has been established.

Recommendations for DWPE due to pesticide residues for which there is an established tolerance should be submitted directly to OIO.

9-8-5 DIRECT REFERENCE AUTHORITY RECOMMENDATIONS

Certain recommendations for DWPE are assumed to have appropriate Center concurrence. These direct reference authorities are memorialized in [Compliance Policy Guides \(CPG\)](#), [Compliance Program Guidance Manual](#) chapters, memoranda from the Center, or other appropriate documents (e.g. [CFSAN delegations](#), etc.).

If direct reference authority has been granted for a particular situation, recommendations for addition to DWPE will not require Center review or evaluation of the analytical worksheets for the violative product.

9-8-6 RECOMMENDATIONS BASED ON EIRs, OTHER GOVERNMENT AGENCIES, MOUs, ETC.

RECOMMENDING OFFICE RESPONSIBILITIES

When inspections conducted by FDA or by foreign or other government competent authorities under a Memorandum of Understanding (MOU) or other agreement reveal conditions or practices warranting DWPE, the recommending office should submit a recommendation to OIO/DIO Import Compliance Branch subjecting product(s) offered for import to DWPE. The responsible recommending office should submit the recommendation to OIO/DIO Import Compliance Branch within fifteen (15) working days of endorsing the report of conditions or practices warranting DWPE.

When the responsible recommending office is satisfied that the appearance of a violation has been overcome, either by re-inspection or submission of appropriate documentation, the recommending office will submit a recommendation to OIO/DIO Import Compliance Branch to remove the DWPE action. The responsible recommending office should submit a recommendation to OIO/DIO Import Compliance

Branch within fifteen (15) working days of the receipt of evidence to overcome the conditions or practices warranting DWPE.

OIO RESPONSIBILITIES

OIO/DIO Import Compliance Branch is responsible for reviewing DWPE recommendations to ensure that actions are timely and that the Import Alert additions and removals are handled appropriately.

When a recommendation for DWPE is received, OIO/DIO Import Compliance Branch will review the recommendation along with the supporting evidence and then review national detention data (if necessary) to determine whether the criteria for DWPE has been met.

Packages, for Import Alert(s) or revised Import Alert(s) consideration/implementation, will be coordinated for agency clearance by OIO/DIO. (See RPM [subchapter 9-15, "Import Information Directives"](#) for clearance procedures).

FDA's Compliance Management Services (CMS) system serves as the central repository for all DWPE evidence.

9-8-7 DETENTION WITHOUT PHYSICAL EXAMINATION RECOMMENDATIONS

A recommendation for DWPE consideration should be submitted whenever there is information that would cause future shipments of a product(s) offered for entry to appear violative within the meaning of Section 801(a) of the Act. The recommendation may be based on the violative history of a product, manufacturer, shipper, grower, importer, geographic area, or country. The recommendation may also be based on other information, such as information that food offered for entry was harvested from polluted waters, information that a product was manufactured, processed, packed, or held under insanitary conditions or manufactured in a manner that is non-compliant with Good Manufacturing Practice (GMPs), pursuant to Section 801(a) of the Act. A product, firm, shipper, etc., may also be subjected to DWPE because the product is forbidden or restricted for sale in the country in which it was produced or from which it was exported; adulterated, misbranded, or in violation of Section 505 (unapproved new drug); or appears violative as set forth in Section 536(a). A DWPE may be recommended for an article with no prior history of detentions if the recommendation is adequately supported by information that indicates that future shipments may be violative.

9-8-8 RECOMMENDATIONS BASED ON ONE VIOLATIVE SAMPLE

Under this circumstance, FDA has evidence that at least one sample has been found violative and the violation represents a potentially significant health hazard. The sample collection and/or analysis may have been conducted by FDA or another reputable Federal, State, or local agency.

In the following instances, one violative sample, collected while a product is in import or domestic status, may support a recommendation for DWPE of products from a specific manufacturer, shipper, grower, or from a specific growing area or country (if information is sufficient to establish an appearance that the violation extends to that area/country):

1. The product may have adverse health consequences. The appropriate Center, in most instances, would conclude that the problem would warrant a Class I or Class II recall.
2. The product (fresh, frozen, or processed) contains actionable levels of a pesticide residue, aflatoxin, or chemical contaminant.
3. The product is a violative low acid canned food, or acidified food. (i.e., failure to have a process on file for a specified product or no registration).
4. The product is violative in a way that is likely to continue due to the product's ingredients or formulation. For example, products which bear or contain undeclared significant ingredients (i.e., human allergen), unapproved colors, or violate their applicable standard of identity, or products that are unapproved new drugs, or unapproved new animal drugs, will continue to appear violative until the manufacturer of such products changes the label or formula for the products or obtains agency approval necessary for legal marketing.
5. The product is a post amendment device that is not subject to an approved 510(k) or premarket approval application. A copy of the recommendation should be sent for concurrence to the Center for Devices and Radiological Health (CDRH), Office of Compliance.
6. The product's labeling is violative and/or not in accordance with the Nutritional Labeling and Education Act (NLEA) and such violation is likely to continue until said labeling is corrected by the manufacturer. (See CFSAN Compliance Program for specific procedures).

Recommendations for DWPE based on one violative sample should include documentation of Center concurrence, if such concurrence is required.

Center concurrence is not necessary when the action is covered by direct reference authority, as indicated by, among other things, a [CPG](#). Recommendations should also include a copy of the analytical package.

9-8-9 RECOMMENDATIONS BASED ON INFORMATION AND HISTORICAL DATA

When there is evidence that a product from a specific geographical area or country could pose a health hazard, the appropriate Center or ORA office should recommend DWPE. In such cases, where there is also information that the product is likely to continue to be violative, it may not be necessary to collect and analyze a physical sample.

DWPE may be recommended for products offered for import from a manufacturer, shipper, grower, geographical area, or country based on information showing a pattern of importation of articles that violate the FD&C Act. The information in the recommendation establishing a pattern of continuous violations of the FD&C Act should indicate that actions necessary to remove such violations have not been taken. In such cases, the procedures outlined immediately below would not necessarily apply. Center concurrence is, however, necessary in this situation.

9-8-10 RECOMMENDATION BASED ON MULTIPLE SAMPLES

Recommendations for DWPE based on multiple samples showing violations of the Act should include documentation of Center concurrence with the recommended detentions, or copies of analytical packages if Center concurrence is not required, i.e., where direct reference authority is applicable.

Recommendations for detention without physical examination may be submitted for:

1. Specific product(s) from an individual manufacturer or shipper for violations that do not pose a significant public health hazard, such as decomposition, filth, labeling, etc., when:
 - a. There have been at least three (3) detentions in a recent six-month period or less; and
 - b. These detentions represent at least 25% of the total shipments of that product examined in the applicable time period as known to the recommending office or unit.
2. Specific product(s) from a country or a specific geographic area when:
 - a. There are at least twelve (12) detentions in a recent six-month period or less; and
 - b. These detentions represent at least 25% of the total shipments of that product examined in that time period as known to the recommending office or unit; and
 - c. These detentions represent a significant number of firms that manufacture, ship, or grow the product from the geographic area or country.
3. Multiple products from a manufacturer or shipper when:
 - a. There are at least six (6) detentions in a recent six-month period or less; and
 - b. These detentions represent a variety of products and constitute at least 25% of the total shipments examined from that firm during the applicable time period as known to the recommending office or unit.

FDA may consider additional information in conjunction with sample analysis when considering whether to recommend products from a manufacturer, shipper, geographic

area, or country for DWPE, such as the results of foreign inspections or the other types of information discussed in this chapter.

9-8-11 DETENTION WITHOUT PHYSICAL EXAMINATION OF IMPORTERS ENTRIES

Importers bear the primary responsibility for ensuring that products they import comply with all provisions of the FD&C Act. To carry out this responsibility, they may choose to inspect the foreign manufacturers or growers of products that they import, to enter into agreements with foreign exporters, to make arrangements to have products privately examined and analyzed prior to importation, and/or to take other steps to verify proper labeling and compliance of products with the FD&C Act before offering them for distribution into U.S. commerce.

If the responsible FDA offices have documented an importer's practice of repeatedly offering violative articles for importation and attempting to recondition such shipments only after FDA detention, or of repeatedly attempting to export shipments or withdraw entries after receiving a notice of sampling or other indication of FDA interest (e.g., inquiries regarding product location), DWPE should be recommended covering either specific commodities or all FDA regulated products offered for entry by that importer, as warranted.

DWPE should also be recommended if there is other persuasive evidence that future shipments by an importer may be violative. For example:

1. Information received from other government agencies (e.g. U.S. CBP) concerning violative practices by the importer or the importer's foreign suppliers that would cause the articles to appear violative under section 801(a) (e.g., misdeclaration of products to avoid detention without physical examination);
2. A documented history of attempted importation of violative articles that has resulted in the issuance of a Warning Letter to the importer with no subsequent response from such importer or which does not result in the correction of such practice;
3. Verifiable information in the form of consumer or trade complaints, or otherwise, that has the effect of causing the articles offered for import to appear adulterated, misbranded, or otherwise in violation of the FD&C Act as specified in Section 801(a). This information may include repeated requests for notices of refusal or attempts to cancel or export an entry after receiving a notice of sampling or other indication of FDA interest.

Based on a review of detention data, the responsible FDA office may recommend that an importer be placed on detention without physical examination when the importer exhibits a high percentage of violations of a single product, a group of products, or all products. All such recommendations, formatted as Import Alerts, should be submitted to OIO for clearance. Each recommendation should include suggested charges; however, final charges to be used will be determined by the appropriate Center with input from the FDA Office of the Chief Counsel (OCC) as needed.

9-8-12 RECOMMENDATIONS BASED ON ESTABLISHMENT INSPECTION

Establishment inspections of foreign manufacturers of FDA regulated products that reveal significant deviations from GMPs, insanitary conditions, or other practices that result in the articles manufactured at such facilities appearing to be misbranded, adulterated, or otherwise in violation of the FD&C Act as described in Section 801(a) should result in the recommendation of DWPE of the articles offered for import from such manufacturer. Foreign manufacturers of FDA regulated products who refuse to permit or delay FDA establishment inspection may be subjected to DWPE (see FFDCA 807(b) (foods); FFDCA 501(j) (drugs, medical devices); and 21 CFR 820.1(d) (medical devices)). The recommending office should identify the scope of the recommended action based upon review of the establishment inspection report or other evidence.

The instances of DWPE described above may identify one firm, multiple locations of a firm, or specific products from one or more firms as appropriate. The criteria for determining whether to subject a manufacturer's or importer's articles to DWPE may differ from Center to Center. The recommending office should consult with the appropriate Center or ORA counterpart when making a recommendation for DWPE following FDA inspections of foreign manufacturers.

9-8-13 OTHER SITUATIONS

In cases other than those described above, a recommendation may be made for DWPE if there is a reason to believe, and evidence to support, that future shipments of a product or class of products will appear violative within the scope of Section 801(a).

9-8-14 PARTY NOTIFICATION OF DETENTION WITHOUT PHYSICAL EXAMINATION DECISION

The FDA will notify different parties regarding the application of DWPE depending on the nature and scope of the action. In most instances, a copy of the Import Alert will suffice for notification. FDA notification of DWPE actions should be directed to:

1. National CBP, or other federal agency enforcement branch
2. Local office of CBP (by each appropriate FDA office when necessary)
3. Appropriate foreign embassy or foreign government, (by the Office of International Programs, OC or the appropriate ORA International liaison)
4. Importer/broker associations, as appropriate (by OIO/DIO)
5. Specific foreign manufacturers or shippers, as appropriate (by CFSAN - LACF/AF; CDRH - 510(k), PMA, GMPs; by CDER - pre-approval NDAs, GMPs; by CVM - pre-approval NADAs, GMPs; by CBER - license revocation)

If notification of the specific foreign manufacturer or shipper is deemed impractical or impossible due to incomplete information, distance, communication difficulties, etc., notification should be sent to the importer, requesting transmittal of the notification to the foreign manufacturer and requesting a response to include what steps were taken to correct the conditions which brought about the detention without physical examination.

6. Industry associations as appropriate (by Centers).

9-8-15 REMOVAL FROM DETENTION WITHOUT PHYSICAL EXAMINATION

FDA decisions to remove a product, manufacturer, packer, shipper, grower, country, or importer from DWPE should be based on evidence establishing that the conditions that gave rise to the appearance of a violation have been resolved and the agency has confidence that future entries will be in compliance with the FD&C Act.

When applicable OIO/DIO shall consult with the appropriate FDA office regarding a proposal to remove a firm or product from DWPE. A recommending office may also contact OIO/DIO directly and recommend a firm and or its product(s) no longer be subject to DWPE under a specific Import Alert. An important element of FDA's decision to remove a product, manufacturer, packer, shipper, grower, country, or importer is the extent to which the evidence shows that future shipments will be in compliance with the FD&C Act and implementing regulations.

Evidence establishing that the conditions that gave rise to the appearance of a violation have been overcome may take different forms depending upon the nature of the violation and evidence supporting DWPE for the product:

- If a product has been placed on DWPE because it appears violative under Section 801(a)(1) as the result of adverse findings from an establishment inspection, FDA may require an establishment inspection which demonstrates the firm has adequately addressed their violative conditions before removal from DWPE.
- If a product has been placed on DWPE because it appears violative under Section 801(a)(2), documentation that a product is no longer forbidden or restricted for sale from the government of the country in which it was produced or from which it was exported may be required before removal from DWPE.

FDA may require the manufacturer to submit a description of actions taken to prevent the problem from recurring (such as results of a root cause analysis identifying the source of the violation and a description of corrective actions implemented) before removal from DWPE.

- For those products identified for DWPE because they appear to be violative under Section 801(a)(3), in addition to the actions taken to prevent the problem from recurring as described above, a minimum of five (5) consecutive non-violative commercial shipments may be required to confirm the continued effectiveness of any corrective actions before the agency can consider that the appearance of the violation has been overcome, and that it may be appropriate to remove the DWPE. In some instances, more than 5 consecutive non-violative shipments may be needed.

- Shippers are typically placed on DWPE when the true identity of the manufacturer of the product that appears violative cannot be determined. Therefore, if after a six-month period a shipper subject to DWPE has not offered for entry any shipment that is violative and can provide documentation to FDA indicating the steps taken to ensure that the shipper does not offer for entry, articles that do not comply with the FD&C Act, the shipper may be removed from DWPE. However, if the manufacturer of the violative product is subsequently identified, removal of such product from DWPE should be based on specific information that overcomes the appearance of a violation and should be submitted by the manufacturer, and not by the shipper.

NOTE: FDA may audit these entries to ensure the validity of the analysis.

However, depending on the nature of the apparent violation, a proper registration, scheduled process filing, 510(k) substantial equivalence order, Premarket Approval Application (PMA), NDA or NADA, re-inspection, or other documentation may be necessary before the appearance of a violation is overcome and the DWPE is removed.

If during the review to determine whether the appearance of a violation has been removed an apparently violative entry is offered, the review process may be discontinued until information is submitted to show that the problem has been corrected.

Under some circumstances, more than the minimum number of in compliance consecutive shipments may be necessary to establish that the violative practices or conditions have been fully resolved. For example, a shipper, grower, etc., who after being removed from DWPE once again begins to ship the same type of violative products, may need to present more than five (5) consecutive non-violative shipments to remove the appearance of a violation and to be considered for removal from DWPE. When there is a continued history of entry of the same non-compliant product(s), documentation showing that the cause of the violation has been fully corrected may also be necessary.

Splitting shipments into several entries or lines should not be considered as a means to increase the number of non-violative shipments. FDA needs to be confident that articles offered for importation are in compliance not just on one day, but over the course of a reasonable time period. Otherwise, such articles will continue to APPEAR violative. If there is reason to conclude that two or more entries (or lines) represent a single related shipment or lot, these should be considered to be a single shipment.

Shipments should represent routine commercial entries, and should not be divided or staged, such that they are presented essentially to establish a pattern of compliance. Shipments that consist of less than 10 to 15 cartons, which do not represent normal industry practice (e.g., unless the product is a high value commodity normally shipped in smaller quantities such as specialty cheese, etc.), may not be considered in the DWPE removal process. FDA needs to be certain that adequate product is available for representative sampling and private laboratory analysis, as well as for possible audit

sampling by FDA. (Refer to [ORA Laboratory Procedures Manual](#) (LM), [Volume III, Section 7](#) for procedures regarding private laboratories). The Office of Regulatory Science (ORS) should be contacted regarding the acceptance/non-acceptance of laboratory data.

Shipments presented for consideration for removal from DWPE should be in compliance with the FD&C Act or other statutes enforced by the Agency. Special situations may occur in which data presented may not conclusively demonstrate full compliance of the entry with the FD&C Act. In such situations, FDA staff may have additional evidence which, while allowing the shipment to be removed from DWPE, may still preclude the shipment's release.

9-8-16 REMOVAL OF PRODUCTS MANUFACTURERS/COUNTRIES EXCEPT FRESH PRODUCE

Recommendations for removal from DWPE should be forwarded to OIO/DIO Import Compliance Branch for review when documentation establishes that the appearance of a violation has been removed. The recommendation should identify the entry numbers that have been analyzed or examined and found to be in compliance. In addition, other documentation may be necessary to verify that violative conditions no longer exist, e.g., product formulation information, information establishing label revisions, information showing a change in the use of food or other chemical additives, etc. The following guidelines should also be met:

1. Specific products from an individual manufacturer - the last five shipments have been documented to be in compliance with the FD&C Act.
2. Specific products from a country or a specific geographic area - the last twelve (12) shipments have been established to be non-violative. These twelve shipments should include a representative number of manufacturers/shippers from the geographic area or country offering the products for entry.
3. Multiple products from a specific manufacturer - the last twelve (12) shipments have been established to be non-violative. These twelve shipments should represent the range of products normally entered by the firm or each of the products covered by the detention without physical examination if only specific products are listed.

NOTE: For detentions without physical examination based on country or geographic problems with a product, shippers should not be removed from detention without physical examination. Shippers should ensure that the manufacturer of the articles they import is shown on entry documents so that FDA can determine whether the manufacturer has corrected the Problem(s) with the Products.

9-8-17 REMOVAL OF FRESH PRODUCE

Chemical Contamination:

Recommendations to remove fresh produce from detention without physical examination for chemical contamination may be made by the responsible FDA office upon consideration of all relevant information and criteria. OIO/DIO Import Compliance Branch should be notified of all such recommendations.

Pesticides:

Once an illegal pesticide residue has been found, past experience has shown that future shipments of the affected food may likely contain the illegal residue(s) throughout the growing and shipping season, or longer. FDA, or other interested party, may recommend removal of a grower from DWPE when the grower has entered a minimum of five (5) consecutive recent shipments without violation and when:

1. The grower demonstrates through adequate documentation that the residue problem no longer exists;

OR

2. The country/grower/importer demonstrates through adequate documentation that each lot of produce to be offered for entry originated in fields that were not treated with the pesticide in question;

OR

3. Information is obtained demonstrating that the produce originated in untreated fields, including documentation on the types of pesticides used in the surrounding fields, the dates and method of pesticide application, and the results of analyses from a representative sampling of the allegedly untreated field or lot (i.e., along borders and mid section) showing that the product from the implicated field is in compliance;

OR

4. Information is obtained on the steps that have been instituted to prevent the occurrence of illegal pesticide residues in future shipments.

Recommendations to remove a product or firm from DWPE may be made at any time if supported by information that demonstrates that detention without physical examination is no longer warranted.

FDA may end the detention without physical examination after one year of the effective date if:

- There is a clearly defined growing season, and
- It is not a recurring problem, and
- There is an adequate program (having government support) set up to monitor and address the problem, and

- Evidence has been received which demonstrates that the problem no longer exists. OIO will monitor import alerts concerned with the detention without physical examination of fresh produce to assure that an assessment is made by the responsible FDA offices and/or headquarters as to whether to remove or continue the detention without physical examination of a product/grower after its anniversary date.

9-8-18 REMOVAL OF IMPORTERS

If an importer has been placed on detention without physical examination for the first time for a specific product, a recommendation for removal may be appropriate after the importer supplies acceptable documentation that the last five (5) shipments of that product from a specific manufacturer entered in full compliance with the FD&C Act.

If the importer has been placed on detention without physical examination for the first time for multiple products, a recommendation for removal may be appropriate after that importer supplies acceptable documentation that the twelve (12) most recent entries were in full compliance. The twelve (12) entries should represent the range of products covered by the detention without physical examination and normally entered by the importer.

If an importer is on detention without physical examination and it is not the first time, a recommendation for removal may be appropriate after that importer supplies acceptable documentation that the ten (10) most recent entries were in full compliance, in the case of a specific product, or the last twenty-four (24) entries, in the case of multiple Products.

In addition, a request from an importer that he or she be removed from detention without physical examination should include in sufficient detail, the steps that he or she has taken to prevent the entry of products that appear violative in the future.

9-8-19 REMOVAL BASED UPON AN ESTABLISHMENT INSPECTION

Firms or products placed on DWPE based on a violative establishment inspection, or because the products appear to have been manufactured in violation of GMPs, may generally be removed from DWPE following a reinspection which in some instances may be performed by a reliable entity other than the one that performed the initial violative inspection that confirms that corrective actions have been instituted and after concurrence by the appropriate Center. In some instances, a firm may present information or documentation sufficient to demonstrate that appropriate corrective actions are in place to overcome the appearance of a violation and, with the appropriate Center concurrence, may be removed from DWPE.

9-8-20 NOTIFICATION OF REMOVAL FROM DETENTION WITHOUT PHYSICAL EXAMINATION

The same FDA units responsible for the initial notification of the imposition of the DWPE, per RPM [subchapter 9-8, "Party Notification..."](#) should notify the same parties of the removal of such detention.

9-9 NOTICE OF FDA ACTION - DETAINED FOR NON-MAIL SHIPMENTS

9-9-1 PURPOSE

To provide FDA staff with information for:

1. The evidence to support a detention.
2. Preparation and issuance of the "Notice of FDA Action - Detained."
3. Charges under Section 801, or other Acts enforced by FDA.
4. Custody over detained shipments.
5. Detention of illegal products that are not properly identified for further processing and exportation under 801(d)(3).

9-9-2 BACKGROUND

In developing FDA's automated import system, known as OASIS, the specific form "Notice of Detention and Hearing" has been replaced by the "Notice of FDA Action" with the description of the article sampled and the results of the examination indicating "Detained" for the specific article in the entry. The use of the designation "DETAINED" or similar wording should be considered as meeting the requirements of the wording of the law and regulation when applied to "giving notice thereof to the owner or consignee."

The "Notice of FDA Action - Detained" gives notice of the right to a hearing on the detention for appearance of a violation (21 CFR 1.94). and identifies charges that an import entry may violate under the FFDCA, Public Health Service Act (PHS Act) or other acts enforced by the FDA. Under the FFDCA section 801(a) an article subject to the FFDCA shall be refused admission if it appears to (1) have been manufactured, processed, or packed under insanitary conditions or, in the case of a device, the methods used in, or the facilities or controls used for, the manufacture, packing, storage, or installation of the device do not conform to the requirements of section 520(f), or (2) such article is forbidden or restricted in sale in the country in which it was produced or from which it was exported, or (3) such article is adulterated or misbranded, or in violation of section 505. It also provides the owner or consignee with an opportunity to introduce testimony relative to the admissibility of the lot.

It should be noted that the Act does not provide specifically for the issuance of a notice charging that an entry of imported merchandise appears to be in violation. However, 21

CFR Section 1.94 provides that if it appears that an imported article may be subject to refusal of admission, the director of the responsible FDA office shall give the owner or consignee a written notice to that effect.

9-9-3 EVIDENCE, ISSUANCE OF NOTICE, AND PREPARATION OF CHARGES

Evidence Required for Detention

Every detention must be based upon evidence of a violation of the law(s) enforced by FDA. This does not mean that comprehensive examinations are required as a condition for detention or that detention cannot be based upon very brief examinations if these are sufficient to furnish evidence creating the appearance of a violation.

Furthermore, it is not essential that a detention invariably be based upon examination of a sample, as Section 801(a) of the FFDCA provides for refusal of admission if "it appears from the examination of such samples or otherwise" that the article is violative. However, in those cases in which detention is made without examination, there should be substantial evidence of a documentary type, (i.e., a violation in a previous shipment of the entered product from the same firm-see RPM [subchapter 9-8 "Detention without Physical Examination" for additional procedures](#)) to warrant a charge of violation.

Issuance of Notice of FDA Action - Detained

The Notice of FDA Action - Detained which lists articles as being detained is addressed to the filer, the importer of record who is legally responsible for assuring compliance with all laws and regulations affecting the importation of the merchandise in question, and consignee (if different from the importer of record). Copies should also be sent to whomever else was sent copies of the "Notice" for the sample collected. See RPM [subchapter 9-21 "Notice of Sampling"](#) for specific procedures on issuance of this notice.

Preparation of Charges

The statement of charges on the Notice of FDA Action - Detained issued for a detained product is the only information the importer has regarding the apparent violation(s) with which the importation is charged. It should be sufficiently informative and complete for the importer to understand clearly the alleged violation(s) so that the importer can prepare a reply for the hearing.

A separate charge should be made for each apparent violation. See [Exhibit 9-5](#) to this chapter for charges used in OASIS. The charge should cite the section of the FFDCA violated, quote the pertinent portion of that section, and make a brief statement of the specific way in which the product appears to be in violation. Charges are drafted in accordance with Section 801 of the FFDCA, as: "The article is subject to refusal of admission pursuant to Section 801(a)(***) in that it appears to ****" (***) completed as appropriate for charge). Charges are based on the section of the FFDCA and not the regulations unless the FFDCA is not specific enough to identify the exact violation.

Under the OASIS procedure for issuing the Notice of FDA Action for a detained product, the individual responsible for the decision as to the compliance of the article will select the appropriate charge from the list of charges available in the OASIS system. The selected charge will be incorporated into the Notice of FDA Action and the annotation required to specify the particular concern(s), where applicable, will be incorporated by the responsible FDA office. For example, if the article is being detained for the presence of a particular pesticide residue, the responsible FDA office would annotate the charge provided by OASIS (using the narrative field) with the name of the specific pesticide residue found or alleged to be present.

See [Exhibit 9-6](#) example of the "Notice of FDA Action" issued under the OASIS which includes the identification of article(s) for detention.

9-9-4 CUSTODY OF DETAINED SHIPMENTS

US CBP regulation and the FFDCA [19 CFR Part 113, 21 U.S.C. 381(b)] provide that a bond considered necessary for the protection of the revenue or assurance of compliance with any pertinent law, regulation or instruction be posted for merchandise. The bond includes a requirement that up to 3 times the value of the entry of merchandise be posted to cover cases involving default on the conditions of the bond [19 CFR Part 113.62(m)(1)].

All formal entries of FDA regulated product are considered by CBP to be "Restricted Merchandise" and as such are required to have a bond established prior to conditional release by CBP. Informal entries, those entries whose value is currently less than \$2,500, are usually not imported under bond. Informal entries subject to FDA review may be requested to have a bond established for them in accordance with CBP regulation. Accordingly, physical possession of a shipment need not be retained by CBP pending FDA examination when the bond (single entry or term bond) is in place. See 19 CFR 12.3. However, if there is reason to believe that the shipment will not be held intact, arrangements should be made with CBP officials to maintain physical possession of the shipment. [See procedures under RPM [subchapter 9-16 "Priority Enforcement Strategy for Problem Importers"](#)]

9-9-5 DETENTION OF VIOLATIVE PRODUCTS THAT ARE NOT PROPERLY IDENTIFIED FOR FURTHER PROCESSING AND EXPORTATION UNDER 801(D)(3)

The "FDA Export Reform and Enhancement Act of 1996," referred to as the "Export Reform Act," Public Law 104-134 became law on April 26, 1996. Technical amendments were enacted on August 6, 1996 (Public Law 104-180). The Export Reform Act contains provisions allowing the importation of certain products, including drug and device components, food and color additives, and dietary supplements, which would otherwise be considered non-compliant with the FFDCA and be subject to refusal of admission, when intended for further manufacturing into products to be exported.

When a product is imported under the provisions of Section 801(d)(3) of the Act, the statute requires the importer to submit a statement to the Secretary (FDA) at the time of importation that such article is being imported or offered for import with intent to be incorporated by the initial owner or consignee into a drug, biological product, device, food, food additive, color additive, or dietary supplement that will be exported by such owner or consignee from the United States in accordance with Section 801(e) or 802 of the Act, or Section 351(h) of the Public Health Service Act. Failure to provide this information at the time of importation should be viewed by the responsible FDA office as evidence that the product does not meet the conditions of Section 801(d)(3). Therefore, if the information is not provided at the time of importation, and if the product is otherwise subject to refusal of admission pursuant to Section 801(a) of the Act, the responsible FDA office should issue a Notice of FDA Action - Detained in accordance with normal procedures. If no response is received by the responsible FDA office to the Notice of FDA Action - Detained that the product meets the requirements for notification of intent for import for export, a Notice of Refusal should be issued. See RPM [subchapter 9-11 "Notice of Refusal of Admission, Instructions](#), "When Should the Notice of Refusal of Admission be Issued?" Once issued, cancellation of the Notice of Refusal should only be considered under unusual circumstances at the discretion of the responsible FDA office. See RPM [subchapter 9-11 "Notice of FDA Action - Refusal of Admission", Instructions](#), "Re-opening of a Case" and RPM [subchapter 9-17 "Import for Export"](#), for additional information and procedures for import for export entries.

Relevant Exhibits

[Exhibit 9-5 Specimen Charges](#)

[Exhibit 9-6 Notice of FDA Action](#)

9-10 RESPONSE (HEARING) TO NOTICE OF FDA ACTION - DETAINED

9-10-1 PURPOSE

To provide operating procedures for FDA personnel regarding who can respond to a Notice of FDA Action - Detained; time frames for responding; and conduct of the hearing.

9-10-2 BACKGROUND

Section 801(a) of the FFDCA provides the owner or consignee of FDA regulated imported goods with an opportunity to appear before the Secretary of Health and Human Services to introduce testimony relative to the admissibility of their imported shipment.

21 CFR Section 1.94 provides that if it appears that an imported article may be subject to refusal of admission, the director of the responsible FDA office shall give the owner or consignee a written notice stating the reasons therefore. This regulation further provides that this notice shall specify a place and period of time during which the owner or

consignee shall have an opportunity to introduce testimony, either orally or in writing, as to the admissibility of the shipment.

In developing FDA's automated import system, OASIS, the specific form **"Notice of Detention and Hearing"** has been replaced by the issuance of a **"Notice of FDA Action,"** which contains a description of the article(s) and action taken for a specific entry. The use of the designation "DETAINED," or other similar wording, under the heading of "Current Status," should be considered as meeting the requirements of the wording of the law and regulation when applied to "giving notice thereof to the owner or consignee." See RPM [Exhibit 9-6](#) for an example of "Notice of FDA Action" for detention.

9-10-3 ELIGIBILITY OF RESPONDENTS

Section 801(a) of the FFDCA and FDA regulation 21 CFR 1.94 provide the owner or consignee an opportunity to introduce testimony relevant to the admissibility of the article if it appears that an imported lot may be subject to refusal of admission. However, the regulations are rather complicated as to the definition of "owner or consignee." 21 CFR 1.83(a) defines, for the purpose of the regulation, the owner or consignee as the person who has the right of a consignee under Sections 483, 484, and 485 of the Tariff Act of 1930, as amended (19 U.S.C. 1483, 1484, 1485).

For the purposes of the Tariff Act, only the declared consignee as shown on the bill of lading may be the importer, unless bill of lading endorsements by this consignee confer his rights to other persons. For the purposes of the Tariff Act, the consignee (importer) is to be regarded as the owner of the imported goods. If the consignee (importer) is not the true owner of the goods, the true owner may file with the District Director of CBP a declaration of ownership, which bestows upon the true owner all of the rights of a consignee. Thus, we are obligated by statute to recognize as eligible for the presentation of testimony, the consignee (importer) or the true owner (if the true owner is not the consignee) if there is on file with CBP a declaration of ownership.

In addition to the consignee (importer) and the true owner, we also recognize the eligibility of the importer of record to present testimony. (The importer of record is the person or firm who guarantees, by bond, proper custody and handling of the imported shipment in compliance with the laws governing such shipment. The importer of record may be the broker, consignee, true owner, or whoever owns the bond covering the shipment.) In most cases, it is the importer of record who responds to the "Notice of FDA Action - Detained."

A designated representative of the consignee (importer), true owner, or importer of record may appear in the consignee's (importer's) behalf; however, unless known to be authorized representatives, the responsible FDA office should require proper documentation designating the individual(s) to be a bonafide representative for the purpose of the hearing. Recognition of others may open the way for claims by the consignee (importer), true owner, or importer of record that FDA has denied or abridged the importer's right to be heard, or for complaints that FDA has permitted unauthorized persons to intrude into the case.

9-10-4 HEARINGS AND POSTPONEMENTS

The "Notice of FDA Action - Detained" provides an opportunity for the introduction of testimony or the filing of a statement in writing within ten days (or longer if circumstances require a longer time for response) following the date of detention shown on the notice (excluding Saturdays, Sundays, and holidays). This is indicated on the Notice by the reference to a "Respond By" date. The "introduction of testimony" may take many forms, including a telephone conversation, a FAX or mail, and does not have to be introduced in person. However, if the consignee (importer), true owner, or importer of record requests a hearing as such, it should be scheduled for the earliest possible date.

The response period may be extended at the request of the respondent if it is made within the 10-day time-frame shown in the "Notice of FDA Action - Detained," and the requestor provides a reasonable basis for extension, and the requested extension is confirmed in writing. It is preferable for extension requests to be made in writing, but this is not mandatory. Such requests should be answered by the responsible FDA office, in writing. If the request is granted, the new time frame should be clearly stated in the response letter.

Generally speaking, requests for extension for indefinite or excessively long periods should not be granted. This also applies to requests for extensions based upon reasons other than to obtain or prepare evidence pertaining to the specific charges of the detention. However, extensions should only be granted if some type of resolution is actively being pursued.

9-10-5 CONDUCT OF HEARING: PERSONAL APPEARANCE OF RESPONDENT

The import hearing provided by section 801(a) of the Act is a different procedure from a hearing pursuant to Section 305 of the Act. Under section 801(a), it is the respondent's opportunity to present a defense of the importation and/or to present evidence to show how the importation may be made eligible for entry. This type of hearing may vary from a series of telephone conversations to a more formal 305 type of meeting. Formal memoranda covering import hearings are not required, although a written record should be made for the files.

The hearing officer (generally it is the appropriate ORA compliance officer, however, it may be any individual designated by the responsible FDA office to conduct such a hearing) should avoid any indication of prejudice or pre-judgment until all evidence is submitted and should assure that the respondent has been provided ample opportunity to present all relevant evidence. If the question arises, the respondent should be made aware of their rights of appeal to a higher level of review in the agency, including to the specific Center responsible for the detained article, to the Associate Commissioner for Regulatory Affairs, to the Commissioner of FDA, to the Secretary of Health and Human Services; and to file legal actions with the court.

The hearing should be confined to relevant matters, and the respondent should be required to confine their comments to the submission of relevant evidence and not be permitted merely to attempt to question, probe, or pass judgment on FDA's basis for detention.

If the facts in the case are such that a decision can be reached regarding the validity of the detention charges at the termination of the hearing, the hearing officer should so advise the respondent of the decision with confirmation by the issuance of the appropriate "Notice," (Refusal, Release, etc.). A copy of the appropriate "Notice" should be sent to the importer of record, if this person is not the respondent.

There is no need to dictate a summary of the hearing in the presence of the respondent, as is done during a "Section 305 meeting," nor is it necessary to provide the respondent with a copy of our memorandum covering the hearing.

Occasionally, a respondent at an import hearing attempts to weigh the relative desirability of appealing a refusal of admission against submitting a request for an authorization to relabel, recondition, etc. ([Form FDA-766](#)), or reopen the basic question of the shipment's legality if relabeling or reconditioning is unduly burdensome. The respondent should be advised that orderly procedure requires that the respondent first present a view on the validity of the FDA charge(s), and then, if the respondent concludes that the charges are valid, a request for an authorization to relabel or recondition or refusal can be submitted. This should not be taken as preventing a discussion, at the appropriate time, of what is needed to bring the article into compliance. Once the hearing has been held and a [Form FDA-766](#) has been submitted for an authorization to relabel or recondition, the hearing should not be reopened for the purpose of determining whether the article is subject to refusal of admission.

On occasion, a respondent will request that a Notice of Refusal of Admission be issued immediately so the merchandise can be exported. These requests should also be confirmed in writing by the respondent. Requests for issuance of a Notice of Refusal of Admission should be acted upon without delay.

9-10-6 CONDUCT OF HEARING: WRITTEN REPLY (MAIL, FAX, ETC.) FROM RESPONDENT

The response to a Notice of FDA Action - Detained by mail is no different from a hearing where a verbal response is provided. The hearing officer must consider the evidence developed by FDA and that presented in the written response, and then make a decision as to whether or not the importation is violative as charged in the Notice of FDA Action - Detained. All such responses should be replied to in writing, e.g., appropriate "Notice" with a clear statement of the hearing officer's decision. A copy of this Notice should be sent to the importer of record, if the person is not the respondent.

Questions regarding appropriateness of respondent, procedures for conducting the hearing, or other concerns not specifically identified in these procedures, should be referred to OIO (301-796-0356).

9-11 NOTICE OF FDA ACTION - REFUSAL OF ADMISSION

9-11-1 PURPOSE

To provide operating procedures for FDA personnel for issuing the Notice of Refusal of Admission. This section covers all articles excluding drugs valued at \$2500 or less. For those products see RPM [subchapter 9-4 Notice of Refusal of Admission and Administrative Destruction for Mail Shipments of Drugs](#).

9-11-2 BACKGROUND

Section 801(a) of the FFDCA directs the Secretary of the Treasury to issue a Notice of Refusal when it appears from examination of samples, or otherwise, that an imported shipment is in violation. This Section also orders the destruction of any such shipment refused admission, unless it is exported within 90 days of the date of the notice, or within such additional time as may be permitted pursuant to such regulations.

9-11-3 INSTRUCTIONS

Who Should Issue the Notice of FDA Action - Refusal of Admission?

The language of the law places the responsibility for issuing the Notice of FDA Action - Refusal of Admission upon the Secretary of the Treasury who in turn has delegated this responsibility to the CBP. Traditionally, this notice is issued by the responsible FDA office over the facsimile signature of the Regional or District Director of CBP in accordance with local agreement. Each FDA issuing office shall have a facsimile stamp of the signature of the Regional or District Director of CBP prepared for this purpose and supplied to the appropriate personnel, or have written delegation of authority from the District Director of CBP to issue the Notice of FDA Action - Refusal of Admission under FDA personnel signature. A new stamp should be prepared each time there is a change of personnel in the Regional or District Director of CBP position.

The name and contact information of the compliance officer or the responsible FDA office that issues the Notice of Refusal of Admission is automatically indicated by OASIS on the notice.

When Should the Notice of FDA Action - Refusal of Admission be Issued?

A Notice of FDA Action - Refusal of Admission is issued under the following circumstances:

1. A response to a Notice of FDA Action – Detained is not received within the specified ten day time frame (excluding Saturdays, Sundays, and holidays) and an extension of time for responding has not been granted. (Additional time may be noted due to circumstances affecting FDA operations).

2. Efforts to relabel or recondition the detained shipment pursuant to an approved application ([Form FDA-766](#)) have failed.
3. When a detained shipment has been reconditioned pursuant to an approved application ([Form FDA-766](#)), and we have agreed to the exportation of the reject material, a Notice of FDA Action - Refusal of Admission is issued covering the rejects.
4. After a hearing relative to the validity of the charges for detention, the hearing officer rules that the charges are valid and a [Form FDA-766](#) has not been submitted.

NOTE: If a detention action is being appealed by the importer do not issue the Notice of FDA Action - Refusal of Admission until the appeal is decided. The responsible FDA office should notify the CBP office of the delay to assure liquidation of the bond does not occur.

Distribution of the Notice of FDA Action - Refusal of Admission

The Notice of Refusal of Admission is always issued to the importer of record (who is the same person or firm who was issued the Notice of Sampling). In accordance with local practices, copies may also be sent to the customhouse broker and the consignee when neither is the importer of record. All persons or firms who are sent copies of the Notice of Sampling and Notice of FDA Action - Detained must also be sent a copy of the Notice of Refusal of Admission.

Two copies of the Notice must also be sent to CBP.

Charges on the Notice of FDA Action - Refusal of Admission

The Notice of FDA Action – Refusal of Admission should contain only those charges that are applicable at the time of refusal.

If during the detention and hearing period, sufficient testimony is provided to overcome one or more of the charges listed, a new Notice of FDA Action – Detained does not need to be issued. Charges that have been overcome will instead be omitted from the Notice of FDA Action – Refusal of Admission when it is issued.

If it becomes necessary to add new charges or amend existing charges on the last issued Notice of FDA Action - Detained, a new Notice of FDA Action - Detained should be issued to reflect all applicable charges (including amendments, additions, or removal of charges by FDA). The importer of record should be given a new 10-day detention and hearing period (excluding Saturdays, Sundays and holidays or additional time when appropriate) to allow for the submission of testimony/evidence or [Form FDA-766](#) Request for Reconditioning for all charges.

When to Close the Case

After the Issuance of the Notice of Refusal of Admission, the case should be kept in an open status until the receipt of the return copy of the Notice of Refusal from CBP showing the exportation or destruction of the shipment.

If the return copy is not received from CBP within 100 days, a letter inquiring as to the status of the shipment, or other agreed upon procedure established with your local CBP port, should be made.

It is important to monitor the final disposition of refused shipments, as FDA has encountered the distribution of such merchandise into domestic channels instead of exportation or destruction. FDA staff should follow the procedures for follow-up to refusals.

Requests for Extension Beyond the Ninety Day Period

If request are received for an extension beyond the 90 day period to export or destroy a refused shipment, the requestor should be referred to the appropriate CBP office. Since the Notice of Refusal of Admission is the responsibility of CBP, FDA cannot grant such extensions.

Reopening of a Case

Unless a Notice of Refusal of Admission was erroneously issued by FDA, consideration should not normally be given to requests to void the Notice in order to give the requestor an opportunity for a hearing or time to submit an application ([Form FDA-766](#)) requesting authorization to relabel or recondition. Indiscriminate voiding of this Notice tends to indicate to the importer of record that it is not necessary to respond within the prescribed period to the Notice of FDA Action - Detained and, also, will generate additional paperwork by both FDA and CBP. The latter result is counterproductive to our efforts to process all import matters in a timely manner.

If the compliance officer is of the opinion that the voiding of the Notice is advisable, concurrence must be obtained from the CBP office responsible for insuring the exportation or destruction of the shipment. After the receipt of CBP's concurrence, a letter voiding the Notice should be issued to the requestor with copies to CBP and all persons and firms receiving a copy of the Notice of FDA Action - Refusal of Admission. This letter should provide no more than a ten day period (excluding Saturdays, Sundays, and holidays) to afford the opportunity for a hearing or the submission of a [Form FDA-766](#).

Note: Because of the concern for liquidation of the Bond prior to final disposition of a detained entry, some FDA offices have instituted procedures to issue the Notice of Refusal to CBP before a final decision on reconditioning or appeal have been made. FDA offices should follow their local procedures established with their CBP offices when such a practice is used.

9-12 RECONDITIONING

9-12-1 PURPOSE

To establish operating procedures for processing applications ([Form FDA-766](#)) requesting authorization to bring detained merchandise into compliance.

9-12-2 BACKGROUND

Section 801(b) of the FFDCA provides that an importer of record (also the owner or consignee) may submit to the FDA a written application ([Form FDA-766](#)) requesting authorization to bring into compliance an article adulterated, misbranded, or in violation of Section 505 by relabeling or other action, or by rendering it other than a food, drug, device, or cosmetic. This Section also provides that the application should be covered by a bond for the payment of liquidated damages in the event of default. The approval of the application is at FDA's discretion.

9-12-3 WHO MAY FILE AN APPLICATION

Generally speaking, the owner or consignee (provided this firm or individual guarantees by a bond, proper custody and handling of the shipment) or their designated agent (i.e. customhouse broker, consultant, etc.) is the only one who has the legal right to submit an application to recondition or render the detained article not a food, drug, device or cosmetic. Under certain circumstances, the importer (broker) or other designated agent authorized to act on the matter on behalf of the owner, or manufacturer (if it is a Rad. Health item) may also file an application, provided it is covered by a bond in the event of default. However, before approving an application submitted by the owner or consignee, the importer of record should be contacted to ensure that he has no objection.

Frequently, applications are received from customhouse brokers or ultimate consignees who have not posted a bond covering the shipment. Such applications should not be considered and should be returned to the applicant with a notation that we can accept applications only from the importer of record, owner, or consignee, provided the application is covered by a good and sufficient bond, unless appropriate authorization to act on behalf of the owner in the matter has been provided to the responsible FDA office.

9-12-4 MECHANICS IN PROCESSING APPLICATION

The [Form FDA-766](#) contains five sections that are described below.

Section 1 - Proposal

The applicant fills out the top portion (page 1) of the form and submits to the responsible FDA office which issued the Notice of FDA Action - Detained. A detailed description of

the method by which the article(s) will be brought into compliance must be given. For example, such proposed methods as "fumigation and cleaning" are not adequate without the identity of the fumigant, method and duration of application, detailed description of cleaning, etc. In addition, the applicant should indicate the disposition of reject material. (Generally, the application should provide for all information identified by Regulation 21 CFR Sections 1.95 and 1.96).

Section – FDA Action on Application Section

The "FDA Action on Application" section of the form is used by FDA in either approving or disapproving the application. The form should be returned to the applicant with a copy to the district file and a copy may be forwarded to CBP for their information.

If the district questions the adequacy of the proposed method, the matter should be referred to the appropriate headquarters center for evaluation and advice.

If past experience has shown that the proposed method will not succeed, the application should be disapproved. Applications should be approved only if it appears that the relabeling or other action will be successful and result in an acceptable product.

It is suggested that approved applications include the statement "ARTICLES SHOULD BE HELD INTACT PENDING THE RECEIPT OF FDA'S RELEASE NOTICE." If it later becomes necessary to recommend a bond action to CBP, this statement serves to formally advise the applicant of FDA procedures and his or her responsibilities to hold the merchandise until a release notice is received from FDA.

If the proposal involves a reconditioning of an adulterated product where the sanitary condition of the equipment and facilities is a critical factor, FDA should not approve the application until the condition, that FDA be notified within a specified time before the start of the reconditioning to enable us to inspect the reconditioning firm, is added by the applying party. An example of such a situation would be the reconditioning of insect contaminated spices where the cleaning of the product under insanitary conditions would adulterate the article under Section 402(a)(4) of the Act.

Applications should not be "approved with the following condition." If there are conditions which we feel should be covered in the proposed procedure it should be denied and inform the applicant that the FDA will reconsider another application if the matter is covered. For example, an application should be denied when the matter of rejects has not been resolved. If the applicant fails to propose an acceptable disposition of rejects, the application should be denied; inform the applicant of the reason for denial on the [Form FDA-766](#) and suggest that a new application which includes disposition of rejects will be considered. Only minor points, such as date of completion, etc. should be specified under the "approved with the following condition".

Section 3 - Importer's Certificate

The "Importer's Certificate" section of the [Form FDA-766](#) is used by the applicant to advise the FDA that the relabeling or other action has been completed and that the goods are ready for inspection/sample collection. In making this certification, the applicant should fill-in the original copy of the application which was returned to him or her (as described in RPM [subchapter 9-12, Section 2 - FDA Action on Application](#), above) and then submit the application to the FDA.

Section 4 - Report of Investigator/Inspector

This "Report of Investigator/Inspector" section of the [Form FDA-766](#) is completed by the examining FDA or CBP official. This section is later used by the designated division in preparing the subsequent Release Notice or Notice of FDA Action - Refusal of Admission.

Section 5 – Data on Reconditioning Articles

The "Data on Reconditioned Articles" section of the [Form FDA-766](#) is completed by the examining FDA or CBP official. This section is later used by the designated division office in preparing the Form FDA-790 "Charges for Supervision" and quantity information on the subsequent Release Notice or Notice of FDA Action – Refusal of Admission.

9-12-5 AMENDED APPLICATIONS

Any changes at any time by the applicant in the reconditioning proposal must be made by the filing of an amended application and must be approved by the FDA. Granting of verbal requests for changes may result in misunderstandings and may create problems if it becomes necessary to initiate bond action against the applicant at a later date.

9-12-6 REQUESTS FOR ADDITIONAL TIME TO COMPLETE RECONDITIONING

At times the applicant cannot complete the reconditioning operation within the specified time period. Additional time may be granted by FDA upon a written request from the applicant and the showing of reasonable grounds.

Requests for extensions of unduly long periods should not be granted, as the possibility of accidental or intentional diversion and additional adulteration of the shipment increases with the time factor. Normally, a second request for an extension of time should not be granted unless the applicant shows compelling reasons to do so.

9-12-7 UNSUCCESSFUL RECONDITIONING OF ADULTERATED ARTICLES

At times the applicant is not successful in the reconditioning of an adulterated shipment, particularly in cases where the product is contaminated with filth (insects, rodent excreta pellets, etc.). Authorization should not be granted for a second attempt at reconditioning without the benefit of another application ([Form FDA-766](#)).

The applicant may submit a second application if he so desires. However, this application should not normally be approved unless it contains meaningful changes in the reconditioning operation to insure a reasonable chance at success. A second application should not be approved if it merely is a resubmission of the original application.

In approving a second application, FDA should include in the "FDA ACTION ON APPLICATION" section of the [Form FDA-766](#) "IF THIS ATTEMPT AT RECONDITIONING DOES NOT BRING THE ARTICLES INTO COMPLIANCE FUTURE APPLICATIONS TO DO SO MAY NOT BE CONSIDERED."

Request for a third attempt at reconditioning generally should not be granted. It is our opinion that to allow unlimited attempts at reconditioning only encourage importers to import grossly adulterated articles into the U.S.

9-12-8 DISPOSITION OF LOTS NOT RECONDITIONED TO THE FDA'S SATISFACTION

If the applicant is not able to recondition a shipment to the FDA's satisfaction, a Notice of FDA Action - Refusal of Admission should be issued in the usual manner. See RPM [subchapter 9-11 "Notice of FDA Action - Refusal of Admission."](#) If FDA supervisory charges are involved, a [Form FDA-790](#) should be issued. See RPM [subchapter 9-13, "Supervisory Charges."](#)

9-12-9 RECONDITIONING OPERATIONS

Relabeling of New Drugs

At times an importer of record may desire to bring a drug shipment detained on a new drug charge into compliance by revising the labeling to remove claims which placed the product into the category of a new drug. Sometimes such a drug appears to be composed of harmless ingredients. A typical example is Chinese herbal medications labeled for the promotion of blood circulation, sexual rejuvenation, headaches, anemophobia, back neuralgia, bone pain, acute or chronic neuralgia and other pain caused by rheumatism.

Do not permit the relabeling of a drug detained on a new drug charge as a means to bring the item into compliance. To do otherwise is not in the best interest of the consuming public. Experience has shown that such drugs may contain undeclared

ingredients, such as phenylbutazone and aminopyrine, which present serious hazards to the users. Likewise, it should be noted that any drug seized in domestic commerce on a new drug charge cannot be relabeled and introduced into commerce, but if condemned by the court must be destroyed.

Reconditioning of Green Coffee and Cocoa Beans Due to the Presence of Live and/or Dead Insects

This procedure was originally instituted for reconditioning green coffee beans detained under Administrative Guideline 7403.01 due to the presence of live and/or dead insect infestation ([CPG 510.500](#)). The procedure has now been expanded to include cocoa beans ([CPG 515.750](#)).

In the past when green coffee beans were detained for live and/or dead insect infestation, the importer of record submitted an Application for Reconditioning ([Form FDA-766](#)) indicating fumigation and cleaning prior to delivery to the roasting plant. The coffee industry contended that part of the processing of coffee beans at most roasting plants includes a cleaning procedure for removal of dead insects and extraneous material. The cleaning and rebagging before processing purportedly causes duplication of cleaning and results in additional charges for the importer and ultimately for the consumer.

To avoid duplication the following alternate reconditioning procedure can be used if the importer chooses.

After a detention due to live insect infestation is issued, the importer of record or consignee must submit an Application for Reconditioning ([Form FDA-766](#)). The form shall identify the procedure for fumigation (including name and amount of fumigant, time of exposure etc.) which is to be used. The application shall also include the name and address of the roasting plant where the cleaning phase will be accomplished; the identity of the equipment to be used in the cleaning operation; the date and time cleaning operations are to begin; and that a signed statement will be submitted to the FDA attesting that the reconditioning was properly carried out by the processor when the entire reconditioning has been completed. When it is deemed necessary, for monitoring purposes, the [Form FDA-766](#) should be approved with the condition that rejects (tailings) are to be held for the FDA's examination and subsequent destruction under U.S. CBP or FDA supervision.

As part of the approval of this application ([Form FDA-766](#)) the fumigation must be accomplished prior to permitting the lot's movement to the roasting plant. ORA, at its discretion, may examine the lot to determine the effectiveness of the fumigation. If the stated date or time of cleaning has to be changed, the importer should notify the FDA office supervising the reconditioning at least 72 hours prior to the time noted in the application.

At the time of the initial submission of the [Form FDA-766](#) application under this procedure, the file should be checked to determine if there has been a recent inspection

of the cleaning facility. If not, the application should be approved with the condition that the roasting plant will be inspected to determine if it is acceptable to the FDA prior to the movement of the beans to that plant. If the plant is found acceptable, FDA will advise the importer that the lot may be sent to the roasting plant. Inspections should be made without undue delay to avoid causing importers excessive storage charges.

After the initial inspections FDA may exercise discretion to make follow-up inspections to determine if the plants' cleaning operations are being maintained to properly recondition detained lots.

All time to conduct inspections to determine if the processors plant and equipment is acceptable and those made to check on specific lots after reconditioning shall be included in the supervisory charges issued to the importer of record. All movement of detained lots shall be under CBP's bond and by acceptable conveyances.

The procedure outlined above, is to be used, with the exception of the fumigation procedure, when the detention is for dead insect infestation only. As previously stated this procedure is not to be accepted when the detention is for insect damaged and/or moldy coffee beans.

Reconditioning of Biologicals

Unlicensed biologicals or biologicals without an effective IND which were refused admission are not subject to reconditioning except in the instances where the intended use of the product is changed to render the product a non-biological, non-drug product, and is so reflected in the associated labeling. Center for Biologics Evaluation and Research (CBER) concurrence with any reconditioning application for a biological product is required.

9-13 SUPERVISORY CHARGES

9-13-1 PURPOSE

To provide operating procedures for charging expenses in connection with the relabeling, or reconditioning of food, drugs, devices, tobacco products, and cosmetics being imported or offered for import, pending FDA's decision as to the admission of the product. The procedure includes documenting those expenses with a [Form FDA-790 "Charges for Supervision,"](#) in conjunction with a [Form FDA-766 "Application for Authorization to Relabel or Recondition Non-Compliant Articles"](#)

9-13-2 BACKGROUND

Section 801(c) of the FFDCA [21 U.S.C. 381(c)] requires the owner or consignee of FDA-regulated articles being imported or offered for import to pay for all expenses, including travel, per diem or subsistence, and salaries of officers or employees of the United States, in connection with the supervision of the relabeling or other action ("reconditioning") authorized by FDA under the provisions of FFDCA section 801(b) to

bring the articles into compliance with the Act, or to render the articles other than a food, drug, device, or cosmetic. This includes such expenses in connection with the supervision of the destruction or export of rejected articles or portions thereof, as may be specified in FDA's relabeling or reconditioning authorization. The amount of such expenses is determined by regulation. See 21 CFR 1.99.

In 1985, U.S. CBP financial management consolidated all billing operations for FDA supervisory charges at their Accounting Services Division (ASD) in Indianapolis, Indiana. Payments of FDA's supervisory charges are deposited into the U.S. Treasury Miscellaneous Receipts account.

9-13-3 SUPERVISORY CHARGES

In submitting a [Form FDA-766](#) requesting authorization to relabel or perform other action to bring an article into compliance with the Act (see [21 CFR 1.95](#)), the applicant agrees to pay for all supervisory costs in accordance with current regulations. [21 CFR 1.99](#) describes the supervisory costs that the applicant must pay.

The [21 CFR 1.99](#) hourly charge rates for the services of FDA supervising officers and FDA analysts are based on the federal General Schedule (GS) pay scale. At the beginning of each calendar year, ORA HQ sends out an email to the ORA staff to inform the field of the current GS pay scale [21 CFR 1.99](#) hourly charge rates. This email also informs the ORA staff of the current mileage reimbursement rates, which are used to calculate the charges for the travel expenses of the supervising officer, per [21 CFR 1.99](#). References below to "the current rate as given by Regulation ([21 CFR 1.99](#))" and "the current mileage rate" should be construed as referring to the current rates as specified in the aforementioned annual email. These rates should be reiterated on the [Form FDA-790](#) in the "charge per unit" column, for the appropriate line item.

[21 CFR 1.99](#) provides that such costs shall include, but not be restricted to, the following:

1. Travel expenses of the FDA supervising officer.
 - If travel is by government vehicle, charges should be for the mileage costs plus any toll charges. Mileage costs for government vehicle travel should be accounted for on the [Form FDA-790](#) under "Automobile Use" and are calculated by multiplying the current mileage rate by the number of miles traveled. Toll charges should be accounted for on the [Form FDA-790](#) on the "Other Transportation Expenses" line.
 - If travel is by public transportation, the charge is for the actual cost of such travel. Public transportation costs should be accounted for on the [Form FDA-790](#) on the "Other Transportation Expenses" line.
 - Supervisory approval should be obtained prior to charging for any transportation expenses other than those described above but, if approved, should be accounted for and itemized on the [Form FDA-790](#) on the "Other Transportation Expenses" line.

2. Per diem in lieu of subsistence of the FDA supervising officer when away from his or her home station, as provided by law/current regulations.
3. Services of the FDA supervising officer, calculated at the current rate as given by Regulation ([21 CFR 1.99](#)).
 - This rate is designed to account for charges for administrative support of the supervising officer and for the supervising officer's travel time to or from the site of the article, and therefore separate charges should not be assessed for those items.
4. Services of the FDA laboratory analyst, if applicable, calculated at the current rate as given by Regulation ([21 CFR 1.99](#)).
 - This rate is designed to account for administrative support for the laboratory analyst and for the use of FDA laboratories and equipment, and therefore separate charges should not be assessed for those items.

The following costs should not be charged for:

1. Time spent reviewing, approving, denying, modifying, and/or processing the relabeling or reconditioning request and proposal.
2. Services of a compliance officer supporting the supervision (e.g., services such as determining appropriate courses of action, coordinating logistics of the supervision, performing the services described in # 1 above, etc.).
3. Services of any FDA Center personnel or personnel at ORA HQ supporting the supervision. However, charges should include the supervising officer's or FDA laboratory analyst's time spent consulting or otherwise interacting with FDA Center or ORA HQ personnel regarding the supervision, calculated at the current supervising officer or analyst rate as given by Regulation ([21 CFR 1.99](#)).

If multiple supervising officers or laboratory analysts are necessary, then charges should include the services of each of those supervising officers and/or laboratory analysts, calculated at the current rate(s) as given by Regulation ([21 CFR 1.99](#)).

The minimum total charge for services of each supervising officer and analyst shall not be less than the charge for one (1) hour. Time after the first hour shall be computed in multiples of one (1) hour, rounding down for fractional parts less than 1/2 hour. For example, if a supervising officer provides services of:

- More than 0 minutes, but less than 1 hour and 30 minutes, charge for 1 hour.
- 1 hour and 30 minutes or more, but less than 2 hours and 30 minutes, charge for 2 hours.
- 2 hours and 30 minutes or more, but less than 3 hours and 30 minutes, charge for 3 hours, etc.

[21 CFR 1.99](#) states that the cost of supervision includes, but is not limited to, the charges described above. Other appropriate miscellaneous expenses not accounted for above should be charged for as miscellaneous expenses for the actual cost incurred, and should be itemized on the [Form FDA-790](#) on the “miscellaneous expenses” line. However, miscellaneous expenses are only warranted under very unusual circumstances. Therefore, appropriate supervisory approval should be obtained prior to incurring or charging for any miscellaneous expenses.

Incurred supervisory costs should be charged for each relabeling and reconditioning attempt, regardless of whether the attempt is successful.

9-13-4 PREPARATION AND SUBMISSION OF CHARGE SHEET

Future enhancements to FDA’s electronic import system (currently OASIS) may result in electronic processing of the supervisory charge-sheet (with appropriate identification and accounting information) for FDA staff to use when submitting their charges to the CBP Revenue Division. Until these electronic system enhancements are operational, FDA staff should continue to use [Form FDA-790](#).

Charges should be assessed on the [Form FDA-790](#) and [Form FDA-766](#) only after relabeling or reconditioning of the articles are completed. The forms should be filled out and submitted at the same time. The [Form FDA-790](#) “Grand Total” amounts for total time and total charge should be equal to the [Form FDA-766](#) “Time and cost of supervision” amounts.

In addition to the information identified above for supervisory charges, the [Form FDA-790](#) must also include the CBP Entry Number and date of entry, name of the Importer of Record, carrier, product description, name of the consignee (if different from the importer of record), FDA sample number (if applicable), and appropriate FDA office address.

Scan the completed [Form FDA-790](#) and the FDA Notice of Release, FDA Notice of Refusal, or FDA Notice of Partial Release for each entry and samples covered by the bill, and email a copy of each document to REIMBSVCS@cbp.dhs.gov, addressed to:

U.S. Customs and Border Protection
Revenue Division - Reimbursable Team
6650 Telecom Drive Suite 100
Indianapolis, IN 46278

Contact (also available at the CBP Revenue Division directory ([link](#)):
Sheri Malicoat
Office 317-614-4520

Maintain the original completed [Form FDA-790](#) and copies of the FDA Notice of Release, FDA Notice of Refusal, or FDA Notice of Partial Release in the FDA file. By including a copy of the FDA Notice of Release, FDA Notice of Refusal, or FDA Notice of

Partial Release with the completed [Form FDA-790](#), there should be no problem identifying the exact entry and samples being covered by the bill.

If submission of these documents by email is not possible, mail the original completed [Form FDA-790](#) and 1 copy, along with a copy of the FDA Notice of Release, FDA Notice of Refusal, or FDA Notice of Partial Release to the above address and contact above. Maintain copies of the completed [Form FDA-790](#) and the FDA Notice of Release, FDA Notice of Refusal, or FDA Notice of Partial Release in the FDA file.

DO NOT send a copy of the completed [Form FDA-790](#) directly to the applicant. It is the responsibility of CBP to contact the applicant to obtain payment of the bill. CBP will also add on to the bill any expenses incurred by their personnel in connection with an entry.

9-13-5 PAYMENT OF SUPERVISORY CHARGES

CBP will instruct the applicant to send payment to CBP, Revenue Division, not to the local FDA office. If the applicant sends payment to FDA, the FDA recipient should return the payment to the organization or importer by registered mail with instructions to submit the payment to CBP at the above address.

FDA is not routinely notified by CBP when payment is received. If the applicant refuses to make payment, CBP will take appropriate action against the importer's bond or place a lien against the importer's future importations.

9-14 BOND ACTIONS

9-14-1 PURPOSE

To increase the effectiveness of FDA's import operations by appropriately utilizing the CBP bond provisions, in conjunction with FDA's enforcement discretion, in an effort to deter the distribution of imported articles prior to FDA release.

9-14-2 BACKGROUND

Sections 801(b) and 536(b) of the FFDCA and 21 CFR 1.97 provide for the delivery to the owner or consignee of a lot offered for entry into the United States, pending a decision to admit the lot upon the execution of a bond (commonly referred to by FDA as a "redelivery bond"). This bond is filed with the CBP and provides for the payment of liquidated damages in the event of default. The individual or firm posting the bond is referred to as the "Importer of Record."

This bond contains a condition for redelivery of the lot, or any portion thereof, upon demand of CBP and also a provision for the performance of conditions as may be

legally imposed for the relabeling or other action necessary to bring the article into compliance or rendering it other than a food, drug, device, or cosmetic.

FDA personnel should utilize their judgment when evaluating cases of bond violations and penalty recommendations. While it may be accurate to state that FDA "rarely mitigates", it should be pointed out that FDA has, and may wish to mitigate, when, in its judgment, appropriate circumstances are present. Some examples of appropriate circumstances are stated in Penalty Recommendation.

9-14-3 BOND VIOLATION

Importers are not specifically required by law to hold a shipment in any given location once a bond has been filed, pending a decision by FDA whether or not to sample. However, in the event FDA decides to collect a sample, CBP can require, under terms of the bond, that the importer return the entire shipment or any portion thereof for sampling, if the shipment has left the port area. If unable to redeliver upon demand by CBP, the importer is subject to assessment of liquidated damages.

In advising importers who inquire about making immediate distribution of any entry, FDA personnel should recommend that distribution be withheld pending an Agency decision on admissibility. Generally speaking, a bond violation occurs when the importer fails to redeliver merchandise, upon CBP demand, that has been distributed for sale before sampling and/or release by FDA or before an authorized FDA representative expressed that the merchandise may proceed without FDA examination

Following are examples of situations which may, if the merchandise is not redelivered on Customs demand, result in bond violations:

1. Distribution of a shipment before FDA has decided whether or not to sample;
2. Distribution of a shipment after FDA has elected to sample but before the sample(s) can be collected;
3. Distribution of a shipment that appears to be violative, before or after the receipt of a Notice of FDA Action - Detained;
4. Distribution for sale of a shipment before FDA can inspect and/or sample the merchandise that was relabeled or reconditioned pursuant to an approved Application For Authorization To Relabel Or Recondition Non-Compliant Articles ([Form FDA-766](#));
5. Distribution of a shipment for which a Notice of FDA Action - Refusal of Admission has issued. As soon as it appears that one of the above situations may have occurred, FDA personnel should report the situation in writing to the CBP Port Director, as an investigation may be initiated by CBP to determine whether a bond violation has occurred. The report to CBP should be strictly factual, with enough background information for CBP to accurately assess the case. The report should, at this point, contain no recommendations nor should it judge the case before the importer of record has had an opportunity to present

evidence. The FDA should offer CBP full cooperation in conducting any investigation that is considered necessary.

If an importer has distributed a shipment before FDA has determined whether to sample or after a Notice of Sampling has issued but before the samples are collected, the written report should ask CBP to require redelivery for sampling purposes.

If, at the time of the aforementioned report to CBP, the shipment had been sampled and a Notice of FDA Action - Detained had already issued on the shipment, a Notice of FDA Action - Refusal of Admission should be issued. The Notice of FDA Action - Refusal of Admission should be executed in the usual manner.

NOTE: A Notice of FDA Action - Detained and Notice of FDA Action - Refusal of Admission are not required in cases where FDA has not sampled the shipment.

Where the articles are distributed prior to FDA sampling, FDA should consider following up in domestic channels, for example, by collecting official domestic samples. Where samples have been collected by FDA and are shown to be violative, and the goods are not redelivered, FDA may consider recommending seizure, or some other action, to remove the violative product from distribution channels.

9-14-4 BOND ACTION PROCEDURES

If CBP, after review of FDA's report along with any other information, determines that the articles are not entitled to admission, CBP may issue a Notice to the importer of record. If redelivery is not made within a specified time (currently 30 days) CBP regulations provide for the issuance of another Notice, of penalty or liquidated damages incurred and demand for payment. CBP has amended the amount of liquidated damages to be assessed to three times the value of the restricted merchandise not redelivered (19 CFR 113.6) and increased the amount of the bond required for such entries to three times the value of the merchandise. These amounts are subject to change. Check CBP regulations for current amounts. The CBP Notice will generally request liquidated damages in the amount prescribed by regulation for the undelivered merchandise, plus duties. This Notice gives the importer of record an opportunity to object to the action if he or she feels there are extenuating circumstances, and to explain in a written petition why he or she should not be subject to the stated penalties.

The importer of record generally will submit a petition to CBP to either void the notice of penalty and liquidated damages or will offer to pay a lesser amount. If there are mitigating circumstances, CBP and FDA may agree to the payment of a lesser amount. See 21 CFR 1.97(b).

If the importer of record refuses to pay the amount agreed upon by CBP and FDA, the importer may seek review with CBP if their petition is denied.

9-14-5 RESPONSIBILITY UNDER THE BOND

When the importer of record is a customhouse broker and not the ultimate consignee, a plea is frequently entered for cancellation of liquidated damages on the basis that the broker had no part in the distribution of the merchandise. It should be emphasized that any importer of record has agreed to the obligations set forth in the bond, most importantly, redelivery. If such bond holders were excused from their obligations, the bond provisions would be unenforceable, and the distribution of imported goods prior to release would be encouraged. It may be pointed out to customhouse brokers that their assumption of the responsibility of importer of record was entirely voluntary. By filing the entry as importer of record, the customhouse broker assumes all obligations under the bond.

9-14-6 PENALTY RECOMMENDATION

In evaluating a bond action case, it should be remembered that the bond penalty is intended to make the unauthorized distribution of articles unprofitable. Very often penalties are so small that such penalties, in effect, encourage the illegal distribution of future imported lots.

In the absence of any aggravating factor, the following mitigating factors may be utilized in determining **if** mitigation is warranted. FDA may agree with mitigation under other circumstances.

1. The merchandise was exported after detention but prior to the issuance of a Notice of FDA Action - Refusal of Admission because the importer was not aware he/she was supposed to wait for the Refusal before exportation. The importer is able to supply documentation that the specific merchandise detained was, indeed, exported.
2. A shipment was released by CBP under an Immediate Delivery Entry (I.D.) and distributed prior to FDA release because it was the initial entry subject to the FFDCA by the importer who **was not aware** of FDA requirements.
3. Conditions out-of- control of importer - Examples:
 - a. An entry is stored in a public storage warehouse pending FDA clearance but is inadvertently shipped even though the importer has issued instructions to hold the merchandise until further notice. The importer must be able to document the issuance of such instructions, which must be verifiable by FDA.
 - b. A shipment being held pending FDA clearance is stolen or damaged or destroyed in an accident. **FDA personnel should obtain written documentation of the theft or accident from the importer before considering recommending mitigation.**
4. It is the responsible party's first/only failure to redeliver within two (2) years, and the firm's cooperation with FDA has been positive in providing access to records, initiating recalls, etc.

5. There exists either a non-violative FDA analysis or "acceptable" private laboratory analysis for which audit sample is not available. **NOTE:** repetitive failure (more than once within two (2) years) to have audit samples available constitutes an aggravating factor. See aggravating factors below.
6. Importer has an excellent compliance history with FDA.
 - a. The importer has had only one or two bond offenses since doing business, constituting a small percentage of the importer's total entries which FDA has chosen to examine; and
 - b. The importer has an excellent recorded history of entering product in compliance with the Act and has fully cooperated with FDA while in business; and
 - c. The importer makes a reasonable attempt to retrieve the entry as soon as it is brought to his/her attention.

FDA staff may recommend mitigation of bond penalties based on other factors FDA deems pertinent. Although often used by importers in the past as "extenuating circumstances," the following are **not** considered examples of true mitigating circumstances:

1. The amount of merchandise missing
2. The seriousness of the violation

Note: FDA may consider a firm's history of previous bond violations to show that the importer (e.g., broker serving as importer of record) was aware of FDA and CBP procedures, and that mitigation may not be appropriate.

In addition, there are some aggravating factors which would generally preclude any mitigation. These factors follow.

1. Attempt to deliberately evade FDA surveillance.
2. Fraud
3. Un-redelivered product has resulted in injury or poses a risk to the public health.

9-14-7 MITIGATION INSTRUCTIONS

The "redelivery bond" is a CBP requirement and the mitigation process is a CBP procedure. Therefore, FDA will not consider mitigation until a mitigation petition is filed with CBP and forwarded to FDA for evaluation.

As with the basic decision to mitigate, FDA may, based on judgment and evaluation of the facts, make a recommendation on the degree of mitigation. The following general procedures should be considered in determining the amount of mitigation:

1. In instances involving the documented exportation of the merchandise, first time importers, and situations out of control of the importer, (see items 1

through 6 in [Penalty Recommendation](#)) FDA may, based on an evaluation of the facts in the petition, agree to mitigate the penalty to a nominal amount or recommend no penalty.

2. In all other instances, the responsible FDA office should generally consider mitigating the penalty to the level of the value of the non-redelivered merchandise. The degree of mitigation can vary depending on the district's evaluation of the facts in the petition. However, except for those instances noted in item 1. of this section, mitigation below the value of the non-redelivered merchandise should be considered only in exceptional circumstances.

If the office has doubts concerning the amount of the penalty recommendation, they should submit the case to OIO for review and advice.

9-14-8 TRACKING OF PENALTY ACTIONS

Until this functionality is available in OASIS, each office shall maintain a log of bond violations and assessment of penalties, in the event that it becomes necessary to check on the past violations of an importer of record. The specific format for such a log is at the office's discretion; however, it should contain at least the following information when available: name and address of the importer of record; product involved; value of merchandise not recovered; penalty paid; date of action; sample number; reason for the detention; and concise reason for the bond action. It is no longer necessary to send a list of bond actions to OIO.

9-15 IMPORT INFORMATION DIRECTIVES

9-15-1 PURPOSE

To identify and disseminate import information (problems, violative trends, etc.) for providing an effective import coverage program.

To formalize the procedures for initiating, preparing, clearing, issuing, revising, and canceling import information directives (Import Alerts and Import Bulletins).

9-15-2 BACKGROUND

Prior to 1972, FDA had no formal system to disseminate import problem information, although Import Circulars were occasionally issued for that purpose. FDA's coverage of imported products was often conducted on a district-by-district basis, resulting in less effective consumer protection.

A formal system known as Import Alert Procedures was established in 1972. Import Alerts replaced the Import Circulars. Detailed procedures for initiation, preparation,

clearance, issuance, revision, and cancellation of alerts were added in later RPM revisions.

The FDA Import Alert Retrieval System (FIARS) was made operational in August 1987. FIARS is a computerized format for Import Alerts and Bulletins, enabling users to search for an alert or bulletin by keyword or full text search. The FIARS program is updated by OIO after new alerts or bulletins are issued by EMS.

9-15-3 APPROACH

Import information directives consist of the following documents issued by OIO:

- Import Alerts identify problem commodities and/or shippers and/or importers and provide procedures for import coverage. Import Alerts will identify those products or shippers that have met the criteria for detention without physical examination. See RPM [subchapter 9-8](#) for discussion of detention without physical examination.
- Import Bulletins are generally informational only. While the information may identify possible problems, bulletins may not provide policy or coverage procedures, although in some cases sample collections will be advised.

9-15-4 IMPORT ALERTS

Import alerts significantly improve the uniformity of enforcement in import problem areas. Import alerts may have a significant impact on national and international economic and trade matters.

Initiating an Import Alert

New import alerts may be proposed by ORA units or offices, the centers, or any FDA unit. Recommendations for import alerts should have the concurrence of the appropriate management of the requesting unit.

Submit recommendations for import alerts to OIO. Include the following information in the recommendation memorandum:

- Purpose of the import alert.
- All pertinent background information such as sample results, violation rates or trends, etc.
- The national significance of the problem (health hazard, etc.).
- The volume of entries, number of importers, foreign shippers, countries involved, other product information such as whether it is seasonal in nature, etc.
- An accurate and complete description of the product, including its packaging and how it is to be stored.

While not required, the submission of a proposed draft of the import alert with the recommendation is highly recommended. FIARS guideline document #00-05 provides the import alert format.

After review, OIO will prepare a clearance package containing an import alert draft, the [Form FDA-2306 \(Clearance Record\)](#), and any other pertinent information. If the data is incomplete or insufficient the initiator of the draft will be advised.

Import Alert Clearance Procedures:

OIO is responsible for proper clearance and issuance of import alerts. The clearance package will be sent to the appropriate center, OIO, and OCC for clearance; and to the Office of Regulatory Science (ORS) and OIO management as necessary. If revision is necessary, the package should be returned to OIO for correction. Upon clearance, OIO will issue the alert via electronic mail service (EMS), load the alert into CMS and provide appropriate screening in the national entry database.

Clearance Timeframes:

Every effort should be made to expedite clearance of import alerts. Each clearance point should attempt to review and clear each alert within 2 days. Import alerts involving health hazards should be hand-carried to the next clearance point and/or telephone clearance should be obtained.

When clearance delays are encountered, clearance units should inform appropriate OIO staff (301-796-0356). Upon approval, OIO will issue the import alert via electronic mail.

Review of Import Alerts

As conditions permit, all import alerts over two years old will be reviewed semi-annually by OIO to determine whether they are current. This review will include an evaluation of detention activity for the previous one year period, the health significance of the problem, etc. When the evaluation so indicates and the Centers agree the alert will be deleted or revised as needed.

Import Alert Filing Procedure

Import Alerts will be numbered within industry code (i.e., import alerts dealing with seafood begin with industry code "16").

9-15-5 IMPORT BULLETINS (IB)

OIO will issue Import Bulletins on an as-needed basis. Bulletins are usually advisory only and may not disseminate policy or procedures. They will issue on the responsibility of OIO. They will be numbered chronologically within Industry Code preceded by "B" (16-B01, etc.). Import Bulletins are generally valid for 90 days after issuance. Any information from ORA and FDA units which falls into this category may be forwarded for consideration as an Import Bulletin.

OIO will review Import Bulletins to see if information has developed which indicates the need for an alert. If individual offices or units develop such information they should notify OIO.

9-16 PRIORITY ENFORCEMENT STRATEGY FOR PROBLEM IMPORTERS

9-16-1 PURPOSE

To provide procedures for dealing with importers or other individuals who engage in business practices that appear designed to evade the lawful regulation of imports. The procedures outlined in this chapter should not be considered all-inclusive, nor are they intended to limit local options. Situations that appear to involve criminal activity (e.g. smuggling, falsification of records) should also be referred to the Office of Criminal Investigations (OCI) for their information and follow-up, as appropriate.

Priority attention should be given to firms with a history of any of the following actions:

1. Distributing imported articles in domestic commerce following receipt of a Notice of FDA Action specifying the intention of Sampling, or the Detention or Refusal of the articles; or prior to receipt of a Notice of FDA Action specifying the articles are released.
2. Repeatedly importing violative articles.
3. Falsifying documents at time of entry, reconditioning, or re-export, including misdeclaring articles to avoid detention without physical examination or other regulatory action.
4. Re-entering previously refused articles into the United States.
5. Failing to recall or redeliver to CBP, at its request, an article for which a Notice of FDA Action specifying that the article was refused by FDA has been issued.
6. Introducing or delivering for introduction into domestic commerce (after entry) any article which is adulterated or misbranded, or which is a new drug without an approved New Drug Application.
7. Committing any prohibited act. See 21 USC 331.

9-16-2 BACKGROUND

In developing OASIS, the specific forms "May Proceed Notice," "Release Notice," "Notice of Sampling," "Notice of FDA Action - Detained," and "Notice of Refusal" have been replaced by the issuing of "Notices of FDA Action," which includes a description of the specific FDA action (May Proceed, Release, Sampling or Intention of Sampling, Detained, or Refusal) identified for the specific line in the entry. The use of the designations "Product May Proceed," "Product Released by FDA," "Product Collected by FDA," "Product Detained by FDA," or "Product Refused Entry by FDA," or similar wording should be considered as meeting the standard, "giving notice thereof to the owner or consignee." See 21 USC 381(a); 21 CFR 1.94.

In 1988, the Agency conducted a short-term enforcement operation aimed at determining the disposition of food articles refused admission. Thirteen percent of articles refused admission for non-labeling violations had been distributed in interstate commerce, rather than redelivered for export or destruction.

In 1990, the Agency discovered an importer of ceramic dinnerware circumventing detention without physical examination by declaring the entries as statuary, a non-regulated article.

Between 1990 and 1992, New York District, in conjunction with the CBP, investigated and documented an importer's history of violative practices regarding the importation of frozen seafood products. Practices included repeatedly importing violative articles; falsifying documents and manipulating articles to avoid detention without physical examination; refusing or not permitting timely inspection of entries; importing previously refused articles; and smuggling. As a result of the investigation, in 1992 the firm's president was indicted by the U.S. District Court in New Jersey. He was subsequently convicted on 138 counts for submitting false documents to FDA and for illegally re-importing previously rejected salmonella contaminated seafood. On February 5, 1993, all frozen seafood products imported by the firm were placed on detention without physical examination.

Between 1992 and 1995, Florida District and OCI, in conjunction with CBP, investigated and documented an importer's history of violative practices regarding the importation and handling of frozen shrimp. Practices included repeatedly importing violative articles; falsifying documents to avoid detention without physical examination; manipulating articles in attempts to have packers removed from detention without physical examination; and laboratory shopping (sending samples of product that is detained without physical examination to different private labs and then submitting to FDA only the analysis which shows the product in compliance, even though the other lab found the product violative). Further, Florida District identified three shipments of shrimp imported by the firm which were seized because of decomposition. Prior to the seizures, the firm attempted to sell the decomposed shrimp, which had been rejected by eight consignees and the National Marine Fisheries Service. The firm also was discovered washing decomposed, imported shrimp with a copper sulfate solution in an attempt to conceal the decomposition. On March 10, 1995, all frozen shrimp imported by the firm was placed on detention without physical examination. As a further result of the investigation, the firm and its top management were indicted by the U.S. District Court in Florida. The firm's vice president was convicted on 12 felony counts, including conspiracy, obstructing justice, violating CBP law, and tainting shrimp and selling it with the intent to defraud and mislead.

9-16-3 APPROACH

The following enforcement approaches have general applicability. They should be considered when dealing with firms engaged in the types of practices listed in the "[Purpose](#)" section above, when conventional import coverage and enforcement avenues appear insufficient to address the problem. The approaches include review and approval

of reconditioning proposals ([FDA-766](#)), the use of Warning Letters (sequential, when appropriate), recall, seizure, injunction, or prosecution.

As always, use of enforcement discretion should be considered in determining the appropriate regulatory response. When egregious actions are encountered, a sequential approach may not be appropriate. Also, situations that appear to involve criminal activity (e.g., smuggling, falsification of records) should be referred to OCI for their information and follow-up, as appropriate.

WARNING LETTERS

Issuance of Warning Letters to remind firms of their responsibilities to import articles that comply with the provisions of the FFDCA and other laws enforced by FDA, and to assure that only non-violative articles enter domestic commerce in the United States, is often an appropriate first action. Warning Letters may be issued to the importer of record, owner, or consignee (if other than the importer of record) with copies to CBP, and may be issued for the following reasons:

1. Failure to hold an entry intact pending receipt of a Notice of FDA Action specifying that the article was Released by FDA. A copy of the Warning Letter should be attached to the redelivery request sent to CBP when such a request is made.
2. The first documented attempted entry with misleading information. Misleading information includes, for example, low-acid canned foods from a non-registered plant entered under another processor's Food Canning Establishment (FCE) number; or articles from firms subject to detention without physical examination; or articles declared as non-regulated articles to avoid detention without physical examination or other agency action.
3. The first documented instance of submission of a foreign government certification document or private laboratory analytical report that does not match the entry in question.
4. An importer's failure to provide FDA with information regarding the availability for sampling or location of an entry for which a Notice of FDA Action specifying FDA's intention of sampling has been issued.
5. To inform an importer that FDA has requested that CBP deny it permission to file an entry bond, thus restricting its shipments to CBP's custody until admissibility has been determined.
6. Consistently importing violative articles not already subject to detention without physical examination. The importer should be notified that this practice may result in future entries being detained without physical examination.
7. Any other situation which warrants an official notification to the firm and further opportunity for compliance before other action is taken.

The Warning Letter should state that any distribution of refused articles or articles sampled or intended for sampling that were distributed prior to release are in violation of the FFDCA or other applicable acts enforced by FDA, and may result in domestic seizure or other sanctions, including injunction or prosecution.

RECONDITIONING PROPOSALS

The FFDCA provides that when an article is submitted for entry is found to be violative, the importer has the option of exporting it, destroying it, rendering it not subject to the Act, or requesting authorization from the agency to attempt to bring it into compliance with the Act.

If the importer of record decides to attempt to recondition a detained article, section 801(b) of the Act (21 USC 381 (a)) provides that the owner or consignee (by practice, FDA also accepts applications from an importer of record, with a properly posted bond, as the agent of the owner or consignee) may submit to the FDA a written application [Form FDA-766](#) requesting authorization to bring into compliance an article that is adulterated, misbranded, or in violation of Section 505. See 21 USC 381 (a)(3). The owner or consignee may bring the article into compliance by relabeling or other action, or by rendering it other than a food, drug, device, or cosmetic. (Refer to RPM [subchapter 9-12, "Reconditioning."](#))

The approval of the reconditioning application is at FDA's discretion. The Agency should require appropriate controls and provisions as a part of any application before it approves the reconditioning. The application is an agreement between the importer (or other appropriate party submitting the application) and the Agency.

If FDA has documented an importer's practice of consistently importing violative articles not already subject to detention without physical examination and only attempting to recondition the articles after detention, FDA may require, as part of any reconditioning application, that the importer agree to destroy any article not brought into compliance during reconditioning, in lieu of permitting re-export of the violative article.

The responsible office should consult and obtain the concurrence of both the OIO and the appropriate Center Compliance Office before initiating a decision requiring a specific importer to destroy rather than re-export violative articles as part of every reconditioning process.

The information supplied should include, but not be limited to, the following:

1. Documentation of the firm's pattern of importing violative articles.
2. Documentation of prior warning to the firm of their obligation to import the article in compliance with the FFDCA or other acts enforced by FDA.
3. Documentation which may establish that the article can be imported in compliance and thus would not require reconditioning after importation.

REQUESTS FOR VOLUNTARY RECALLS

Although requests for voluntary recalls duplicate a request for redelivery action to some degree, they also offer definite advantages. Experience indicates that requesting the firm to initiate a voluntary action, such as a recall, may result in a more favorable response by the firm than a demand for redelivery. A recall may occur more promptly because it can be initiated in a matter of days, while redelivery may not take place for 90 days or more. This is especially significant in hazard-to-health situations. A recall may provide FDA with further knowledge of the status of the violative merchandise being returned and usually makes it easier to maintain control of the article. This ultimately leads to improved consumer protection.

FDA management should very carefully encourage the firm to consider a voluntary recall under the following situations:

1. When a potential health hazard situation exists.
2. When there is evidence of distribution of detained or refused merchandise.

When an importer fails to respond fully or in a timely manner to a Warning Letter, or we are notified by CBP that an Importer has not responded to a Notice of FDA Action Specifying Refusal of the product, it may be an indication the goods are no longer intact. A visit to the importer may be appropriate and, if articles are missing, attempt to determine the firm's intentions with respect to corrective action.

When a potential health hazard situation exists and the article has been illegally distributed, appropriate press coverage may issue naming firm, product, and country of origin. Issuance of all publicity must be in accordance with guidelines.

Import recalls are to be conducted in full accordance with the procedures in this RPM. [Chapter 7- Recall Procedures](#). Supervision of the disposition of returned articles may be made either by FDA or CBP. If disposition will be by destruction, it is suggested that FDA provide the supervision. If the articles are to be exported, CBP or FDA may handle the supervision.

SEIZURE

Seizure is another enforcement approach that may be considered to gain control over violative imported articles. Seizure is an action against an article. Consequently, it will be necessary to show, through laboratory analysis or otherwise, that the article seized is actually violative. An importer's history of illegal actions, while relevant, is not itself sufficient to support seizure. Whatever the importer's previous history, it will be necessary to show that the article itself is violative. Seizure may be considered for an article which:

1. Represents a potential hazard to health and has been or is likely to be distributed in domestic commerce following receipt of a Notice of FDA Action specifying that the article is Detained or Refused; or

2. Has been fraudulently identified/represented in documents submitted to the Agency; or
3. Is identified by the Agency as a previously refused article.

When an imported article is seized, and condemned, it is subject to the provisions of section 304(d) (21 USC 334(d)) which may allow for re-exportation of the article, provided specified conditions are met. Under 21 USC 334(d), certain condemned imported articles may be re-exported under limited circumstances. Re-exportation is not available for condemned unapproved new drugs (see 21 USC 355), or foods in violation of the emergency permit control provision (see 21 USC 344). Such articles must be destroyed.

In order to be able to re-export condemned imported articles, the party seeking re-export must satisfy several threshold conditions:

1. The violation did not occur after the article was imported.
2. The party seeking re-export "had no cause for believing that it was adulterated, misbranded, or in violation before it was released from CBP custody."
3. The party seeking re-export must "establish that the article was intended for export at the time the article entered commerce." An example of where it may be possible to demonstrate that a product was intended for export at the time it entered commerce would be when products are imported for purpose of transshipment to a destination outside the U.S.
4. Compliance with 21 USC 381 (e) (1):
 - a. Intended for export.
 - b. Accords with the specifications of the foreign purchaser (unless the article is to be exported to the original foreign supplier, in which case there is no need to comply with this requirement).
 - c. May not be in conflict with the laws of the country to which it is intended for export (unless the article is to be exported to the original foreign supplier, in which case there is no need to comply with this requirement).
 - d. Labeled on the outside of the shipping package that it is intended for export.
 - e. Not sold or offered for sale in domestic commerce.

Therefore, there are circumstances where the seizure of an article may not accomplish more than detention and refusal of the article, other than stricter control over the goods before re-export and compliance with the applicable requirements of Section 801(e) (21 USC 381(e)).

Consequently, in evaluating whether a seizure is an appropriate course of action, FDA should consider whether the facts in the case would justify recommending to a court

that re-export of the article would be an unsatisfactory resolution. Among the points to consider are:

1. Does a potential health hazard exist?
2. Does the previous history of the person in possession of the articles indicate that the person may attempt to re-enter the articles into the United States at a later date?
3. Did the violation occur after the article was imported?
4. Did the importer have cause to believe that the article was in violation before entry?
5. Does the article meet the legal specifications of the country to which it would be exported?
6. Was any portion of the article sold or offered for sale in domestic commerce?
7. Is the article in violation of 21 USC 342(a)(1), (2), or (6), 344, 351(a)(3), 352(j), 355 or 361(a) or (d)?
8. If the article is a drug will it be re-exported to the original foreign supplier?

Under certain circumstances, FDA may recommend seizure of violative articles under 21 USC 334 while the articles are still under import status, rather than allow re-export as provided under 21 USC 381(a). Generally, seizure of articles while in import status may be appropriate if the articles must be destroyed (pose a serious health hazard or it is likely that the articles will be reintroduced into the United States), or the public health requires that certain conditions be imposed (e.g., conditions in 21 USC 381(e)(1)).

As with citation, prosecution, and injunction, samples collected for seizure consideration should, whenever possible, include a 702(b) portion. See 21 USC 372 (b). Such samples should be collected, sealed, analyzed, and otherwise handled in accordance with procedures normally applied to domestic samples.

State embargo authority and CBP holds are alternative methods to gain control over violative articles. CBP may also release an article at our request so that an immediate domestic seizure may be conducted. Moreover, if a violative article represents evidence of a crime, it may be seized pursuant to a criminal search and seizure warrant. These avenues should also be considered, especially if an importer is likely to attempt to quickly re-export the article.

INJUNCTION

If injunction is the action of choice, the case should be developed in accordance with the procedures set forth in RPM [Chapter 6 - Judicial Actions](#), subchapter 6-2, "Injunctions." Injunctions may require a pattern of actual violations with some recognizable danger of a recurrence. The monitoring of an injunction is resource intensive. These facts should be taken into consideration when evaluating this course of action. Also consider that an injunction often results in a hearing more quickly than does

a prosecution, particularly if a Temporary Restraining Order (TRO) is requested. This can result in quick corrective action as well as more rapid and efficient redelivery if this response is requested in the injunction. Also, the burden of proof is less in civil cases than in criminal cases, and injunction does not preclude subsequent prosecution for the same violation.

When developing an injunction case against an importer or consignee, there must be a well- documented history of an illegal practice.

A TRO requires a heightened showing of harm. See RPM [Chapter 6 - Judicial Actions](#), subchapter 6-2, "Injunctions" regarding the prerequisites for a TRO in conjunction with an injunction action.

CITATION/PROSECUTION

Citation/prosecution should be used when conventional import enforcement approaches are determined to be inadequate to correct violative practices, or the violation is sufficiently egregious to warrant punishment.

When citation/prosecution is the action of choice, refer to RPM [Chapter 6 - Judicial Actions](#), subchapter 6-5, "Prosecution" for the appropriate procedures.

FDA should consider the potential impact of developing citation/prosecution recommendations as the action of choice in the following instances:

1. Where there is repetitive illegal distribution of articles after issuance of a Notice of FDA Action specifying the intention of Sampling or Detention; or
2. Where the importer submits false or misleading entry documents; or
3. Where the importer submits false or misleading private laboratory analytical results or false certifications; or
4. Where the importer submits false or misleading export documents; or
5. Where the importer repeatedly brings previously refused articles into the United States; or
6. Where evidence of other fraud exists.

This list is not all inclusive and there may be other situations where citation/prosecution is appropriate.

Any recommendation for citation, prosecution, or injunction must be supported by fully documented instances of attempts to circumvent normal import procedures. For a felony prosecution recommendation, there must be a fully documented attempt to do the same, with evidence of the intent to defraud or mislead. It is not necessary, in developing a citation/prosecution recommendation, to show that each specific entry is actually violative. However, physical evidence that documents the violative nature of an

entry (or of several entries) would be useful to highlight the likely result of the firm's pattern of behavior.

It is important to remember that sample collection and analytical procedures in these cases, as for seizures and injunctions, should differ from routine import work. OCC has consistently advised us that when an import physical sample is collected for use in an anticipated legal action, a sealed 702(b) portion should be available (21 USC 372 (b)). This request is further supported by procedures provided in the RPM. Proper chain of custody should also be maintained for these samples. Ordinarily, check analyses should be conducted on such samples. In instances where CPGs exist and instructions differ for domestic legal actions as opposed to import detention, FDA should follow the procedures for domestic legal actions in terms of types of analyses, check analyses, etc.

Importers of articles detained without physical examination should not feel free to distribute and sell such articles without risk of criminal penalty. Criminal action may be possible against importers violating FDA's detention without physical examination actions or who routinely ship articles without a Notice of FDA Action indicating the articles are Released. Refusal to allow inspection is a violation of the FFDCA. Subsequent entry pursuant to an inspection warrant may yield evidence providing the basis for a felony violation for refusal to allow inspection. Distribution of an article prior to receipt of a Notice of FDA Action indicating the article May Proceed or is Released should be considered refusal to permit inspection, as authorized by section 704 (21 USC 374).

In addition to charges under the FFDCA and CBP law, Title 19 (note especially, 19 USC 1592 and 1595a), and/or Title 18 charges may also be considered. These include 18 USC 1001, false statements; 18 USC 1505, obstruction of justice (when a firm knowingly and willingly interferes with an FDA inspection by distributing imported articles not released by FDA from import status); 18 USC 542, entry by use of a false statement; 18 USC 545, smuggling; and 18 USC 371, conspiracy.

9-17 IMPORT FOR EXPORT (IFE)

9-17-1 PURPOSE

This subchapter covers articles offered for import under the import for export (IFE) provisions of the FFDCA section 801(d)(3). This section is intended to provide uniform procedures for handling such importations by all FDA offices. This subchapter represents the Agency's current thinking on the application of the import for export provisions of the Act.

9-17-2 BACKGROUND

The FDA Export Reform and Enhancement Act of 1996 (Export Reform Act), Public Law 104-134, amended sections 801(d)(3) and d(4) of the Act to allow the importation of certain articles that are unapproved or otherwise do not comply with the Act, provided

that those imported articles are further processed or incorporated into products that will be exported from the United States, by their initial owner or consignee in accordance with section 801(e) or section 802 of the Act or section 351(h) of the Public Health Service Act (PHSA). On June 12, 2002, the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act), Public Law 107-188, was signed into law. Section 322 of PL 107- 188 amended section 801(d)(3) of the Act. The amended provision is effective September 9, 2002.

Under the amended provision of the Act, importers wishing to import certain violative articles that are intended for further processing or incorporation into another product and subsequent export must provide FDA with certain information at the time of initial importation. The articles include drugs (or components), devices (or components or accessory of a device or other article of a device requiring further processing, which is ready or suitable for use for health-related purposes), food additives, color additives and dietary supplements. The information includes a statement that confirms the intent to further process or incorporate such article into a product to be exported and identifies entities in the chain of possession of the imported article. Importers also must provide certificates of analysis, as necessary to identify the article, unless the article is a device or an article described in Section 801(d)(4) [Section 801(d)(3)(A)(i)(III)].

Under section 801(d)(3)(A)(ii), at the time of initial importation and before delivery to the importer, initial owner, or consignee, a good and sufficient bond must be executed providing for liquidated damages in the event of default, in accordance with CBP requirements.

The initial owner or consignee of the article must maintain records of the use and/or destruction of such imports and must submit the records or a report to FDA upon request [Section 801(d)(3)(A)(iv) and (v)]. The initial owner or consignee must destroy any article or portion not used in an exported product [Section 801(d)(3)(A)(iii)].

The amended section 801(d)(3)(B) provides that FDA may refuse admission of an article that could otherwise be imported under section 801(d)(3)(A) if there is credible evidence or information indicating that such article is not intended to be further processed by the initial owner or consignee or incorporated into a drug, biological product, device, food, food additive, or dietary supplement that will be exported in accordance with section 801(e) or section 802 of the Act or section 351(h) of the PHSA. The "import for export" requirements for blood, blood components, plasma, and source leukocytes differ from those for drugs and other biological products. The Act allows for the importation of these blood products and components provided they comply with section 351(a) of the PHSA or FDA permits such imports "under appropriate circumstances and conditions" as determined by CBER (section 801(d)(4) of the Act). Tissue products may be imported only if the importation complies with regulations promulgated under section 361 of the PHSA. The Bioterrorism Act did not amend section 801(d)(4). However, if CBER approves a particular request for import under section 801(d)(4), the import must comply with all applicable requirements of the amended section 801(d)(3) of the Act. [Section 801(d)(4)]. The import also must

comply with all applicable export requirements when the product is exported. [Section 801(d)(3)(A)(i)(I) and (iii)]. The Bioterrorism Act did not amend section 801(d)(4). However, if CBER approves a particular request for import under section 801(d)(4), the import must comply with all applicable requirements of the amended section 801(d)(3) of the Act. [Section 801(d)(4)]. The imported article also must comply with all applicable export requirements when the product is exported. [Section 801(d)(3)(A)(i)(I) and (iii)]. The Bioterrorism Act also amends section 301 of the Act. The amended section 301(w) prohibits the making of a knowingly false statement in any statement, certificate of analysis, record or report required under section 801(d)(3); the failure to submit a certificate of analysis; the failure to submit or maintain records; the release into interstate commerce of any article or portion imported into the United States under section 801(d)(3) or any finished product made from such article or portion, except for export in accordance with section 801(e) or section 802 of the Act, or section 351(h) of the PHSA; and, the failure to export or destroy any articles or portions not incorporated into a finished product.

Section 801(d)(3) requires that the imported article or portions must be further processed or incorporated into a drug, biological product, device, food, food additive, color additive or dietary supplement that will be exported.

9-17-3 INSTRUCTIONS FOR INFORMATION SUBMISSION, ENTRY REVIEW AND DOMESTIC FOLLOW-UP

Information Submission

When a drug or device component, food additive, color additive, or dietary supplement is imported under section 801(d)(3), the importer is required to submit a statement to FDA at the time of each importation with the following information:

1. That such article (the components, parts, accessories, or articles) is intended to be further processed by the initial owner or consignee or incorporated by the initial owner or consignee into a drug, biological product, device, food, food additive, color additive, or dietary supplement that will be exported from the United States by the initial owner or consignee in accordance with section 801(e) or section 802 of the Act or section 351(h) of the PHSA [Section 801(d)(3)(A)(i)(I)]; and
2. Identification of the manufacturer of such article and each processor, packer, distributor, or other entity that had possession of the article in the chain of possession from the manufacturer to such importer of the article [Section 801(d)(3)(A)(i)(II)]; and

3. The statement must be accompanied by such certificates of analysis as are necessary to identify such article unless the article is a device or is an article described in section 801(d)(4). [Section 801(d)(3)(A)(i)(III)].

The statement required to be provided to FDA pursuant to section 801(d)(3)(A)(i) must include a declaration that the article is intended to be imported for further processing by the initial owner or consignee and information identifying the article and the initial owner or consignee. The statement should include:

1. Identification of all entities that had possession of the article in the chain of possession which should include information sufficient to accurately identify the entity such as the name of each entity (including business and trade names), complete physical address, transaction dates, and any other information to aid in identification such as telephone and fax number, and e-mail address.
2. Information sufficient to identify the chain of possession of the article through each entity, which could include information such as product coding, lot, batch, or other identification numbers. For medical devices, device history records required of domestic and foreign manufacturers, pursuant to 21 CFR820.184, may provide information to assist in meeting this requirement.
3. For imported articles subject to section 801(d)(4), the manufacturer in the chain of possession can be considered to be the initial collection agency, e.g., a blood collection center for purposes of information required under section 801(d)(3).

Certificates of analysis, as are necessary to identify the imported article, must accompany the statement filed pursuant to 801(d)(3)(A)(i). [Section 801(d)(3)(A)(i)(III)]. The submission of such certificates is not required if the imported article is a device or is an article described in 801(d)(4). Certificates of analysis, or equivalent documentation should provide the article's formulation, ingredients, components, or assay, as appropriate to the type of article.

For drug products, certificates of analysis could include documents that:

1. Assure the identity of the substance and its components in the chemical and drug industries. A batch certificate could be a certificate of analysis.
2. Establishes a drug ingredient is certified to meet USP requirements could be a certificate of analysis.
3. Provide sufficient information to determine the level, potency, identity, strength, quality and purity of the drug component and whether prohibited material has been used in the imported article could be considered certificates of analysis.

For other products, documents that convey assurance as to the identity of the article

and its components or substances could be a certificate of analysis. Sufficient information should be provided to determine if prohibited material has been used in the imported article. For an article of food additive or color additive, a document indicating specification of purity or documents establishing the article is a “certified” color or of “food grade” or “Codex Alimentarius” grade food additive could meet the requirement of a certificate of analysis.

When the initial owner or consignee of the imported article is not the importer, the importer should provide FDA with information identifying the initial owner or consignee with the entry. In cases where the importer is not the initial owner or consignee and the article is intended for multiple owners or consignees, each of whom will serve as the initial owner or consignee for a portion of the article, the importer should submit a separate statement identifying each owner or consignee and indicating the amount of the entry each is to receive. Failure to provide this information at the time of importation may be viewed by FDA as evidence that the product does not meet the conditions of section 801(d)(3). FDA recommends the Information required by section 801(d)(3) be provided electronically by uploading to the entry or entry line via ITACS.

If the information required by section 801(d)(3)(A) is provided and it is determined that the IFE conditions are met, a “May Proceed” decision may be issued. If the information required by section 801(d)(3)(A) is not provided at the time the article is offered for import, and if the product is otherwise subject to refusal of admission pursuant to section 801(a), FDA may issue a Notice of FDA Action - Detained in accordance with normal procedures. See RPM [subchapter 9-9 "Notice of FDA Action – Detained for Non-Mail Shipments"](#)). If a response to the Notice of FDA Action - Detained is not received by the responsible FDA office within the designated time (10 days, excluding Saturday, Sunday, and Holiday, or date requested by on the notice, or additional time as deemed necessary by the responsible FDA office), a Notice of Refusal should be issued. See [RPM subchapter 9-11 "Notice of FDA Action - Refusal of Admission" Instructions](#), "When Should the Notice of FDA Action - Refusal of Admission be Issued?". Once issued, cancellation of the Notice of Refusal should be considered only under unusual circumstances at the discretion of the FDA. See RPM [subchapter 9-11 "Notice of FDA Action - Refusal of Admission" Instructions](#), "Reopening of a Case".

If the FDA has evidence or information indicating that the imported article is not intended to be further processed by the initial owner or consignee, or incorporated by the initial owner or consignee, into a product included in section 801(d)(3) that will be exported in accordance with the Act or the PHSA, the entry should be referred to the compliance branch as a detention recommendation and FDA may issue a Notice of FDA Action - Detained in accordance with normal procedures. In certain circumstances, application of section 801(d)(3)(B)'s refusal authority may be appropriate. If during the detention and hearing period evidence or information is received that satisfies the requirements outlined in section 801(d)(3), and it is determined that the IFE conditions are met, then FDA may issue a release.

Submission of Entries and Entry Review

Filers must declare when an imported article is intended for further processing or incorporation into a product that will be exported in accordance with section 801(d)(3)(A)(i) of the Act. Declaration for electronic entry submission is made by transmitting the intended use code "Import for Export" and the Affirmation of Compliance (A of C) "IFE" as well as by providing documentation required in accordance with section 801(d)(3)(A)(i). The filer should also declare the "importer, initial owner or consignee" responsible for further processing or incorporating the imported article into the product to be exported, by providing the name and address of such firm or individual in the FDA consignee field of the entry. The appropriate FDA Firm Establishment Identifier (FEI) number for the entity may also be provided as part of the entity identification. (See [FDA Supplemental Guide](#))

When the article is intended for multiple owners or consignees, a separate FDA entry line should be created for each owner or consignee as provided for in the ACE/ITDS system.

For manual entry submissions, or when FDA has requested supporting paper entry documents for an electronic "IFE" entry, all documentation required by section 801(d)(3) should be included in the filer's entry documents, including the statement and a certificate of analysis, as necessary. For electronic submissions, documents should be uploaded to the entry or entry line. When the imported article is intended for multiple owners or consignees, a separate statement and certificate of analysis, as necessary, should be submitted for each owner or consignee indicating the portion of the entry each is to receive. The responsible FDA office should reconcile the quantities provided and any product not accounted for should be detained if otherwise subject to refusal of admission pursuant to section 801(a) as noted above.

If all required documentation is provided and the conditions required by section 801(d)(3) FD&C Act [\[21 U.S.C. 381 \(d\)\(3\)\]](#) have been met, including a declaration that the entry line is import for export, a "May Proceed" may be issued. The filer may be held responsible for the accuracy of the information transmitted to FDA through FDA's filer evaluation.

NOTE: If receiving a non-ABI entry declared as IFE, refer to the Entry Review Job Aid for specific instructions on creating a manual entry in ER.

Domestic Follow-up

As indicated in IOM 5.2.2 Domestic Follow-up of Import for Export Entries and IOM 5.7.7.5 – Import for Export, follow up for IFE entries/lines is conducted during establishment inspection of the initial owner or consignee. When a domestic inspection is conducted at the initial owner or consignee's facility where the article imported pursuant to section 801(d)(3) is being further processed or incorporated into a product intended for export, the inspection should include appropriate review of the domestic manufacturer's compliance with section 801(d)(3). The FDA office responsible for

conducting an inspection of the initial owner or consignee can obtain IFE entry/line information and documentation from the Import for Export Section in OSAR Firm 360 and ORADSS report IMP046 Import for Export Entry Lines and Documents to determine if the firm has records of IFE entry/lines. For example, the investigator should request the manufacturer's import, export, and/or destruction records during an inspection.

The records/reports should include documentation indicating that the imported article was further processed or incorporated into another product and was exported in accordance with section 801(e) or section 802 of the Act, or section 351(h) of the PHSA, or destroyed. The records should establish that the entire amount of the product or article imported is used or exported or destroyed; that the exported products are labeled in conformance with section 801(e)(1) and meet the other requirements of section 801(e)(1) or section 802 of the Act or section 351(h) of the PHSA, as appropriate.

Please note, for drug and medical device products, an initial owner or consignee may be allowed to retain a sample of the imported article in order to comply with GMP regulations concerning sample retention.

Any follow-up regulatory actions regarding the failure of the initial owner or consignee to meet the requirements of section 801(d)(3) should be referred to the applicable [OIO](#) [DIO center liaisons](#).

9-17-4 TIME FRAME FOR HOLDING IMPORTED PRODUCT

Section 801(d)(3) allows for the importation of otherwise prohibited products and articles for manufacturing, further processing or incorporation and export. The amended provision does not impose any specific limitations on how long a product can be held in the United States before it must be further processed or incorporated into a product and exported or destroyed.

9-17-5 IMPORTED FOR FURTHER PROCESSING

The legislative history of the Export Reform Act indicates that section 801(d)(3) was intended to allow manufacturing and processing activities not previously permitted under the Act, and the legislative history of the Bioterrorism Act does not alter that intent. The terms "further processed" and "incorporated" can cover a wide range of activities. These can include packaging or labeling of finished products and specialized processing (such as sterilization) of a product. FDA recognizes that in some instances, it may be advantageous to manufacture a product in a foreign country and then ship it to the United States for specialized packaging or labeling. Merely storing an article or product in the United States before export is not considered "further processing."

9-17-6 PRODUCTS SUBJECT TO DETENTION WITHOUT PHYSICAL EXAMINATION

The import for export provision does not preclude the importation of articles that otherwise would be subject to detention without physical examination based on an FDA examination of previous shipments or a foreign inspection that documented significant GMP violations, or manufactured by a foreign firm that has refused to permit an FDA GMP inspection [21 CFR 820.1(d)]. Therefore, if these articles are offered for import in compliance with section 801(d)(3) or (4) such articles generally could be allowed unless other grounds exist for refusal of admission. Further procedures on criteria for accepting products for IFE that would otherwise be detained without physical examination products may be issued by each Center.

9-17-7 COMPLIANCE WITH RELEVANT EXPORT PROVISIONS

At the time of importation, FDA ordinarily will not know if the finished product will be exported under the provisions of section 801(e)(1) or section 802 of the Act or section 351(h) of the PHSA. Importers, initial owners, and consignees of articles imported or offered for import pursuant to section 801(d)(3) or (4) should determine whether the intended finished product meets the requirements of one or more of the export provisions (section 801(e)(1) and section 802 of the Act and section 351(h) of the PHSA). If they do not meet such requirements, they must destroy any products that may not be legally exported under the Act or the PHSA, as applicable. [Section 801(d)(3)(A)(i)(I) and (iii)].

9-17-8 IMPORTATION OF FINISHED GOODS FOR STORAGE AND EXPORT WITHOUT FURTHER PROCESSING AND OTHER ARTICLES NOT INCLUDED UNDER SECTION 801(d)(3)

Products and articles imported under section 801(d)(3) must be furthered processed or incorporated into a drug, biological product, device, food, food additive, color additive or dietary supplement that will be exported from the United States. This provision does not allow the import of violative products intended only for storage.

Importers of electronic products subject to performance standards are required by U.S. Customs regulation, 19 CFR 12.91, to file the form FDA 2877. Block A7 on form FDA 2877 needs to be checked to indicate that the device is for medical device processing under import for export.

Since the wording of the amended section 801(d)(3) specifically identifies only food additives, color additives, and dietary supplements as the only food articles that can be imported for export, FDA should not accept notification of import for export of other foods that do not meet the criteria of a food additive, color additive, or dietary supplement. Similarly, neither cosmetics (as defined by section 201(i) of the Act) nor tobacco products (as defined by section 201(rr)(1) of the Act or any product deemed to be a tobacco product under regulations promulgated under section 901 of the Act), meet the criteria for import for export under the provisions of section 801(d)(3) and any offers for entry for such importations should be refused admission as appropriate.

The amended section 801(d)(3) also identifies specific products into which articles imported pursuant to the section can be incorporated for export. These are drugs, biological products, devices, foods, food additives, color additives, and dietary supplements. Cosmetics and tobacco products are not listed as products that fall within this provision. Therefore, violative color additives intended for processing into a cosmetic product do not fall within the scope of section 801(d)(3), and entries for such importations should be refused admission, as appropriate.

9-17-9 IMPORTATION OF VIOLATIVE COMPONENTS FOR FURTHER PROCESSING INTO OTHER COMPONENTS AND UNFINISHED PRODUCTS

Many manufacturers assemble their products in various stages. These manufacturing steps may include sending partially completed products to firms in the United States for further manufacturing or processing, but not into a finished product. Neither the statutory language of the amended section 801(d)(3) nor the legislative history of the Export Reform Act or the Bioterrorism Act require that violative components allowed to be imported must be incorporated into "finished products." Because components, or "subassemblies," are the finished product of the U.S. manufacturer (although not necessarily a consumer ready product) and would constitute a drug, biological product, device, food additive, color additive, or dietary supplement within the Act's meaning, the agency has concluded that articles imported for use in the manufacture of such products fall within the scope of the import for export provision. Therefore, such products are subject to the requirements of section 801(e) or section 802 of the Act or section 351(h) of the PHSA.

9-17-10 IMPORT FOR EXPORT PROVISIONS FOR PRODUCTS MANUFACTURED IN FOREIGN TRADE ZONES

Foreign Trade Zones are federally sanctioned sites that, only for tariff purposes, are considered outside of the "Customs territory" of the United States. Nevertheless, products stored or manufactured in a Foreign Trade Zone are within the territory of the United States for the purposes of the Act and are expected to meet the same requirements as other products regulated by FDA. See CPGs [110.600 "FDA Authority Over Products of Foreign Origin Located in Foreign Trade Zones, Bonded Warehouses, or on Bonded Carriers"](#), and [110.200 "Export of FDA Regulated Products from U.S. Foreign Trade Zones"](#). These include the requirements of section 801(d)(3) and section 801(d)(4).

9-17-11 RECORDS AND INFORMATION TO BE PROVIDED TO FDA UPON REQUEST

Section 801(d)(3)(A)(iv) requires that the initial owner or consignee maintain records on the use or destruction of the imported articles or portions and to provide records when requested. The initial owner or consignee is also required to submit a report to FDA, upon request, that provides an accounting of the export or destruction of such imported article or portions and the manner in which such owner or consignee complied with the

requirements of section 801(d)(3). The records should include the statements and any certificates of analysis required to be submitted at the time of import as described above. Additional records could include documentation with more specific identification of the product such as Customs entry number, date, quantities, manufacturing process and controls and intent of the importation (i.e., further processing into product intended for exportation). Records on export or other disposition need to be retained (section 801(d)(3)(A)(iv)) and should include information such as quantity, dates, destination, shipping, means of destruction, and any records required under the export record keeping and notification regulation. 21 CFR 1.101.

9-17-12 AGENCY CONTACTS

Questions regarding the procedures to be followed by FDA or by industry relating to interaction with CBP should be addressed to the OIO at imports@fda.hhs.gov or 301-796-0356.

9-18 IMPORTATIONS FOR TRADE SHOWS/FAIRS, EXHIBITS AND SPECIAL EVENTS

9-18-1 PURPOSE

To provide operating procedures for FDA personnel regarding articles subject to regulation by the FDA which are imported as exhibits for trade shows, fairs, and exhibitions and regulated articles which are imported for use by participants in special events such as athletic competitions.

9-18-2 BACKGROUND

The responsible offices, as well as the OIO Import Program, frequently receive inquiries regarding the importation of regulated articles to be used as trade show exhibits to promote business opportunities in the United States. Also, persons who are participating in special events or athletic competitions such as The Olympics, Special Olympics or World Cup ski races, may request that foods, devices, or medications be brought into the United States for the sole use of the participating athlete or team. Although many of the articles have not been approved for use in the United States, and under normal circumstances would be detained, the FDA does not normally restrict foreign visitors from bringing with them native foods or required medications for their own use or consumption while in the United States.

Exhibits are usually imported for a short period and may be exported or destroyed following the conclusion of the event. Exportation may be to another trade show in another country or back to the country of origin. Products imported for special events and athletic competitions are usually used in the United States and any remaining products are exported or destroyed after the event is over.

9-18-3 CBP REQUIREMENTS

United States Customs regulations, 19 CFR Part 147, "Trade Fairs" govern the entry of merchandise intended for exhibition or for use in constructing, installing or maintaining foreign exhibits at trade fairs which have been so designated by the Secretary of Commerce. The regulations also contain provisions concerning CBP supervision of the merchandise and the disposition of the merchandise after the fair has closed.

A special form, "Entry for Exhibition" is used by CBP for exhibitions under the Trade Fair Act of 1959. Articles are entered under bond and may be permitted immediate delivery to the location where they are intended to be exhibited, placed in public storage for examination and subsequent delivery to the site of the trade fair, or into bonded warehouses for delivery at a later date. Articles are segregated from domestic articles and from imported articles entered under the provisions of the general Customs laws that are released from CBP custody.

Disposition of the articles used in trade fairs takes place under CBP supervision at any time within 3 months of the closing date of the fair.

9-18-4 PROCEDURES FOR TRADE SHOWS, FAIRS, AND EXHIBITIONS

A Customs regulation, 19 CFR 147.23 (b), addresses the compliance of articles with the FFDCA and states, "The entry of food products shall conform to the requirements of the FFDCA and the regulations issued thereunder." Therefore, foods entering for exhibits should meet the requirements of the Act in that they are not adulterated or misbranded, and they should comply with applicable food standards and labeling regulations. Although the Customs regulation addresses food products specifically, OIO interprets this section of the Customs regulation to include all FDA regulated articles. Therefore, medical and radiological devices, pharmaceuticals, cosmetics, biological products, electronics and tobacco products may not be adulterated or misbranded and should comply with FDA regulations applicable to that product line.

In general, articles used as exhibits may be handled in several ways: if all articles comply with FDA regulations, the general importing procedures would apply. However, for non-complying articles, it may be possible for an importer or importer's agent to request release of the entry, through the responsible FDA office, for the sole purpose of exhibition at the event and providing for the supervised destruction or re-exportation at the conclusion of the event. The request for release is made by the importer of record or agent to the responsible FDA office where the event is to be held and the local CBP office.

- FDA generally will permit release of articles which may not be in full compliance with U.S. laws and regulations where a placard is used at the point of display, advising that the product may not be in compliance with applicable FDA regulations and that FDA should be contacted for further information for procedures to bring the products into compliance.

- When large shipments of non-complying articles that are intended for promotion at a trade function, are encountered by FDA, representative products of the entry may be released for display purposes upon receipt of a request from the importer or agent to the responsible FDA office. However, release of commercial size shipments of non-compliant products destined to be used for promotion at a trade show will be evaluated by FDA on a case by case basis.
- An example of a model letter for responding to inquiries regarding importation for trade shows or exhibitions is attached as [Exhibit 9-10](#).

9-18-5 SPECIAL EVENTS

For special athletic events, any foods, medications or devices which are being brought into the U.S. for an individual athlete or team use should be held under the supervision of the team physician or trainer.

The amounts of both foods and medications should be commensurate with the duration of the stay. An inventory of the food items and medications being entered should prevent any undue delays when the team or athletes arrive.

Fans, family members and non-participants are not restricted in bringing in familiar food items or medications for personal use. This would also apply to individual athletes or participants who may be traveling alone. However, it may be advisable to have a prescription or letter from a physician accompany necessary medications. Further information regarding articles imported for personal use may be found in the subchapter [9-2, "Coverage of Personal Importation."](#)

A statement for responding to inquiries regarding importation for special events is attached as [Exhibit 9-11](#).

9-19 SECURED STORAGE (TEMPORARY REMOVAL DUE TO PENDING REVISION)

Temporary Removal Due to Pending Revision

9-20 COMMUNICATION CONCERNING ASSESSMENT OF CIVIL MONETARY PENALTIES BY CBP IN CASES INVOLVING IMPORTED FOOD

Procedures for Industry and FDA Employees

NOTE: For the purpose of this subchapter, all references to foods include both human and animal foods.

9-20-1 PURPOSE

To establish procedures to ensure that FDA is aware of the assessment, by CBP, of civil monetary penalties against violators in cases involving unsafe food and that CBP is aware of any events for which civil monetary penalties are an appropriate regulatory action.

9-20-2 BACKGROUND

CBP has enforcement programs under existing statutory authorities that allow for the imposition of civil penalties. Under 19 U.S.C. 1592, CBP may impose a civil penalty against any person who by fraud, gross negligence, or negligence, enters, introduces, or attempts to enter or introduce, any merchandise into the United States by means of any document or electronically transmitted data or information, written or oral statement, or act which is material and false or by means of any omission that is material. Civil penalties can be assessed in amounts up to the domestic value of merchandise so imported. Under 19 U.S.C. 1595a(b), CBP may assess a penalty against any person who directs, assists financially or otherwise, or is in any way concerned with introducing, or attempting to introduce any article into the United States contrary to law. Penalties assessed under 1595a (b) also may be in an amount equal to the domestic value of the merchandise. CBP has assessed penalties against importers that substitute, rather than export merchandise that FDA has refused.

While this procedure is currently in operation at CBP, FDA does not always understand the requirements for providing adequate information to CBP for assessment of a civil penalty. Conversely, FDA is not always kept aware of CBP's assessment of civil monetary penalties involving importation or exportation of food.

9-20-3 INSTRUCTIONS

FDA should alert the local CBP Port Director when a situation is encountered for which assessment of civil monetary penalties may be appropriate under the above authorities. FDA should coordinate with their local CBP office to make sure CBP informs the local FDA office of the imposition of civil monetary penalties involving the entry or attempt to enter any FDA-regulated food product. CBP should, in turn, develop procedures to receive recommendations for, and to inform FDA of, the imposition of civil penalties for violative importations of food.

FDA should meet with local CBP quarterly to discuss enforcement actions, including civil monetary penalties. FDA offices who meet with CBP should provide a quarterly report to OIO identifying jointly conducted enforcement actions and/or assessments of civil monetary penalties against importers of FDA-regulated foods.

9-21 NOTICE OF SAMPLING

9-21-1 PURPOSE

To provide operating procedures for FDA personnel in the use of the "Notice of Sampling" or "Notice of FDA Action" for collecting samples of imported articles subject to the laws and regulations enforced by the FDA.

9-21-2 BACKGROUND

Sections 536(a) and 801(a) (21 USC 360mm and 381(a)) of the FFDCA direct that notice of sampling shall be given to the owner or consignee of articles imported or offered for import into the United States. FDA regulation (21 CFR 1.90) defines this requirement, stating that such notice is given not only for samples collected but may also be issued for samples that "will be" collected ("notice of delivery of, or intention to deliver, such sample."). The regulation also requires that the owner or consignee receiving the notice "shall hold such article and not distribute it until further notice from the office or unit director or the collector of Customs of the results of examination of the sample."

In developing OASIS, the specific form "Notice of Sampling" has been replaced by the "Notice of FDA Action." The Notice of FDA Action informs the recipient to the sample collected or of FDA's intention of sampling for each line in the entry. The use of the designation "Product Collected by FDA" or similar language should be considered as meeting the standard "giving notice thereof to the owner or consignee." See 21 USC 381(a).

9-21-3 INSTRUCTIONS

Issuing the Notice of Sampling

Traditionally, the Notice of Sampling was issued by the responsible FDA office over the facsimile signature of the Regional or District Director of CBP, in accordance with an agreement between FDA and CBP. Under the procedures used in the OASIS system, however, the notice is no longer signed over a facsimile signature. At ports remote from a FDA office, local CBP officials may be re-delegated this responsibility of collecting, sampling and delivering the samples to FDA.

Notices of Sampling issued in OASIS are unsigned. They carry the name, address, phone number of the person creating the Status and Notice (often different individuals will be responsible for this operation for FDA).

When to Issue the Notice of Sampling

The law, as cited above, specifies that the Notice must be issued each time a sample is collected. For the purpose of this procedure, a Notice of Sampling or the Notice of FDA Action covering the collection of a sample will issue for each article identified for:

1. Physical collection of article submitted to the laboratory for examination;

2. Documentary collections, including labels, photographs, radiological health articles, mail entries, and personal importations.

When collection data is entered into OASIS a new Notice will be generated.

Notice of Sampling Terms Used by OASIS For Notification to Filer, Importer, etc. at Entry Level

Under OASIS, when an entry is filed through the CBP/AACE to FDA the following electronic messages are sent to CBP and the filer to identify the collection of a sample or intent to collect a sample: (wording use to explain the meaning of the OASIS message may not be exactly the same as presented here due to up-dates in the OASIS system)

1. FDA REVIEW: All FDA regulated articles in the entry must be held intact and not distributed, pending receipt of written notice or additional message from FDA.
2. FDA HOLD: Further FDA action is being taken on one or more lines in the entry.
3. FDA DO NOT DEVAN: All containers or trailers comprising this entry must be held unopened pending FDA examination, or receipt of written notice or additional message from FDA. (importer/consignee and/or filer) Notify FDA when the containers or trailers will be available. All FDA regulated articles will be examined or sampled by FDA. Following CBP release, the unopened containers or trailers may be moved to a location approved by FDA.
4. FDA EXAM/SAMPLE: All FDA regulated articles in the entry must be held intact and not distributed, pending receipt of written notice or additional message from FDA. (importer/consignee and/or filer) Notify FDA when the products will be available. The articles will be examined or sampled by FDA. Following CBP release, the article may be moved to a location approved by FDA.

Notice of Sampling Terms Used by OASIS for Notification to Filer, Importer, etc. at Line Level

Under OASIS the following terms will be used by the FDA at the line level to identify the collection of a sample or intent to collect a sample: (wording use to explain the meaning of the OASIS message may not be exactly the same as presented here due to up-dates in the OASIS system)

1. FDA EXAM: Articles must be held intact and not distributed, pending receipt of written notice or additional message from FDA. The article will be examined or sampled by FDA. Following CBP release, the article may be moved to a location approved by FDA.
2. FDA EXAM/NOTIFY: Articles must be held intact and not distributed, pending receipt of written notice or additional message from FDA. The article will be examined or sampled by FDA when available. (importer/consignee

and/ filer) Notify FDA when the article will be available. Following CBP release, the product may be moved to a location approved by FDA.

3. FDA EXAM DO NOT DEVAN: All containers or trailers comprising this entry must be held unopened pending FDA examination or receipt of written notice or additional message from FDA. (importer/consignee and/or filer) Notify FDA when the containers or trailers will be available. All FDA regulated articles will be examined or sampled by FDA. Following CBP release, the unopened container or trailers may be moved to a location approved by FDA.
4. FDA EXAM REDELIVER: Articles must be held intact and redelivered for FDA examination or sampling. (importer/consignee and/or filer) Contact FDA for redelivery instructions. A written notice with specific information regarding this request will be sent to the filer, importer of record, and consignee.

In those situations where the article is identified as subject to detention without physical examination, or where the action being recommended is for the detention of the article and no additional documentary or physical sample is collected, the notice to the filer to HOLD for FDA Review should be considered as satisfying the requirement for giving notice to the importer. This will also meet the requirement for the article to be held intact until final determination on admission has been made.

Distribution of the Notice of Sampling

For notices issued in OASIS, the firm or person whose name is provided as the Importer of Record in the ACE shall be issued the Notice of FDA Action for the collection of the sample. Copies of the notice generated by OASIS will also be identified for distribution to the filer and consignee, where applicable. Notification to CBP is handled through the FDA/ACE interface. No documents are sent to CBP under OASIS for this notification.

For entries submitted as paper entries, the responsible FDA office will enter the data from the entry documents into the OASIS system, appropriately identify the responsible firm or person shown on the CBP Entry Summary (3461/3461ALT or other appropriate entry document) as the importer of record, and provide them with a Notice of Sampling produced by OASIS. Additional distribution of notices should be made as identified for ACE entries.

Section 801(b) (21 U.S.C. 381(b)) states in part: "Pending decision as to the admission of an article being imported or offered for import, the Secretary of the Treasury may authorize delivery of such article to the owner or consignee upon the execution by him of a good and sufficient bond providing for the payment of such liquidated damages in the event of default as may be required pursuant to regulations of the Secretary of the Treasury." The importer of record, who may or may not be the owner or consignee, is the person or firm that posts the CBP redelivery bond covering the importation of the articles and is legally responsible for assuring compliance with all laws and regulations affecting the importation. The importer of record may be a custom house broker, filer, bank, or other entity that is not directly involved with the ownership of the entry. The bond is subject to forfeiture, and the importer of record is subject to regulatory action for

violation of the laws and regulations pertaining to the shipment (19 CFR 113.62(I) Consequence of Default).

All persons or firms who are sent a Notice of Sampling or Notice of FDA Action for sampling, must also be sent other official documents pertaining to the sample, i.e., Notices of FDA Action for Release, Detention and Hearing, and/or Refusal of Admission.

Failure To Hold Articles Identified for Examination and/or Sampling

If, after an entry has been filed, electronically or manually, and a Notice of Sampling or Notice of FDA Action has been issued for the entry to be held for examination or sampling, FDA finds that the entry or a portion thereof was not held, and there was disregard of the Notice by the importer, a written request to CBP asking for redelivery of the merchandise should be made. If the distributed article is not returned to CBP for FDA's examination or sample, a bond action should be sought through OASIS or current written procedures. See RPM [subchapter 9-1 "Bond Action"](#) for procedures on request for redelivery/bond action.

For more information, refer to the ["MOU with U.S. Customs Service to Establish a Working Relationship for Cooperative Enforcement \(225-79- 4003\)"](#), 10/01/80 (Old designation CPG 7155g.03, new designation Section 2-A General Import Agreements) and ["MOU with U.S. Customs Service regarding Identifying Roles and Authority Concerning Electronic Products \(225-74-6004\)"](#), 10/01/88 (Old designation CPG 7155g.01).

Multiport Coverage

Many importers maintain distribution points throughout the country and will move articles to those locations for immediate distribution upon receipt of their releases from CBP and other agencies. As long as the articles are under the importer's full control and are not further distributed, or has been delivered to their consignee but are still under the full control of the importer, the importer may request the article be examined by the FDA office in whose jurisdiction the article is held. This practice should not be encouraged, nor should importers consider the allowance of such practice to be a license to request all their importations be examined at destination. Allowing movement and requesting foreign examination/sample should be at the discretion of FDA, depending on the article to be examined or sampled.

Under certain conditions, filers may use various means of filing entries, for example multiport entries for clearing cargo. Under these provisions of CBP, the filer may be in one port location (port A) but enter the cargo in port B. However, the cargo itself may be physically located at port C, and the examination will take place at port D. For FDA coverage, the examination of the cargo may be dependent on the FDA location where the cargo is entered and/or where it is physically located. Coverage of such importations should be evaluated on a case by case basis. Ultimately, the FDA office responsible for the entry will be that office covering the responsible CBP port for the entry.

Simultaneous Multiple Entries

The following procedures are being provided to assist FDA in the collection of import compliance samples from multiple, simultaneous entries (within a 24 hour period) of the same product(s) from the same manufacturer/grower or shipper:

The responsible FDA office will identify each entry individually for coverage. OASIS does not include provisions for consolidating multiple entries under one number, since all actions are based on individual entry numbers. However, FDA may relate one entry to another to show they are making their determination of admission on all associated entries from the one entry sampled/examined.

Documentation MUST show a direct relationship between the samples, e.g., date of manufacture, production codes, fields of harvest, etc.

This procedure is recommended whenever compliance sample of suspect multiple shipments are collected. It may also be used when multiple entries are made to accommodate different consignees with the same product, such as canned foods.

Under no circumstances where FDA staff receive paper entries should different Importer's Entry Notification for portions of the same entry be accepted or processed. Each notification should represent a unique entry. If this situation is encountered, FDA may wish to reject the notifications and request the broker to consolidate the information into one notification. Under the OASIS procedure, where entries are filed through the CBP ACE, this procedure may not be applicable.

Also, under the OASIS screening procedures, if FDA notices a trend to separate shipments from the same manufacturer, shipper, or grower in order to receive a favorable "May Proceed" on as many portions of the same product through the screening process, FDA may consider requesting, as appropriate, the particular product/manufacturer combinations be screened as "examination" to assure all shipments are provided to FDA for review before being may proceeded.

Single Entry of Multiple Commodities

Under the OASIS procedures, when an entry consisting of multiple food items is presented, the responsible FDA office must issue a single Notice of FDA Action identifying all items in the entry for FDA hold/examination. In the case of paper entries, designate the entire entry to be held as "foodstuffs", or use another appropriate term.

There is no prohibition against issuance of one Notice of FDA Action for collection of samples for an entire multiple commodity entry. In the OASIS procedures, the Notice will indicate the specific lines that are to be covered by FDA. The intent of the Notice is to provide the owner/consignee with information as to whether the sample(s) have been collected or will be collected. It may not be possible to know in advance of an examination what problems or conditions will be encountered before the entry is examined. Therefore, Notice of FDA Action identifying all commodities present as

"HOLD ALL" pending examination does not conflict with FDA regulation or policy. See Notice of FDA Action statements under "B", "When to Issue the Notice of Sampling".

Because the exact article to be examined/sampled may not be known until after the vehicle transporting the goods has been unloaded, one Notice is issued to assure that all products are held for examination. FDA has authority to request that the entire entry be held pending examination, and whether numerous individual Notices, or one blanket Notice is issued, the effect is the same: the entire entry must be held.

When the importer advises FDA of the location and the availability of articles in the entry, the FDA personnel will visit the site to perform the examination and/or collection. At this time, a new Notice of FDA Action for the collection of the specific articles is issued. Any article not covered by a specific Notice of FDA Action will be designated as "Released" or "May Proceed."

(Note: See exhibit 9-6 for examples of Notices which include identification of products sampled by FDA.)

9-22 GRANTING AND DENYING TRANSPORTATION AND EXPORTATION (T&E) ENTRIES

9-22-1 PURPOSE

To provide uniform procedures regarding circumstances when Transportation and Exportation (T&E) entries will be granted or denied.

9-22-2 BACKGROUND

CBP regulation 19 CFR 18.10, "Kinds of Entry", lists the various entries and withdrawals that may be made for merchandise transported in bond. One kind of entry is the transportation and exportation (T&E) entry. A T&E filed with CBP, allows a party to transport merchandise in bond through the U.S. and export the merchandise intact to a foreign destination without the payment of duties. See 19 U.S.C. 1553, 19 CFR 18.11, and 19 CFR 18.20.

T&E entries may be made for products which are being transported through the U.S. to be exported. In addition, articles that have been refused admission may be entered under T&E after the importer requests and receives written authorization from the proper governmental authority and/or complies with any applicable regulations. When FDA receives notice from CBP that articles refused by FDA will move under T&E bond to a distant port to be exported under CBP supervision, FDA generally will not object to movement of the refused articles. In addition, when FDA receives notice from CBP that product regulated by FDA, not offered for import will move under T&E entry to a distant port to be exported under CBP supervision, FDA generally will not object to movement. In most instances FDA may waive the written authority requirement. There may be situations, however, where denial of a request for a T&E entry is appropriate.

FDA has been aware of possible weaknesses in T&E entry procedures for movement of refused merchandise to other ports for exportation. For example, in 1975 an incident involving frog legs demonstrated the potential for diversion into domestic commerce when refused articles are transported under T&E bond.

The frog legs case (U.S. v. 76,552 pounds of Frog Legs, 423 F. Supp. 329 (S.D. Texas, 1976)) highlighted the risks of T&E movement of refused articles. In that case, adulterated frog legs, reportedly being exported to Mexico, were in fact being diverted to domestic commerce, thus circumventing FDA authority to prevent violative merchandise from reaching the American public.

In response to this and other incidents of diversion, FDA met with CBP to discuss concerns regarding movement under a T&E entry of violative merchandise. CBP agreed that violative shipments should not be permitted movement under T&E procedures where FDA objected. This approach was taken to prevent the granting of T&Es in a haphazard manner and to eliminate the opportunity for merchandise to become lost, stolen, or diverted.

The availability of T&E entry for "restricted and prohibited merchandise" is described in the CBP regulations. Section 18.21(b) of the CBP regulations authorizes CBP to deny release of this type of merchandise under a T&E entry unless the agency responsible for regulating the article provides written permission. Prohibited articles offered for T&E entry without the requisite written authority may be seized pursuant to 19 CFR 18.21(b). However, it is the practice of CBP and FDA that where FDA has no objection to in-bond movement of violative merchandise through the United States for export to a foreign destination, CBP may issue a T&E entry without FDA written permission. When FDA objects to such movement, it would so notify CBP in writing.

There may also be circumstances where regulatory action such as seizure is appropriate for articles moving under a T&E entry. Often, articles will begin moving under T&E entry prior to FDA receiving notice from CBP or the importer. In the case where a request for T&E is to transport violative articles which FDA believes may be intended for future importations into the U.S., regulatory action against the article, even though it may already be moving under T&E entry, may be appropriate. For example, because of transportation concerns, violative drugs that represent a health risk may be shipped to the U.S. prior to entry into Mexico or other nearby countries. The importer may request a T&E entry from CBP. After receiving notice from CBP or the importer that the articles are moving under T&E entry, if FDA is aware that the drugs may be sold to individuals in the United States, FDA may decide it is appropriate to seize the drugs to prevent them from illegally entering domestic commerce.

In one instance, a quantity of unapproved drugs that was being transported from Romania through the United States under a T&E entry to Tijuana, Mexico was condemned and ordered destroyed by CBP. Section 801(b) of the FFDCA, involving conditional release for movement of products under CBP redelivery bond, did not apply

because that provision does not apply to merchandise that is not eligible for legal import under the FFDCA. CBP ordered destruction because it was the only way to ensure that the drugs would not be re-imported into the United States. The claimant had stipulated that the drugs were new drugs and that no new drug application had been submitted or approved. See *U.S. v. 300 oz. Gerovital Lotion, and 25,000 Gerovital Tablets, More or Less*, 492 F. Supp 114 (C.D. Cal. 1980).

9-22-3 INSTRUCTIONS

If an article has been refused admission under the FFDCA, FDA will consider objecting to T&E entry under the following circumstances:

1. The article presents a definite hazard to the health of the consumer (e.g., article containing toxins or pathogens)
2. There is evidence that the T&E entry procedure is being abused and violative merchandise is being diverted into domestic commerce (e.g. the frog legs case cited previously).
3. The distance that the violative product is to be moved is so great that it might be lost, stolen or diverted, and/or that the movement would be very difficult to control and/or monitor.
4. The importing firm has a history of diverting violative merchandise into domestic commerce. See RPM [subchapter 9-16 "Priority Enforcement Strategy for Problem Importers"](#).

If the merchandise has been entered as a consumption or warehouse entry, the following statement should appear on the Notices of Detention and Refusal:

"DO NOT ISSUE T&E - PERMISSION AS REQUIRED PURSUANT TO 19 CFR 18.21(b) IS NOT GRANTED FOR THE ISSUANCE OF A TRANSPORTATION AND EXPORTATION ENTRY"

If the merchandise has been entered as a T&E, and CBP has notified FDA of the entry, CBP should be notified in writing that FDA opposes granting of the T&E entry.

NOTE: In developing OASIS the FDA forms for Notice of Sampling, Release, Detention and Hearing, Refusal, etc., have been replaced by "Notice of FDA Action," with the description of the action identified for the specific article in the entry.

Until OASIS is modified to issue a T&E statement, FDA staff operating under OASIS should annotate their Notice of FDA Action appropriately and forward a copy of the Notice to the local CBP office and other notified parties.

Decisions to reconsider T&E movement, or submit regulatory actions, where appropriate, are at the discretion of the responsible FDA office.

Questions regarding use of T&Es should be directed to OIO, and appropriate Center.

9-23 EXHIBITS

- 9-1 Exhibit 9-1 has been deleted. See [Exhibit 9-6](#) instead.
- 9-2 Exhibit 9-2 has been removed as an exhibit. See [Form FDA-766](#) “Application for Authorization to Relabel or Recondition Non-Compliant Articles”
- 9-3 [Model Letter For Use in General Mail Importations](#)
- 9-4 [Model Letter For User in Detentions of Drugs and Devices](#)
- 9-5 [Specimen Charges](#)
- 9-6 [Notice of FDA Action](#)
- 9-7 19 CFR 12.21-12.23
19 CFR 21.21-23 has been removed as an exhibit. 19 CFR Part 21 is available at <http://www.gpo.gov/fdsys/granule/CFR-2011-title19-vol1/CFR-2011-title19-vol1-part12>
- 9-8 21 CFR 601.33
21 CFR 601.33 has been removed as an exhibit. 21 CFR Part 601 is available at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=601>
- 9-9 21 CFR 601.22
21 CFR 601.22 has been removed as an exhibit. 21 CFR Part 601 is available at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=601>
- 9-10 [Letter Responding to Inquiries Regarding Importation for Trade Shows/Fairs and Exhibitions](#)
- 9-11 [Statement Responding to Inquiries Regarding Importation for Special Events](#)
- 9-12 Charges for Supervision Form FDA-790
Exhibit 9-12 has been removed. Form-790 is available in the [2021 IOM Chapter 6, Exhibit 6-3 Charges for Supervision](#), form found in the [intranet](#).

EXHIBIT 9-3

MODEL LETTER FOR USE IN GENERAL MAIL IMPORTATIONS

(LETTERHEAD)

A mail shipment of an article from a foreign country addressed to you is being detained at the U.S. Post Office. All products of this kind must meet the requirements of the Federal Food, Drug, and Cosmetic Act or other laws enforced by the Food and Drug Administration. These laws are designed to protect you from, among other things, unsafe or misrepresented foods, drugs, biologics, cosmetics, devices, and other articles. The product addressed to you does not appear to comply with the law. Please read the enclosed Notice of FDA Action - Detained carefully since it explains why FDA believes that the product sent to you is in violation. The Notice does not in any manner accuse you of violating any law.

If you have good reason to believe that the product does comply with the law and wish to discuss it with us, you may personally come to this office, telephone, or write to us within the time limit shown on the Notice.

If you do not wish to claim this shipment, you may disregard the Notice and the shipment will be returned to the sender without cost to you. The shipment will be returned to the sender automatically if we do not hear from you within the time limit shown on the Notice.

Sincerely yours,

Enclosure:

EXHIBIT 9-4

MODEL LETTER FOR USE IN DETENTIONS OF DRUGS AND DEVICES (LETTERHEAD)

A mail shipment addressed to you of a drug (device) from a foreign country is being detained at the U.S. Post Office. All products of this kind must meet the requirements of the Federal Food, Drug and Cosmetic Act which is designed to protect you from products that have not been shown to be safe and effective and that are not labeled in a truthful, accurate and non- misleading manner.

Please read the enclosed Notice of FDA Action - Detained carefully, since it explains why the product addressed to you appears to violate U.S. law. The Notice does not accuse you in any manner of violating any law.

If the drug is not approved for distribution in the United States, FDA may consider releasing the product to you for your own personal use if you provide a statement containing:

- adequate documentation that the product is for your own use and for treatment of a serious condition; include the name and address of the doctor licensed to practice in the United States who is responsible for your treatment with this product; or
- adequate documentation that the product is for the continuation of treatment of a serious condition begun in a foreign country.

Send your statement to this office and we will promptly review your submission and consider release of the product.

If you have good reason to believe that the product does comply with the law and you wish to discuss it with us, you may come in person to this office, telephone, or write to us within the time limit shown on the Notice.

If you do not wish to claim this shipment, you may disregard the Notice and the shipment will be returned to the sender without cost to you. The shipment will be returned to the sender automatically if we do not hear from you within the time limit shown on the Notice.

Sincerely yours,

Enclosure:

EXHIBIT 9-5

SPECIMEN CHARGES

Suggested wording for charges under the Acts enforced by FDA may be found on Import Alerts, and as part of reference tables of the OASIS automated system.

Charge codes will no longer be listed in this exhibit. The current list of Violation Codes and the text associated with those codes can be found on FDA's Internet Site at the following link:

www.fda.gov/ForIndustry/ImportProgram/ActionsEnforcement/ucm459490.htm
www.fda.gov > [For Industry](#) > [Import Program](#) > [Actions & Enforcement](#) > [Import Refusals](#) > [Violation Charge Codes And Charge Statement \(PDF - 107KB\)](#)

EXHIBIT 9-6**NOTICE OF FDA ACTION**

The attached exhibit of Notice of FDA Action is a model and should not be considered all inclusive. The format and wording in the actual Notice of FDA Action issued by FDA from the Operational and Administrative System for Import Support (OASIS) may appear different.

EXAMPLE

**United States Food and Drug Administration
OHAFO Office
Notice of FDA Action**

Entry Number: 111-9871457-6
Notice Number: 2
November 6, 1996

Filer:

XYZ Freight Services Attention: George
1500 Main St.
New Orleans LA 70130

- Port of Entry: 2704, Los Angeles,
Carrier: NOL LINE
Entry Date: November 2, 1996
Arrival Date: November 4, 1996
- Importer of Record: Thompson's Pastry Shop Inc., Lafayette, LA
- Consignee:
a: Thompson's Pastry Shop Inc., Lafayette, LA
b: Commodities Inc. Bismarck, ND

HOLD DESIGNATED

Documents Required and Notify FDA of Availability

Summary of Current Status of Individual Lines

<u>@ LINE:</u>	<u>ACE/FDA</u>	<u>Product Description</u>	<u>Quantity</u>	<u>Current Status</u>
* a	001/001	PINEAPPLE, DEHYDRATED	500 CT	RELEASED 11-6- 96

<u>@ LINE:</u>	<u>ACE/FDA</u>	<u>Product Description</u>	<u>Quantity</u>	<u>Current Status</u>
* a	002/001	DEHYDRATED GINGER SLICES	10 KG	Collected by FDA 11-06-96
 @ LINE:	 <u>ACE/FDA</u>	 <u>Product Description</u>	 <u>Quantity</u>	 <u>Current Status</u>
* b	003/001	PAPAYA, DEHYDRATED	10 KG	Detained 11-06- 96

* Status change since the previous notice. Read carefully the sections which follow for important information regarding these lines.

- @ Consignee id

FDA will not request redelivery for examination or sampling, if the products not released by FDA are moved, following USCS conditional release to a location within the local metropolitan area or to a location approved by the FDA office at the number below.

All products in this entry not listed above may proceed without FDA examination. This notice does not constitute assurance the products involved comply with provisions of the Food, Drug, and Cosmetic Act or other related acts, and does not preclude action should the products later be found violative.

Please provide documentation concerning all products in this entry to the FDA office below. Include the USCS document (e.g. CBP-3461 or CBP-7501) and commercial invoice for these products, annotated to show the ACE/FDA line numbers sent electronically.

Also, advise FDA upon actual availability, and include date, location, and warehouse control number, where applicable, for all lines in this entry.

Mary T Smith, Inspector
U.S. Food & Drug Administration
(213) 555-1212
2nd and Chestnut Streets
Philadelphia, PA 19106

DETENTION WITHOUT EXAMINATION

The following products are subject to refusal pursuant to the Federal Food Drug and Cosmetic Act (FD&CA), Public Health Service Act (PHSA), or other related acts in that they appear to be adulterated, misbranded or otherwise in violation as indicated below:

LINE

<u>ACE/FDA</u>	<u>Product Description</u>	<u>Respond By</u>
003/001	Product: PAPAYA, DEHYDRATED	November 26, 1996

FD&CA Section 402(a)(1), 801(a)(3); ADULTERATION

The article appears to be held in a container containing a poisonous or deleterious substance which may render it injurious to health.

FD&CA Section 402(a)(2)(B), 801(a)(3); ADULTERATION

The article appears to be a raw agricultural commodity that bears or contains a pesticide chemical which is unsafe within the meaning of Section 408(a). The article appears to contain quinalphos.

You have the right to provide oral or written testimony, to the Food & Drug Administration, regarding the admissibility of the article(s) or the manner in which the article(s) can be brought into compliance. This testimony must be provided to FDA on or before the dates shown above

SAMPLES COLLECTED

LINE

<u>ACE/FDA</u>	<u>Product Description</u>	<u>Est. Cost</u>
001/001	PINEAPPLE, DEHYDRATED	\$ 15.00

- Sample: 10 KG Collected 1 KG from each of 10 cartons

LINE

<u>ACE/FDA</u>	<u>Product Description</u>	<u>Est. Cost</u>
002/001	DEHYDRATED GINGER SLICES	\$.23

- Sample: 1 KG Collected approximately 4 ounces from one carton. LINES RELEASED

LINE

<u>ACE/FDA</u>	<u>Product Description</u>
001/001	PINEAPPLE, DEHYDRATED

These products are released. This notice does not constitute assurance that the product released complies with all provisions of the Food, Drug, and Cosmetic Act, or other related Acts, and does not preclude action should the product later be found violative

Notice Prepared by: Thomas N Jones (QA5)
U.S. Food & Drug Administration

EXHIBIT 9-10

LETTER RESPONDING TO INQUIRIES REGARDING IMPORTATION FOR TRADE SHOWS/FAIRS AND EXHIBITIONS

(LETTERHEAD)

This is in response to your inquiry regarding importing articles regulated by the Food and Drug Administration (FDA) for use as exhibits in trade shows/fairs or other exhibitions.

With the exception of most meat and poultry products, all food, drugs, biologics, cosmetics, medical devices, electronic products that emit radiation, and tobacco products as defined in the Federal Food, Drug, and Cosmetic (FD&C) Act and related Acts, are subject to examination by FDA when they are being imported or offered for import into the United States.

All imported products are required to meet the same standards as domestic goods. For example, imported foods must be pure, wholesome, safe to eat, and produced under sanitary conditions; drugs and devices must be safe and effective; cosmetics must be safe and made from approved ingredients; radiation-emitting devices must meet established standards; and all products must contain informative and truthful labeling in English.

GENERAL PROCEDURES

The Federal Food, Drug and Cosmetic Act (the Act), Section 801, directs FDA to refuse admission of any article that appears to be in violation of the Act.

To ensure that FDA is notified of all regulated products imported into the United States, the importer, or his/her representative, must file an entry notice with U.S. Customs and Border Protection and acquire a bond to allow the importer to take delivery of the goods prior to FDA's decision on the admission of the goods. FDA is notified by Customs of the entry and makes a decision as to the article's admissibility. If FDA does not wish to examine the entry, the product is allowed to proceed into the United States. When a sample of an article offered for import has been requested by FDA, the owner or consignee is required to hold the shipment and not distribute it until further notice is received regarding the results of the examination of the sample.

Generally, if FDA samples an entry, an FDA representative will collect the sample from the shipment and have it analyzed in FDA's laboratory. If the analysis shows the product in compliance, the shipment is released into United States commerce. However, if the analysis shows an appearance of a violation, the product is subject to refusal of admission. If it appears that the article is violative, FDA issues a Notice of FDA Action - Detained to the owner or consignee of the article specifying a place and period of time whereby the individual may introduce testimony either verbally or in writing concerning the detention to prove that the product complies with the law, or can submit a petition to

recondition the product to bring it into compliance. The owner or consignee may submit an application to FDA to relabel or perform other actions to bring the article into compliance, or render the article other than a food, drug, device, or cosmetic.

If the product cannot be brought into compliance, it is refused and the importer is required to either re-export or destroy the article under U.S. Customs or other approved supervision. If the refused product is not destroyed or re-exported, CBP issues a notice for redelivery to the importer of record. Failure to redeliver the refused product may result in CBP assessing liquidated damages equal to the value of the merchandise involved in the default or three times the value of the merchandise if the article is restricted merchandise or alcoholic beverages. All FDA regulated products are considered restricted merchandise by CBP.

ARTICLES FOR TRADE SHOWS/FAIRS AND EXHIBITIONS

When articles are being imported where the intent is to display them at an industry or consumer trade show or exhibition and all articles comply with FDA regulations, the general importing procedures as stated above should be followed. However, for non-complying articles, it may be possible for an importer or importer's agent to request release of the entry, through the appropriate FDA office, for the sole purpose of exhibit at a trade function and providing for the supervised destruction or re-exportation of the articles at the conclusion of the function.

FDA generally may permit release of such articles which may not be in full compliance with U.S. laws and regulations where a placard is used at the point of display, advising that the product may not be in compliance with applicable FDA regulations and that FDA should be contacted for further information for procedures to bring the products into compliance.

When large shipments of non-complying articles, intended for promotion at a trade function, are encountered by FDA, representative products of the entry may be released for display purposes upon receipt of a request from the importer to the appropriate FDA office. However, it will be necessary for importers of commercial size shipments of non-compliant product, if for promotion at a trade show, to request release of these types of products which will be evaluated by FDA on case by case basis.

You should contact the appropriate FDA office where the function is to be held for further information or to submit a request for release of products for trade shows, fairs, or exhibitions.

CUSTOMS AND BORDER PROTECTION REGULATIONS

Customs regulations, 19 CFR Part 147, "Trade Fairs" address entry of merchandise for exhibition and your local Customs office should be contacted regarding these requirements.

Sincerely yours,

EXHIBIT 9-11

STATEMENT RESPONDING TO INQUIRIES REGARDING IMPORTATION FOR SPECIAL EVENTS

(The example cited below was for use by the Atlanta Committee for the Olympic Games, but a similar statement could be used for any event. A statement of this nature is intended to be made available by the committee or sponsor of the event to team officials, participants, foreign government representatives, media representatives, and fans.)

STATEMENT FOR THE USE BY ATLANTA COMMITTEE FOR THE OLYMPIC GAMES

(Sponsor Name) (Name of Event)

In keeping with the spirit of the Olympic games, the Food and Drug Administration (FDA) wants you to be comfortable during your stay in the United States, including having access to personal and familiar necessities. The FDA does not normally restrict foreign visitors from bringing native foods or required medications for their own use or consumption while in the United States. However, any medications or pharmaceuticals which are being brought for team use should be held under the supervision of the team physician or trainer. The amounts of both foods and medications should be commensurate with the duration of your stay. Additionally, an inventory of the food items and medications being entered should prevent any undue delay in your team's arrival.

Fans, family members, and other non-participants are also not restricted in bringing in familiar food items. However, it may be advisable to have a prescription or letter from a physician accompany necessary medications. As mentioned above, the amount of foods and medications brought in should be commensurate with the duration of your stay in the United States.

If you have any questions concerning your food or medications when you are in the United States, please contact the local FDA office

Regulatory Procedures Manual

Chapter 10: OTHER PROCEDURES

This chapter includes the following sections:

Section	Topic	Page
10-1	COMMUNICATIONS – OFFICE OF REGULATORY AFFAIRS AND CENTER RESPONSIBILITIES	4
10-1-1	Regulatory Actions that Require Center Concurrence	4
10-1-2	Regulatory Actions prepared by a Center for Program Issuance and/or Follow-up	5
10-1-3	Debarment - Notification Responsibilities of FDA Employees	5
10-2	PRIOR NOTICE.....	10
10-2-1	Purpose	10
10-2-2	Background	10
10-2-3	Prior Notice.....	10
10-2-4	Procedures	11
10-3	REGULATORY MEETINGS	12
10-4	INSPECTION OF FOOD RECORDS – SECTIONS 414(a) and 704(a).....	13
10-4-1	Purpose	13
10-4-2	Authority	13
10-4-3	Statutory requirements for invoking records inspection authority	15
10-4-4	Records that may be accessed and copied under this authority	16
10-4-5	Records that may <i>not</i> be accessed and copied under this authority	16

10-4-6	Procedure for Invoking Records Inspection Authority.....	16
10-4-7	Issuing Form FDA 482c.....	18
10-4-8	Timeframes for compliance	18
10-4-9	Failure to provide records.....	19
10-5	ESTABLISHMENT INSPECTION REPORT (EIR) CONCLUSIONS AND DECISIONS	19
10-5-1	Release of the Establishment Inspection Report.....	19
10-5-2	No Action Indicated (NAI) and Voluntary Action Indicated (VAI) 90 day Decisional Letters for Drug Inspections	19
10-6	INTERSTATE TRAVEL PROGRAM (ITP) CLASSIFICATIONS AND ADMINISTRATIVE ACTIONS	19
10-7	REPORTING AND MONITORING	19
10-8	AD HOC COMMITTEE	20
10-8-1	Purpose	20
10-8-2	Function.....	20
10-8-3	Composition	20
10-8-4	Procedures	21
10-8-5	Responsibilities	22
10-9	APPEAL PROCESS	23
10-9-1	Purpose	23
10-9-2	Who May Appeal	23
10-9-3	What May Be Appealed.....	23
10-9-4	When An Appeal Is Not Appropriate.....	23
10-9-5	Requests For Appeal.....	24
10-9-6	Review Of Appeals	24

10-9-7 Decision On Appeals	24
10-10 EXPERT SUPPORT FOR CASES	25
10-10-1 Purpose	25
10-10-2 Responsibility	25
10-10-3 Criteria For Determining The Level Of Expert Support	25
10-10-4 Documentation	26
10-10-5 List Of Individuals For Expert Support	26
10-10-6 Obtaining And Paying For Expert Support	26
10-11 TESTIMONY; PRODUCTION OF RECORDS; CERTIFICATION OF RECORDS	29
10-11-1 Requests for Testimony	29
10-11-2 Requests for Production of Records	32
10-11-3 Multi-issue Subpoena - Requests for Samples	33
10-11-4 Requests for Certification of Records	33
10-11-5 Requests involving Special Circumstances	33
10-11-6 Disclosure of Non-public information	34
10-11-7 Other Requests for Information – Informal Meetings	35
10-11-8 Definitions	36
10-11-9 References	37
10-12 U. S. CONGRESSIONAL REQUESTS – INSTRUCTIONS FOR ORA EMPLOYEES	38
10-13 REQUESTS FROM STATE AND FEDERAL OFFICIALS – INSTRUCTIONS FOR ORA EMPLOYEES	40
10-13-1 Background	40
10-13-2 Procedures for Handling Inquiries from State Congressional Officials and their Staff	41

10-13-3 Procedures for Handling Inquiries from Federal Agencies	43
10-13-4 Procedures for Handling Inquiries from Other State, Local, Tribal, and Territorial Government Officials and National Associations	43
10-14 APPLICATION INTEGRITY POLICY	45
10-15 EXHIBIT	46

10-1 COMMUNICATIONS – OFFICE OF REGULATORY AFFAIRS AND CENTER RESPONSIBILITIES

10-1-1 Regulatory Actions that Require Center Concurrence

When a decision is made by the Program Division that initiation of a regulatory action is appropriate, the Division should notify the appropriate Center compliance unit regarding its intent to submit a recommendation. Division Compliance staff should also remember to enter the “In Review” profile status as “pending” on the Maintain Profiles screen in eNSpect for each profile class covered when the recommendation is a result of a Current Good Manufacturing Practice (CGMP) or Quality System (QS) inspection of a domestic drug, biologics, or medical device facility. Compliance staff should also notate the Remarks field to explain the action being recommended. When the action recommendation is forwarded to a Center for review, the Remarks field should be updated to reflect that and include the date forwarded. With regard to foreign inspections, Center Compliance staff are responsible for the review and evaluation, and should enter the In Review “pending” status and notate the corresponding Remarks field as appropriate. See “Firm Profile Updates in eNSpect” in Chapter 4 for more information.

The Center will notify Program Division as soon as a case (compliance) officer has been assigned. This early communication will create opportunities to discuss the case, including the overall strategy, as well as the history, violations, rationale, charging scheme, regulatory and policy considerations, local knowledge, and national/program issues.

If, after its initial review of a Program Division's recommendation, the Center compliance unit is inclined not to concur with the Division's recommendation, the Center will promptly notify and provide the Division with an oral explanation for its preliminary decision not to concur with the recommendation. If the Division does not agree with the basis for the potential disapproval, it should provide the Center with additional justification for proceeding with the recommended action within three business days. The additional justification should be limited to information currently available to the Division, not a commitment to gather additional information to support the

recommendation. The Center will consider this additional justification before making a final disposition on the Division's recommendation, apprise the Division of its decision, and prepare the final memo. The Center's final disposition on the recommendation (approved or disapproved) will normally not be delayed if it is determined that an inspection will be necessary to collect additional supporting evidence. The involved compliance officer and the appropriate division should participate in discussions with the Center that occur during the process described in this paragraph. If the official action proposed was not the subject of a formal recommendation from the Division (e.g. BIMO, foreign inspection), the same communication principles should apply between involved Center and Division staff.

10-1-2 Regulatory Actions prepared by a Center for Program Issuance and/or Follow-up

When a decision is made by a Center that a Program Division issuance, involvement and/or follow-up is an appropriate course of action, the Center should notify the appropriate Division compliance unit(s) regarding its intent to prepare a regulatory action, and provide the Division(s) with an opportunity to collaborate on the compliance strategy and the substance of the action.

10-1-3 Debarment - Notification Responsibilities of FDA Employees

1. Background

- a. Purpose and Authority for Debarment - Debarment is a remedial measure taken under section 306 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) to prohibit a person (e.g., an individual, corporation, partnership, or association) from participating in FDA-regulated activities, as described below:
 - i. A person other than an individual may be prohibited from submitting, or assisting in the submission of, any abbreviated drug application. Sections 306(a)(1) and 306(b)(1)(A).
 - ii. An individual may be prohibited from providing services in any capacity to the sponsor of an approved or pending drug product application. Sections 306(a)(2) and 306(b)(1)(B).
 - iii. A person may be prohibited from importing an article of food, or offering an article of food for import, into the United States. Section 306(b)(1)(C).
 - iv. A person may be prohibited from importing or offering for import into the United States any drug. 306(b)(1)(D)

- v. A person may be prohibited from being accredited to inspect eligible device manufacturers and from carrying out activities under agreements with foreign countries to facilitate commerce in devices. Section 306(m)(1).

Debarment may be based on a criminal conviction or on conduct, as identified in section 306 of the Act. See *Persons Subject to Debarment* in paragraph 3 in this subsection.

- b. “Drug Product” - For purposes of section 306, the term “drug product” means a drug subject to regulation under section 505 (new drugs), section 512 (new animal drugs), or section 802 (exports of certain unapproved products) of the Act, or under section 351 (regulation of biological products) of the Public Health Service Act. Section 201(dd).
- c. Other Possible Actions - Civil Penalties
- d. Under section 307(a)(6) of the Act, any person with an approved or pending drug product application who knowingly engages the services of a debarred person is liable for civil penalties.
- e. Under 307(a)(7), debarred individuals are subject to civil penalties for providing services to a person with an approved or pending drug product application.

2. Notification Responsibilities

- a. Authority - Staff Manual Guide (SMG) [7712 - Debarment Proceedings](#) provides general procedures for FDA staff to follow for debarment actions and defines the responsibilities of FDA employees. ORA’s Division of Enforcement (DE) has responsibility for initiating and pursuing debarment actions. All FDA employees have a responsibility to notify DE of any persons that may be subject to debarment and to forward relevant materials to DE within specified timeframes, as detailed below.
- b. Required Notification - In accordance with [SMG 7712](#), all FDA employees have the following responsibilities:
 - i. Ensuring that ORA’s Division of Enforcement (DE) is notified when the employee observes conduct or has notice (from an oral or written communication) that a person may be subject to debarment.
 - ii. Ensuring that DE is provided with copies of all relevant materials (e.g., any written notice or petition for debarment and

information supporting debarment) in the employee's possession.

Send the notification and materials to the attention of the Debarment Specialist, DE via electronic transmission, interoffice or regular mail, or FAX. Include your name, office, and phone number. The debarment specialist can be reached at debarments@fda.hhs.gov or 240-402-8743. Contact the debarment specialist if you have any questions about notification or debarment, or if you need further information.

c. Timeframes for Notification - If the person who may be subject to debarment:

- i. has an approved or pending drug application;
- ii. is an employee of such a person;
- iii. is a clinical investigator;
- iv. is currently engaged in importing food or offering it for import; or
- v. is currently engaged in importing a drug or offering it for import; or
- vi. has been convicted of a felony under section 301(gg) of the Act,

FDA employees will notify DE as soon as is practicable. Otherwise, employees will notify DE within ninety (90) days of receiving the oral or written notice.

d. Requirements Applicable to OCI - The Office of Criminal Investigations (OCI) is responsible for providing quarterly reports to the DE that set forth all convictions that have occurred within the preceding three (3) months that may trigger debarment.

3. Persons Subject to Debarment

The triggering event for debarment is ordinarily a felony or misdemeanor conviction under Federal law or a felony conviction under State law. However, certain conduct may subject a food or drug importer, and, for drugs and biologics, a high managerial agent (and other individuals) to debarment. The types of convictions and conduct that may subject persons to debarment are detailed in section 306 of the Act and summarized below, by product type.

- a. **Foods:** A person (an individual, corporation, partnership, or association) is subject to debarment if the person has been convicted of a felony for conduct relating to the importation into the U.S. of any food, or has engaged in a pattern of importing or offering for import adulterated food that presents a threat of serious adverse health consequences or death to humans or animals. Section 306(b)(3).
- b. **Drug Imports:** A person (an individual, corporation, partnership, or association) is subject to debarment if the person has been convicted of a felony for conduct relating to the importation into the U.S. of any drug or controlled substance (as defined in section 102 of the Controlled Substances Act [21 USCS § 802]), or has engaged in a pattern of importing or offering for import, (i) controlled substances that are prohibited from importation under section 401 (m) of the Tariff Act of 1930 (19 U.S.C. 1201(m)) or, (ii) adulterated or misbranded drugs that are (I) not designated in an authorized electronic data interchange system as a product that is regulated by the Secretary or (II) knowingly or intentionally falsely designated in an authorized electronic data interchange system as a product that is regulated by the Secretary. Section 306(b)(3).
- c. **Drugs (Drugs Applications) – Corporations, Partnerships, and Associations:** A person other than an individual is subject to debarment if that person has been:
 - i. Convicted of a felony under Federal law for conduct relating to the development or approval, including the process for development or approval, of any abbreviated drug application. Section 306(a)(1).
 - ii. Convicted for conduct that relates to the development or approval, including the process for development or approval, of any abbreviated drug application, and is a misdemeanor under Federal law or a felony under State law. Section 306(b)(2)(A)(i).
 - iii. Convicted of a conspiracy to commit, or aiding or abetting, a criminal offense described in i. or ii. above. Section 306(b)(2)(A)(ii).
- d. **Drugs/Biologics (Drug Applications) – Individuals:** An individual is subject to debarment if s/he has been:
 - i. Convicted of a felony under Federal law for conduct relating to the development or approval, including the process for development or approval, of any drug product, or otherwise

relating to the regulation of any drug product under the Act. Section 306(a)(2).

- ii. Convicted of a misdemeanor under Federal law or a felony under State law for conduct relating to the development or approval, including the process for development or approval, of any drug product, or otherwise relating to the regulation of drug products under the Act, or has been convicted of a conspiracy to commit, or aiding or abetting, a criminal offense described in this paragraph or the preceding paragraph. Section 306(b)(2)(B)(i).
 - iii. Convicted of a felony under Federal law or a felony under State law which involves bribery, payment of illegal gratuities, fraud, perjury, false statement, racketeering, blackmail, extortion, falsification or destruction of records, or interference with, obstruction of an investigation into, or prosecution of, any criminal offense, or a conspiracy to commit, or aiding or abetting, such felony. Section 306(b)(2)(B)(ii).
- e. Drugs/Biologics (Drug Applications) – Debarment based on Conduct: An individual is also subject to debarment:
- i. If s/he materially participated in acts that were the basis for a conviction for an offense subject to debarment. Section 306(b)(2)(B)(iii).
 - ii. If s/he is a high managerial agent who:
 - worked for, or worked as a consultant for, the same person as another individual during the period in which such other individual took actions for which a felony conviction was obtained and which resulted in the debarment of such individual;
 - had actual knowledge of the actions described above of such other individual, or took action to avoid such actual knowledge, or failed to take action for the purpose of avoiding such actual knowledge;
 - knew that the actions were violative of law; and
 - did not report such actions, or did not cause such actions to be reported, to an officer, employee, or agent of the Department or to an appropriate law enforcement officer, or failed to take other appropriate action that would have ensured that the process for the regulation of drugs was not undermined, within a reasonable

time after such agent first knew of such actions. Sections 201(bb) and (cc), and 306(b)(2)(B)(iv).

- f. Devices: A person (an individual, corporation, partnership, or association) accredited to inspect eligible device manufacturers is subject to debarment if the person has been convicted of a felony for one or more prohibited acts under section 301(gg) of the Act. Section 306(m).

Section 301(gg) prohibits the knowing failure to notify the Secretary of a condition the accredited person discovered during an inspection that could cause or contribute to an unreasonable risk to the public health as required by section 704(g)(7)(E), or an accredited person's knowing inclusion of false information in an inspection report prepared under section 704(g)(7)(A), or the knowing failure to include material facts in such a report.

10-2 PRIOR NOTICE

10-2-1 Purpose

This section defines "prior notice" and establishes uniform criteria to determine if adequate prior notice has been provided.

10-2-2 Background

Except in a few specifically defined areas, the Food and Drug Administration (FDA) has no legal obligation to warn firms or individuals that they, their practices, or their products are in violation of the law prior to taking formal enforcement action. However, a basic principle of FDA's enforcement policy is the belief that the majority of persons will voluntarily comply with the law when given information as to what is required, what violations appear to exist, and, in the case of violations of regulatory significance, that failure to comply may result in the initiation of enforcement action.

10-2-3 Prior Notice

When it is consistent with the public protection responsibilities of the agency and if a violative situation does not present a danger to health or does not constitute intentional, gross or flagrant violations, it is FDA's practice to afford individuals and firms an opportunity to voluntarily take appropriate and prompt corrective action prior to the initiation of enforcement action. If voluntary correction is not achieved, documentation that adequate prior notice was provided strengthens the agency's position in enforcement actions by establishing that responsible individuals continued violating the law despite having been warned by the agency.

The following factors should be considered in evaluating the adequacy of prior notice (prior warning):

1. The conduct, condition, practice, or product violates the laws enforced by FDA.
2. The notice (warning) adequately identified the violative conduct, condition, practice or product.

Note: Similar violations do not need separate prior notices, for example, separate prior notices are not necessary for each unapproved new drug shipped.

3. Notice (warning) was provided to the firm and the most responsible individuals.
4. The firm was afforded a reasonable amount of time to implement corrections. Corrections may include halting shipments, recalling product in violation, or changing procedures and controls.
5. Consider if situations have occurred that may affect the adequacy of prior notice, such as a change in ownership or responsible management. For example, consider what is known by the new management, and if the "firm" received notice.

Note: Prior Notice may be provided orally or in writing. Where there is no dispute as to what is required to comply with the law, adequate notice may well be the Investigator's discussion of objectionable conditions with responsible management at the conclusion of the inspection. If, however, the violative conduct involves a controversial area, an area in which policy is still emerging, or one that has not been pervasively regulated in the past, written notice (usually in the form of a Warning Letter) may be required prior to the initiation of enforcement action.

Consideration of these factors will facilitate meeting the prior notice requirements for civil and certain criminal actions.

10-2-4 Procedures

Warning Letters are the principal means by which the agency provides prior notice of violations and of achieving voluntary compliance. See RPM Chapter 4, Advisory Actions. However, Prior Notice may be provided by means of a civil suit, administrative action, or other less formal ways, including the following:

1. Enforcement action or notification by State, municipal or other Federal agencies involving the same or similar violations.
2. Issuance of the FDA-483, List of Observations, at the conclusion of an inspection. Issuance of a copy of the FDA-483 to a firm's most responsible person(s) must follow guidance in [IOM Chapter 5 – Establishment Inspections](#).

3. Discussion with management by an FDA investigator, documented in the EIR.
4. Recall Classification Notification Letters.
5. Properly documented meetings or telephone conversations between agency officials and a firm's top management (see section [10-3, Regulatory Meetings](#)).
6. Properly documented advisory communications by FDA Center personnel concerning critical scientific issues.

Note: For further information related to "properly documented" telephone conversations and meetings, see [SMG 2126.2, Memoranda of Telephone Conversations and Meetings with Non-FDA Persons](#).

10-3 REGULATORY MEETINGS

A Regulatory Meeting is a meeting requested by FDA management at its discretion, to inform responsible individuals or firms about how one or more products, practices, processes, or other activities are considered to be in violation of the law. FDA is not required to hold a Regulatory Meeting and, except for a few specifically defined areas (see [RPM Chapter 4, Advisory Actions](#) > Warning Letter Procedures), is not required to provide any other form of prior notice prior to taking an enforcement action.

Regulatory Meetings can be an effective enforcement tool to obtain prompt voluntary compliance, and have been used successfully in a variety of different situations, including:

1. As a follow-up to a Warning Letter when firms have corrected the majority of violative conditions noted in the Warning Letter, to provide additional encouragement, direction, and assistance in achieving compliance. As a follow-up to a Warning Letter, FDA officials may remind a firm or individual in a Regulatory Meeting that failure to make appropriate corrections in a timely manner may result in enforcement action.
2. To communicate documented violations that do not warrant the issuance of a Warning Letter. Under these circumstances, a Regulatory Meeting provides the added benefit of real time, two-way discussion of the violations and the appropriate corrective actions.

A Regulatory Meeting should not be used as a substitute for an Untitled Letter when a particular compliance program calls for the issuance of an Untitled Letter. Also, in most cases, a Regulatory Meeting should not be used to initially communicate violations of regulatory significance. Such violations are generally best communicated in the form of a Warning Letter. However, there are some situations when a regulatory meeting may be used to initially communicate violations of regulatory significance. Examples include:

1. When a Regulatory Meeting is held to communicate a health hazard and the necessity for immediate corrective action to address violative product that is on the market.
2. When a Regulatory Meeting is held in conjunction with the issuance of a Warning Letter to emphasize the significance of the violations.

A successful outcome of a Regulatory Meeting would include a commitment by the responsible individuals to correct the conditions or practices at their facility that are in violation of the law. The divisions, at their discretion, would typically verify these commitments through evaluation of subsequent communication and documentation and/or a follow-up inspection. The inspection classification should reflect the significance of the violations and can be appropriately modified based on the adequacy of the corrective action. In those instances where the corrective actions are not satisfactorily carried out, definitive plans should be made for follow up action by the Division. Consult with the involved Center and DE is advisable.

Any FDA organization with regulatory oversight of a firm or individual has the discretion to decide whether or not to hold a Regulatory Meeting. If a Center decides to hold a Regulatory Meeting concerning observations made by one or more Divisions, the Center should invite any -ORA DE staff involved and consider any objections that such division(s) may have to such meeting. Centers are also encouraged to invite division participation in Regulatory Meetings concerning observations or matters originating in the Center (e.g., unapproved new drug or device issues). Any disagreement between a Center and a Division about whether to conduct a Regulatory Meeting should be resolved by collaborative discussion with the Center, Division, and DE.

For situations that involve corporate-wide violations or multiple divisions, the meeting should include the affected Centers, DE, and the involved Divisions. The location of the meeting should be negotiated by the involved parties.

Summary minutes must be prepared for all regulatory meetings.

10-4 INSPECTION OF FOOD RECORDS – SECTIONS 414(a) and 704(a)

10-4-1 Purpose

This section describes the authority, criteria, and procedure for inspecting records under sections 414(a) and 704(a) of the FD&C Act.

10-4-2 Authority

1. The FD&C Act:

- a. Section 414(a) Records Inspection – Criteria for records access, see subsection [10-4-3](#) below.
- b. Section 414(b)- Authority to issue regulations to establish requirements for the establishment and maintenance of records needed to determine the immediate previous sources and the immediate subsequent recipients of food. See 21 CFR 1.326 to 1.368.
- c. Section 414(c)- Protection of sensitive information. FDA shall take appropriate measures to ensure that effective procedures are in place to prevent the unauthorized disclosure of any trade secret or confidential information that is obtained by FDA pursuant to section 414.
- d. Section 414(d) Limitations- This section shall not be construed -- (1) to limit the authority of FDA to inspect records or require establishment and maintenance of records under any other provision of this Act; (2) to authorize FDA to impose any requirements with respect to a food to the extent that it is within the exclusive jurisdiction of the Secretary of Agriculture pursuant to the Federal Meat Inspection Act (21 U.S.C. 601 et seq.), the Poultry Products Inspection Act (21 U.S.C. 451 et seq.), or the Egg Products Inspection Act (21 U.S.C. 1031 et seq); (3) to have any legal effect on section 552 of title 5, United States Code, or section 1905 of title 18, United States Code; or (4) to extend to recipes for food, financial data, pricing data, personnel data, research data, or sales data (other than shipment data regarding sales).
- e. Section 704(a)(1)(B)- Requirement that, during an inspection, any person (excluding farms and restaurants) who manufactures, processes, packs, transports, distributes, holds, or imports foods provide access to all records and other information described in section 414, when the criteria for records inspection in section 414(a)(1) or (a)(2) are satisfied, subject to the limitations in section 414(d).
- f. Section 301(e)- Authority to treat the refusal to permit access to or copying of any record required by section 414 or 704(a) or the failure to establish or maintain any record required by section 414(b) as prohibited acts.

2. 21 CFR 1.361: What are the Record Availability Requirements?

When FDA has a reasonable belief that an article of food, and any other article that FDA reasonably believes is likely to be affected in a similar manner, is adulterated and presents a threat of serious adverse health consequences or death to humans or animals (SAHCODHA), or when

FDA believes that there is a reasonable probability that the use of or exposure to an article of food, and any other article of food that the FDA reasonably believes is likely to be affected in a similar manner, will cause SAHCODHA, any records and other information accessible to FDA under section 414 or 704(a) of the FD&C Act must be made readily available for inspection and photocopying or other means of reproduction. Such records and other information must be made available as soon as possible, not to exceed 24 hours from the time of receipt of the request.

10-4-3 Statutory requirements for invoking records inspection authority

FDA can invoke its authority to access and copy records when the statutory requirements in section 414(a)(1), 414(a)(2), or section 704 of the FD&C Act are satisfied, whether or not intentional adulteration is known or suspected.

1. Section 414(a)(1) Adulterated Food

If FDA has a reasonable belief that an article of food, and any other article of food that FDA reasonably believes is likely to be affected in a similar manner, is adulterated and presents a threat of serious adverse health consequences or death to humans or animals, FDA has authority to access and copy all records relating to such articles that are needed to assist FDA in making this determination.

2. Section 414(a)(2) Use of or Exposure to Food of Concern

If FDA believes that there is a reasonable probability that the use of or exposure to an article of food, and any other article of food that FDA reasonably believes is likely to be affected in a similar manner, will cause serious adverse health consequences or death to humans or animals, FDA has authority to access and copy all records relating to such article, and any other article of food that FDA reasonably believes is likely to be affected in a similar manner, that are needed to assist FDA in making this determination.

Sections 414(a)(1) and 414(a)(2) apply to any person - *excluding farms and restaurants* - who manufactures, processes, packs, distributes, receives, holds, or imports such article of food. Appropriate credentials and a written notice must be presented and the request for records must be conducted at reasonable times, within reasonable limits, and in a reasonable manner. See 10-4-7.

For foreign firms, section 414 applies to any person (excluding farms and restaurants) who manufactures, processes, packs, transports, distributes, holds, or imports such article intended for U.S. commerce.

10-4-4 Records that may be accessed and copied under this authority

FDA may access and copy all records, as authorized under section 414 and 704 relating to the manufacture, processing, packing, distribution, receipt, holding, or importation of the article of food that are maintained by or on behalf of an entity in any format (including paper and electronic formats) and at any location, which are needed to meet the criteria in section 414(a)(1) or (a)(2). See 21 CFR 1.326.

The Investigator should initially request and review the records most likely needed to establish adulteration and serious adverse health consequences or death to humans or animals. See sections 414(a)(1) and (a)(2). The Investigator, as appropriate, should extend the review to other necessary records.

10-4-5 Records that may *not* be accessed and copied under this authority

FDA's authority under sections 414 and 704(a) of the FD&C Act does not apply to: recipes for food, financial data, pricing data, personnel data, research data (except test marketing a food), or sales data (other than shipment data regarding sales), all of which are excluded under section 414(d). In addition, FDA may not access records from farms and restaurants. See 21 CFR 1.362.

In 21 CFR 1.328, "recipe" is defined as "the formula, including ingredients, quantities, and instructions necessary to manufacture a food product. Because a recipe must have all three elements, a list of the ingredients used to manufacture a product without quantity information and manufacturing instructions is not a recipe." Accordingly, FDA has authority to access such a list of ingredients in a records request.

10-4-6 Procedure for Invoking Records Inspection Authority

The Program Division must obtain ORA/Division of Enforcement (DE) concurrence in accordance with the procedures below before making a request to any person for access to records under sections 414(a) and 704(a). The procedure should be expedited and be initiated upon receiving the firm's refusal. The final determination to invoke this authority should occur within 24 hours of initiating this procedure.

1. FDA's Office of Emergency Operations (OEO) will coordinate activities to obtain ORA/DE concurrence on a records request and should be initially contacted as follows:
 - a. During a domestic inspection, Program Division or other FDA personnel notifies FDA's OEO at 866-300-4374 or 301-796-8240; or via email at Emergency.Operations@fda.hhs.gov – 24 hours/day. OEO may be contacted in advance of an inspection if the refusal of records is likely.

- b. During a foreign inspection, the FDA investigator conducting the inspection notifies the Division of Foreign Human and Animal Food Operations (DFHAFO) for guidance. DFHAFO then notifies OEO.
2. OEO notifies the appropriate Center (CFSAN and/or CVM) and ORA/DE either verbally or in writing.
3. OEO schedules a conference call with the Program Division, appropriate Center compliance unit, ORA/DE, and the Office of Chief Counsel (OCC). Prior to the conference call, the Program Division should prepare a draft recommendation memorandum (Exhibit 10-1) and a draft Form FDA 482c for OEO to distribute to call participants on the call. During the conference call:
 - a. The Program Division must be prepared to address the following:
 - Rationale for why there is a reasonable belief regarding an article of food as required by section 414(a)(1) and/or a reasonable probability regarding an article of food as required by section 414(a)(2) of the FD&C Act;
 - Details surrounding record refusal, including the reason for refusal and FDA's attempts at obtaining necessary records;
 - Date/s of the inspection;
 - List of records to be requested and rationale for why the records meet the statutory requirements of section 414 of the FD&C Act; and
 - Approximate timeframe for when the Form FDA 482c could be issued, if approved, and any concerns surrounding issuance.
 - b. The appropriate Center, with the concurrence of ORA/DE, determines that there is a reasonable belief that the food is adulterated and presents a threat of SAHCODHA, or that there is a reasonable probability that the use of or exposure to the food will cause SAHCODHA.
 - c. ORA/DE concurs with any requests for access to records, and works with the appropriate Center to determine the scope of the request and ensures the requested records are necessary to assess whether the food, and any other food that FDA reasonably believes is likely to be affected in a similar manner, is adulterated and presents a threat of SAHCODHA or whether there is a reasonable probability that the use of or exposure to the food, and any other food that FDA reasonably believes is likely to be affected in a similar manner, will cause SAHCODHA.

- d. The appropriate Center consults with OCC on the determination of whether there is a reasonable belief that the food is adulterated. ORA/DE will consult with the appropriate Center and OCC in determining the appropriate scope of the records request.
4. After concurrence has been reached on the call from ORA/DE, the Center, and OCC, the Program Division finalizes the recommendation memorandum (Exhibit 10-1) and forwards it to the Center for final concurrence. OEO prepares a record of the call and distributes the record to the participants on the call.
5. The delegated official from the Center signs the final determination (Exhibit 10-1). See [SMG 1410.306, Determinations Related to Records Access for Human and Animal Foods under Section 414 of the Federal Food, Drug, and Cosmetic Act](#), for delegations of authority.
6. Once the final determination is signed by the Center, the Center provides the signed memorandum to ORA/DE. ORA/DE conveys the information to the Program Division Director for the facility being inspected (domestic inspection) or DFHAFO (foreign inspection). If it is a foreign inspection, DFHAFO conveys the information to the appropriate foreign inspection investigator.
7. The Program Division maintains the case documentation in CMS, including a record of concurrence by each office. For foreign inspections, the Center is responsible for managing the case in CMS. Once the 482c is issued, the case may be closed. The case may be withdrawn if the decision is made to not pursue the records request.

10-4-7 Issuing Form FDA 482c

After the necessary determination has been made in accordance with the procedures in section [10-4-6](#) above, an investigator or other authorized FDA personnel upon presentation of credentials will issue a written notice, Form FDA 482c, to the owner, operator, or agent in charge, informing that person of the records requested and FDA's legal authority to obtain such records. The Form FDA 482c and the related procedures are described in the Investigations Operations Manual (IOM) [Chapter 5 - Establishment Inspections Subchapter 5.4 - Food](#). FDA may request additional records related to the implicated food at a later time under the same authority. For foreign inspections, consult with OCC.

10-4-8 Timeframes for compliance

For all persons except foreign firms, records and other information requested under this authority must be made available as soon as possible, not to exceed 24 hours from the time of receipt of the request. 21 CFR 1.361. The Division should document in CMS the outcome and the firm's compliance with request.

10-4-9 Failure to provide records

The refusal to permit access to or copying of any record required by section 414 or 704(a) and the failure to establish or maintain any record required by section 414(b) are prohibited acts under section 301(e) of the Act. See 21 CFR 1.363.

10-5 ESTABLISHMENT INSPECTION REPORT (EIR) CONCLUSIONS AND DECISIONS

For further information, see Field Management Directive (FMD) [No. 86 Establishment Inspection Report Conclusions and Decisions](#), or refer to the FDA's [FMD web site](#).

Please remember to update the firm's profile information at each stage in the review process to its conclusion, as appropriate, for any Current Good Manufacturing Practice (CGMP) or Quality System (QS) inspection of a domestic or foreign drug, biologics, medical device or combination product facility that involves compliance activity or status. See "Firm Profile Updates in eNSpect" in RPM Chapter 4 for further information.

10-5-1 Release of the Establishment Inspection Report

For further information on the criteria and instructions for releasing one copy of an Establishment Inspection Report, to the firm's top management or designee at the inspected firm, see Field Management Directive [No.145 Release of the Establishment Report](#).

10-5-2 No Action Indicated (NAI) and Voluntary Action Indicated (VAI) 90 day Decisional Letters for Drug Inspections

For further information on the criteria and instructions for the new NAI and VAI 90 Day Decisional Letters, see Field Bulletin [No.63 - FMD-145 NAI/VAI 90 Day Decisional Letters for Drug Inspections](#)

10-6 INTERSTATE TRAVEL PROGRAM (ITP) CLASSIFICATIONS AND ADMINISTRATIVE ACTIONS

For further information related to ITP see [Compliance Program 7318.029, Interstate Travel Program-- Conveyances and Support Facilities](#).

10-7 REPORTING AND MONITORING

The Field Accomplishments and Compliance Tracking System (FACTS) replaces this section. Please see your FACTS Lead User for further guidance.

10-8 AD HOC COMMITTEE

10-8-1 Purpose

This section outlines the function, composition, and activities of agency *ad hoc* committees that are convened for enforcement purposes, and lists the responsibilities of the field and headquarters units in recommending and carrying out their goals.

10-8-2 Function

There are four principle types of *ad hoc* committees: “strategy,” “referral,” “appeal,” and “seizure/injunction.”

1. Strategy *ad hoc* committees are formed to resolve issues for which agency precedent is lacking on matters that involve complex and difficult enforcement issues, or where there is a dispute between two or more offices over strategy.
2. Referral *ad hoc* committees are formed to consider the referral of a matter to the Department of Justice for further criminal investigations or proceedings. See RPM Chapter 6, “Judicial Actions.”

Note: OCI is responsible for reviewing all matters within FDA’s jurisdiction for which a criminal investigation may be recommended. If the division or center office believes that there is a need for a criminal investigation, they must contact OCI immediately. If OCI concludes that they will not be participating in the matter at the time, the division office or center may then proceed as outlined below under [10-8-4 Procedures](#).

3. Appeal *ad hoc* committees are formed to resolve issues pertaining to a legal, administrative, or regulatory course of action, when enforcement policy is inconsistent, unclear or not fully developed.
4. Seizure/injunction *ad hoc* committees may be convened at any time during the preliminary assessment, case initiation, or concurrent review process (see [RPM Chapter 6](#)) when ORA, the Center Director, or the Deputy Chief Counsel for Litigation, or a designee, cannot agree on the strategy or viability of a seizure or injunction case.

Ad hoc committees may be formed at any point in the case development or review process; however, early identification of the need for an *ad hoc* committee enables a more prompt review of the action.

10-8-3 Composition

The *ad hoc* committee will be chaired by the Director, DE, and will consist of the appropriate directors of Program Office involved and of the center office of compliance,

the Deputy Chief Counsel for Litigation and, if appropriate, the Director, OCI. The Director, OEIO, should be included when the matter involves a foreign inspection. When a committee member is unable to participate in a scheduled *ad hoc* meeting, he or she must designate an appropriate official to serve in his or her absence.

The committee members or their designated representatives should be prepared to make agency decisions on the issues based upon the evidence presented prior to and during the *ad hoc* committee meeting. The committee members are also responsible for identifying and arranging for the participation of any additional personnel and for other resources that they feel are necessary. Personnel should be limited to those individuals who have knowledge of the events at issue or who can significantly help in the decision making process.

10-8-4 Procedures

Requests for forming a strategy, referral, appeal, or seizure/injunction *ad hoc* committee may originate from an appropriate division director and program office director, DE; a Director of Compliance; or the Deputy Chief Counsel for Litigation.

If the parties cannot reach an agreement working on their own or with the help of DE, DE will schedule an *ad hoc* committee meeting.

The person who requests an *ad hoc* committee must submit a memorandum via CMS to DE, OSPOP. The memorandum should specify the type of *ad hoc* committee being requested.

- a. The person who requests a strategy *ad hoc* committee should include in the memorandum the recommended outcome of the meeting.
- b. The person who requests a referral *ad hoc* committee should include in the memorandum a description of the evidence expected to be gained through further criminal investigations or proceedings and the reasons it is necessary to refer the matter to the Department of Justice instead of continuing with an FDA investigation.
- c. The person who requests an appeal *ad hoc* committee does not need to summarize the facts and evidence in the memorandum if the committee participants are already familiar with the case; however, if the committee participants are unfamiliar with the case, the person who requests an appeal *ad hoc* should include sufficient background and supporting information in the memorandum.
- d. The person who requests a seizure/injunction *ad hoc* committee should describe any disputed data, information, or views in the memorandum. When an *ad hoc* committee is requested, the clock for reviewing seizure/injunction cases will be tolled. Therefore, the time it

takes to review the *ad hoc* request will not be applied against the timelines for reviewing seizure/injunction cases, described in section 6-1-5 (4). The *ad hoc* committee will immediately establish a time schedule for its review of the case.

At the *ad hoc* committee meeting, the person who requested the meeting will briefly summarize the reason for the request, recommend an outcome of the meeting, describe any foreseeable problems, and provide whatever information may be useful in reaching a decision.

All decisions made by the *ad hoc* committee, including necessary follow-up and strategy, will be recorded, disseminated, and noted in the appropriate section of CMS by the Compliance Officer assigned to the case.

The *ad hoc* committee may reconvene in cases of significant changes, or revisions to the original *ad hoc* supporting material, the discovery of new information or evidence, or when other issues arise that could impact the original decision of the committee. These changes must first be reviewed under the regular review process. If it is necessary to reconvene the *ad hoc* committee, the original *ad hoc* attendees should make every effort to attend any follow-up *ad hoc* meeting.

In most instances, the committee will reach a decision through consensus of the members. When consensus is not possible, the Director, DE will refer the matter to the Associate Commissioner for Regulatory Affairs (ACRA) with a recommendation for making a final decision.

All committee decisions are subject to review by the ACRA and OCC, and the final decision will not be subject to appeal.

10-8-5 Responsibilities

DE receives the request for convening an *ad hoc* committee review. DE assesses the request to determine if there is a clear indication of a dispute or other issue in need of resolution, determines whether sufficient information was submitted, attempts to obtain a resolution with the parties, and if a resolution cannot be reached, establishes the time and place for the meeting. DE will also disseminate the request and any supporting material to the principal members of the *ad hoc* committee.

The Director, DE, chairs the *ad hoc* committee and issues the final decision based upon the *ad hoc* committee's discussion. If the *ad hoc* committee cannot reach a decision, the Director, DE, refers the matter to the ACRA for a final decision.

The Director, ORO, may recommend convening an *ad hoc* committee based on issues that arise from ORO headquarters based program activities.

The appropriate division directors listed in [subsection 10-8-3 Composition](#) make a final decision on all recommendations for an *ad hoc* committee from the field. The Regional Director serves as a principal on the *ad hoc* committee.

The Division Director may recommend the convening of an *ad hoc* committee and forward the recommendation to DE through the appropriate division directors listed in [subsection 10-8-3](#).

The Director of Compliance of the appropriate Center approves or disapproves all recommendations for an *ad hoc* committee from the center and will serve as a principal on the *ad hoc* committee.

The Deputy Chief Counsel for Litigation will serve as a principal on the *ad hoc* committee to provide legal counsel, and to advise on a particular recommendation.

The ACRA may review all committee decisions.

Committee members who are unable to participate in a scheduled *ad hoc* meeting are responsible for designating an appropriate official to serve in their absence. The committee members are also responsible for identifying and arranging for the participation of any appropriate resource persons they feel are necessary, and for providing necessary background information to those persons.

10-9 APPEAL PROCESS

10-9-1 Purpose

This section sets forth a procedure for the appeal of decisions regarding recommendations for legal or administrative actions.

10-9-2 Who May Appeal

Appeals may be originated by the appropriate division directors listed in [subsection 10-8-3](#) or the Center Directors for Compliance (or equivalent).

10-9-3 What May Be Appealed

Appropriate officials may appeal any decision disapproving a proposed action, administrative or legal, which is allegedly inconsistent, or where there is nonexistent enforcement policy. The directors of the involved offices must have attempted to resolve the disagreement prior to submitting an appeal.

10-9-4 When An Appeal Is Not Appropriate

An appeal is not appropriate when additional information that overcomes the basis for the original denial becomes available. In such cases, the recommendation should be

updated to include the new or additional information and resubmitted to the reviewing office with an explanation for the resubmission and a request for reconsideration.

10-9-5 Requests For Appeal

ORA should submit appeals over the signature of the appropriate division directors listed in [subsection 10-8-3](#). Centers should submit appeals over the signature of the Center Director for Compliance. The appeal memorandum and two copies of relevant supporting material must be identified, indexed, and submitted to the Director, DE.

The appeal memorandum must identify the issues on which the appeal is based, and the reasons for disagreeing with the decision of the declining unit. Recommendations must include a summary of communications regarding attempts to resolve differences of opinion.

10-9-6 Review Of Appeals

DE will review the appeal package to assure that it is complete, determine that an appeal is appropriate, and will determine whether the appeal deals with policy, regulations, or a statute. DE will initially attempt to gain a resolution of the disagreement by the parties to the appeal.

10-9-7 Decision On Appeals

If DE cannot get the parties to agree, an *ad hoc* committee meeting to be chaired by the Director, DE, will be scheduled, following the procedures outlined in section 10-6, *ad hoc* Committee.

The meeting will include the appropriate division directors listed in [subsection 10-8-3](#), the Center Director for Compliance, and the Deputy Chief Counsel for Litigation, if appropriate. If the principals are unable to attend, they will designate a senior compliance official to serve in their absence. Usually only one resource person must accompany the senior compliance official.

Resolution of appeals is by consensus of the *ad hoc* committee members. If the *ad hoc* committee can not reach a consensus, the matter will be forwarded to the ACRA for a final decision.

Decisions made by the *ad hoc* committee will be recorded and distributed to meeting participants. The decision may be limited to a decision on the merits of the case or it may include instructions to develop policy in a particular program area. The ACRA or OCC may review all committee decisions.

10-10 EXPERT SUPPORT FOR CASES

10-10-1 Purpose

This section sets out a procedure for assuring that medical, scientific, technical or other specialized (collectively “expert”) support is available for a case. A witness qualified as an expert by knowledge, skill, experience, training or education, may testify thereto in the form of an opinion or otherwise, if

1. the testimony is based upon sufficient facts or data,
2. the testimony is the product of reliable principles and methods, and
3. the witness has applied the principles and methods reliably to the facts of the case.

Federal Rules of Evidence, “Rule 702. Testimony by Experts”.

For purposes of this section, the term “case” refers to a matter that is or may become a court case or hearing. The term “experts” is used to describe individuals from within or outside of FDA, who may serve as consultants and/or as expert witnesses in a case. FDA may seek expert support whether or not a case is contested or litigated.

10-10-2 Responsibility

The Centers have the primary responsibility for assuring that FDA has appropriate expert support for a case, if needed to support the particular violation. The initial determination as to the need for expert support shall be included in the approval memorandum. The Center Compliance Office, in consultation with OCC, should determine whether or not FDA needs expert support for a case. If the Center determines that expert support is needed, it should consult with its medical or scientific review staffs to ensure that the Center position on the subject represents the consensus of current informed medical or scientific opinion. If necessary, the Center should also consult ORA to make this determination. See also [FDA SMG 2610.2, Obtaining Services of Expert or Fact Witnesses](#) (7/2/98).

The Center should also determine whether FDA will be able to obtain expert support for a case, when it is necessary to do so. The Center should not send a case forward to institute actual legal proceedings until it makes these determinations about expert support.

10-10-3 Criteria For Determining The Level Of Expert Support

FDA requires outside expert support in precedent-setting cases when FDA does not have sufficient in-house expertise. If in-house experts are available, the Center should

contact them to determine whether it should also contact individuals from outside FDA to assess the consensus of current medical, scientific, or technical opinion.

The Center generally should review unprecedented issues and complex cases involving state-of-the-art and/or current good manufacturing practice to determine whether it should obtain concurrence by the experts.

The Center generally needs only limited additional expert support for cases that are sufficiently similar to previous cases, except where a new court decision, regulation, or policy has sufficiently changed the factors to consider.

The Center generally needs to refer only to recent cases when determining the need for expert support in a current case that is identical to a recent case.

10-10-4 Documentation

The Center's approval memorandum for a case should include a section regarding expert support, under a separate heading. This section should summarize the Center's effort to provide assurance of expert support and describe significant issues or concerns related to the expert support. It should also include relevant information about prior or pending court cases, testimony or affidavits developed during a recent court case or hearing, information derived during recent processes to propose or finalize rules, advisory committee meetings, literature searches that support the consensus of current opinion, memoranda of conversations with experts, etc.

10-10-5 List Of Individuals For Expert Support

The Center should develop and maintain a list of experts. The Center might develop this information from a variety of sources, but it is responsible for assuring the adequacy of the expert support for a case. For example, when the Center contacts an expert, it should consider asking that expert to identify other individuals with similar expertise. This may be useful in the case at hand (e.g., if a corroborating witness is needed) as well as in future cases.

10-10-6 Obtaining And Paying For Expert Support

The Center might determine that FDA needs expert support from outside FDA to review a case and/or to serve as an expert witness. In that event, the Center should consult with other FDA components, e.g., Office of Chief Counsel and ORA division offices, to identify the most suitable witness, obtain the services of that individual, and pay for fees. Further background about obtaining the services of experts and paying for expert support is set out in an August 25, 2003, memorandum, *Obtaining Services of and Paying for Expert Witnesses/Consultants--Policy* from Donald Vasbinder, Acting Director, Office of Enforcement, to FDA Center and ORA managers. A copy of the memorandum can be found on Inside FDA - Home > Policies & Procedures > Guidance & Regulations: Enforcement > Payment/Costs.

As explained in that memorandum, it is important to keep in mind the overall principle that each case is brought on behalf of the FDA, not any particular part of the organization. It is the responsibility of all involved elements of the FDA to cooperate and work together to provide the best possible support for all cases, regardless of which particular office may be the lead. Thus, it is the joint responsibility of the Center and field offices to identify and obtain the best witnesses and other case support, with the Office of Chief Counsel responsible for the final determination of use of witnesses if we anticipate a contest or litigating a case. Although the Centers have primary responsibility for assuring the availability of expert support, field offices should work closely with the Centers and provide any possible assistance in the process, such as identifying and suggesting to the Center possible good local experts. Field/Center consultation and cooperation on considering the possible need for and the obtaining of expert support should start as soon as necessary and feasible in the case development process and continue throughout each stage.

The following procedures are to be followed for obtaining and paying for the services of experts when needed for support of court cases or hearings:

1. Decisions are to be made jointly by the responsible Center and field offices on the type and scope of expert support needed for support of cases and hearings. It is also important that, if the agency anticipates that a case will be contested, the Office of Chief Counsel be consulted as to the use of expert witnesses. The office that first identifies the need to obtain expert support is responsible for contacting and consulting with the other offices responsible for the case.
2. For outside (non-FDA) consultants and expert witnesses agreed upon as necessary by all parties to support cases or hearings at any stage (including support for a recommendation, review and approval, and litigation), all costs associated with such services will be shared equally among each major office (other than OCC) having responsibility for the case (e.g., each Center and Division involved). This includes all necessary expenses for such expert services, such as contracting for and consulting with experts, travel and per diem, and other associated expenses necessary for this purpose.
 - a. For outside experts, the responsible Center and field offices involved shall also consult and agree with one another on which office will be designated to take the lead role in actually contacting the expert, negotiating a contract for services, and making sure the necessary paperwork is completed.
 - b. Normally, unless mutually agreed otherwise, the designated lead office for these administrative purposes will be the one having primary responsibility for the aspect of the case that requires the expert support. For example:

- i. The Division would normally be the administrative lead for expert support (such as declarations) required for its regulatory action recommendations, or for expert witnesses needed for testimony for a trial or hearing under the Division's purview.
 - ii. The Center would normally be the administrative lead if either the Center or OCC concluded in reviewing a recommended case that outside expert review is required to ensure adequate scientific support is available before proceeding with the case, or for expert witnesses needed for testimony at a hearing under the Center's purview.
- c. The designated lead office that prepares the necessary paperwork to procure the services for outside expert support is also responsible for ensuring timely payment of all invoices related to the services provided. In order to accommodate the shared- funding arrangement, the following accounting procedures should be employed:
 - i. When an ORA field office is designated as the lead for an outside expert:

The total expense should be charged to the applicable ORA field central funding CAN using category E. Accounting technicians should code field "N" of the DHR as follows:

"E (Last name of witness)"

Copies of each obligating document, including information concerning the Center with which the cost will be shared, should be sent to ORA's, Division of Management Operations (DMO) using the contact information on the division's intranet page. DMO will provide the respective Center a copy of the obligating document for tracking purposes. Each quarter, DMO will contact the budget personnel in the applicable Center to request a transfer of funds to recover half of the total cost.

- ii. When a Center is designated as the lead for an outside expert:

The total expense should be charged to the applicable Center's accounting point. Copies of each obligating document, including information concerning the field location with which the cost will be shared, should be sent to DMO at using the contact information on the division's intranet page. Each quarter, the applicable Center will contact the budget personnel in DMO to request a transfer of funds to recover its half of the total cost.

3. For expert support provided by FDA employees, all such expenses (including travel and per diem) will be borne by the office of the employee involved. Expenses should be paid by the employee's office in accordance with its normal procedures.

NOTE: For expert support by FDA employees, this changes some provisions in sections 5.b. and 7.b.iii. of [FDA SMG 2610.2, Obtaining Services of Expert or Fact Witnesses](#), which are somewhat in conflict.)

10-11 TESTIMONY; PRODUCTION OF RECORDS; CERTIFICATION OF RECORDS

Although FDA receives requests for information orally, in writing, and even in person at FDA offices, from parties including litigants, Congressional representatives and their staffs, and state and other federal officials, only written requests can be processed. Any FDA employee receiving a request should let the requestor know to file it in writing and preferably electronically. Before releasing any information to any person, FDA staff must carefully review the procedures in this Chapter including the special considerations described on [10-11-5 Requests Involving Special Circumstances](#) and in the instructions for ORA employees in [10-12, U. S. Congressional Requests](#) and in [10-13, Requests from State and Federal Officials](#).

10-11-1 Requests for Testimony

FDA regulations at 21 CFR § 20.1 require that requests for testimony of FDA employees in non-FDA proceedings be handled in a specific manner. FDA employees are not permitted to provide testimony, whether written or oral, pertaining to any function of the FDA, or with respect to any information acquired in performing their official duties, unless authorized by the FDA Commissioner or another FDA official to whom this authority has been delegated. The FDA may authorize current FDA employees to provide testimony in any proceeding when the testimony will be in the public interest and promote FDA's objectives and the laws it enforces. 21 CFR § 20.1. While interrupting the normal duties of FDA employees to provide testimony in a proceeding to which the agency is not a party is generally not considered to be in the public interest, FDA may be able to honor a request for testimony by providing responsive documents. The FDA can also certify these documents for presentation in court.

The FDA processes written requests for testimony in accordance with 21 CFR § 20.1. Affidavits, declarations, and employees' responses to depositions, interrogatories, or rogatory letters are considered to be testimony covered by 21 CFR § 20.1. See [10-11-8 Definitions](#). Under no circumstances does the FDA process verbal requests for testimony.

The Director, OSPOP, ORA has been delegated the authority to authorize the giving of testimony under 21 CFR § 20.1¹, and is the agency lead for authorizing all testimony. In addition to the Director, OPSPO, the following officials have the authority to authorize the giving of testimony under 21 CFR § 20.1: the ACRA; and the Deputy ACRA, ORA See [SMG 1410.24](#) for these delegations.

ORA's Office of Partnerships and Operational Policy (OPOP)/ Office of Strategic Planning and Operational Policy (OSPOP)/Division of Information Disclosure Policy Information (DIDP)/Disclosure Policy Branch (DPB) conducts the initial review of all requests for testimony , and DPB then prepares a 21 CFR § 20.1 package for the review and signature of the Director, OSPOP.

FDA employees may be asked to assist DPB in responding to a request for testimony, by identifying suitable individual(s) to testify, drafting authorized testimony, or identifying records (instead of testimony) that are responsive to the request.

If a request involves Congress, employee personnel records, the DHHS Office of Equal Employment Opportunity, the investigation of an FDA employee by the DHHS Inspector General, the testimony of an FDA employee as a private citizen, or the testimony of a former employee regarding FDA-related matters, see the instructions in "Requests involving Special Circumstances" below. Otherwise,

- 1. If you receive a written request for testimony (whether by letter, subpoena, or in any other form) that was submitted by, or on the behalf of any person, contact DPB immediately and send the original request to that office at the address below.**

U.S. Food and Drug Administration
Office of Partnerships and Operational Policy
Office of Strategic Policy and Operational Policy
Division of Information Disclosure Policy

¹ Pursuant to Staff Manual Guide (SMG) [1410.24](#), Disclosure of Official Records and Authorization of Testimony, dated April 27, 2007, the Commissioner of Food and Drugs (Commissioner) has delegated to "Director, Division of Compliance Policy" (DCP), among others, the authority to the make determinations to authorize the testimony of an FDA employee in litigation in which the FDA is not a party pursuant to 21 C.F.R. § 20.1. It is well established that DCP was reorganized into the Office of Strategic Planning and Operational Policy (OSPOP) and kept the same functions. According to SMG 1401.1, Policy and Procedures Governing Regulatory and Administrative Delegations of Authority (DOAs), paragraph G, delegations to an organization remain in effect in a successor organization with the same functions. Therefore, as the successor organization to DCP, Director of the Office of Strategic Planning and Operational Policy (OSPOP) has the authority to grant requests for testimony pursuant to 21 C.F.R. 20.1. The OSPOP Director will have primary responsibility for ORA's 20.1 authorizations.

Note: Per the SMG, the Deputy Associate Commissioner for Regulatory Affairs (Deputy ACRA), ORA; the Director and Deputy Director, Office of Enforcement OE, ORA; and the Director, Division of Compliance Policy, OE, ORA are all delegated the authority to grant requests for testimony or to authorize the giving of testimony under Sec. 20.1 of 21 CFR. These officials may not further redelegate this authority.

Disclosure Policy Branch
c/o Testimony Specialist
12420 Parklawn Drive
(Element Bldg., RM. 4042)
Rockville, MD 20857

To expedite processing, a scanned copy of the testimony request should also be sent to the FDA Outlook address for the ORA OSPOP Testimony – Info Sharing Team at ORAINfoshare@fda.hhs.gov.

2. If you are contacted by individuals requesting testimony:

- a. Either refer the individuals to a Testimony Specialist at the FDA Outlook address for the ORA OSPOP Testimony – Info Sharing Team in DIDP/DPB, or advise them that FDA does not process verbal requests for testimony and that they should submit a written testimony request to the address for DPB shown above, well in advance of their desired due date to allow time for evaluating and processing the request; and that they should include information about the hearing body, date, location, and purpose of the proceeding; the nature and scope of the testimony the FDA is being asked to provide and the use to which it will be put; the name(s) of the FDA employees, if known, being asked to testify; the requester's interest in the matter sought to be disclosed; the requester's rationale for considering that the testimony is in the public interest and will promote the objectives of FDA and the laws it enforces; and any other relevant background. Refer them to 21 CFR § 20.1(c) for FDA's procedures on how to make these requests.
- b. Do not make any commitment regarding the availability or willingness of a witness to testify in any particular case.
- c. Document the conversation, and send DIDP/DPB a memorandum by email and contact that office to confirm receipt.

3. If you have been authorized to testify:

- a. Before presenting testimony, contact the assigned OCC attorney, to obtain legal advice; and the appropriate FDA component, to obtain any technical advice you believe you need and, if needed, information about funding travel.
- b. After presenting testimony, submit a summary memorandum or copy of the testimony or a transcript of the testimony to the Testimony Specialists in DPB and to OCC. If the Director, OSPOP, authorizes the testimony for a hearing in a state court, the summary memorandum

you prepare should address not only the individual's testimony, but also any other portions of the hearing that the individual attended.

10-11-2 Requests for Production of Records

The Director, OSPOP, is the agency official with delegated authority who is the lead for responding to subpoenas for the production of records made pursuant to 21 CFR § 20.2¹.

If a request involves Congress, employee personnel records, the DHHS Office of Equal Employment Opportunity, the investigation of an FDA employee by the DHHS Inspector General, the testimony of an FDA employee as a private citizen, or the testimony of a former employee regarding FDA-related matters, see the instructions for ORA employees in [10-12, U.S. Congressional Requests](#) and in [10-13, Requests from State and Federal Officials](#). Otherwise,

1. If you receive a written request or a subpoena, including a subpoena duces tecum, for the production or certification of records:

Send the request to the address for the Testimony Specialist, DPB shown above.

2. If you are contacted by an individual requesting the production or certification of records:

- a. Either refer the individuals to the Testimony Specialist, DPB; or advise them that FDA does not process verbal requests for records and that they should submit a written request to the address for the Testimony Specialist, DPB (shown above in "If you receive a written request for testimony") well in advance of their desired due date to allow time for evaluating and processing the request; and that they should include

¹ Pursuant to Staff Manual Guide (SMG) [1410.24](#), Disclosure of Official Records and Authorization of Testimony, dated April 27, 2007, the Commissioner of Food and Drugs (Commissioner) has delegated to "Director, Division of Compliance Policy" (DCP), among others, the authority to make determinations to authorize the testimony of an FDA employee in litigation in which the FDA is not a party pursuant to 21 C.F.R. § 20.2. It is well established that DCP was reorganized into the Office of Strategic Planning and Operational Policy (OSPOP) and kept the same functions. According to SMG 1401.1, Policy and Procedures Governing Regulatory and Administrative Delegations of Authority (DOAs), paragraph G, delegations to an organization remain in effect in a successor organization with the same functions. Therefore, as the successor organization to DCP, Director of the Office of Strategic Planning and Operational Policy (OSPOP) has the authority to grant requests for testimony pursuant to 21 C.F.R. 20.2. The OSPOP Director will have primary responsibility for ORA's 20.2 authorizations.

Note: Per the SMG, the Deputy Associate Commissioner for Regulatory Affairs (Deputy ACRA), ORA; the Director and Deputy Director, Office of Enforcement OE, ORA; and the Director, Division of Compliance Policy, OE, ORA are all delegated the authority to grant requests for testimony or to authorize the giving of testimony under Sec. 20.2 of 21 CFR. These officials may not further redelegate this authority.

specific information about the records requested, the requested due date, and any other relevant background. Refer them to 21 CFR § 20.2 for FDA's procedures for processing these requests.

- b. Do not make any commitment regarding the availability of records.
- c. Document the conversation, and send DPB a memorandum by email or and contact that office to confirm receipt.

10-11-3 Multi-issue Subpoena - Requests for Samples

If you receive a subpoena or a request that seeks FDA records, testimony, and actual samples for litigation (not for first party request for a 702(b) sample), you should: (1) refer the sender of the request/subpoena for the samples to the Testimony Specialist, DPB, who, if needed, will consult with OCC for a response pursuant to 21 CFR § 2.10, and if involved, OCI; and (2) process the remaining portion of the request/subpoena as a request for testimony and for records.

FDA considers a request/subpoena for analytical results to be a request for records.

10-11-4 Requests for Certification of Records

FDA processes requests for certification of records in accordance with 21 CFR § 20.3. If you are asked to certify records, contact DPB by email at the FDA Outlook address for the *ORA OSPOP Testimony – Info Sharing Team*. DPB will forward requests for the certification of records to the appropriate component for direct response.

10-11-5 Requests involving Special Circumstances

If you receive a request that involves:

1. An FDA proceeding or a DHHS proceeding where FDA is involved – contact DPB, if that office is not already involved or aware of the request. DPB will coordinate with other entities as needed.
2. Congress – contact FDA's Office of Legislation, except as noted in instructions for ORA staff in sections [10-12, Congressional Requests](#) and in [10-13, Requests from State and Federal Officials](#) below.
3. Employee personnel records related to litigation – contact DPB. DPB will coordinate with other entities as needed.
4. An investigation of an FDA employee by the DHHS Inspector General - contact FDA's Office of Internal Affairs (HFH-560) in the Office of Criminal Investigations.

5. The DHHS Office of Equal Employment Opportunity – contact FDA’s EEO and Diversity Management Office (HF-15), in the Office of Shared Services.
6. Testimony as a private citizen - Some testimony as a "private citizen" (i.e., not in one's official FDA capacity) may raise special concerns such as possible conflict of interest or may require approval as an outside activity.

NOTE: If the individual’s planned testimony is based on information derived during FDA employment, the employee must contact DIDP/DPB for clearance of this testimony under 21 CFR § 20.1. For testimony as a private citizen, employees also should refer to the Standards of Ethical Conduct for Employees of the Executive Branch, 5 CFR § 2635.805, and the HHS Supplemental Standards of Ethical Conduct, 5 CFR § 5501.106. Contact FDA’s Ethics and Integrity Staff for further information regarding approval of the testimony as an outside activity.

7. Testimony by former FDA employees - Requests for the testimony of former FDA employees are not covered specifically by 21 CFR § 20.1. However, we encourage former employees to contact DPB if they receive a request or subpoena to provide testimony regarding FDA-related matters, because FDA may assist that individual on behalf of FDA. Advise former employees that there may be other restrictions on their ability to provide the requested testimony, including possible conflict of interest concerns and statutory and regulatory restrictions on the release of trade secrets and other kinds of confidential information.

10-11-6 Disclosure of Non-public information

FDA generally discloses information pursuant to a request or subpoena if that information is neither exempt from disclosure under FOIA nor prohibited from disclosure by other law, and the disclosure is consistent with FDA’s [part 20](#) regulations.

In certain circumstances, with the appropriate authorization, transmittal procedures, and disclosure reviews, FDA may share certain non-public information that is otherwise exempt or prohibited from disclosure, e.g., 21 CFR § 20.85 (disclosure to other federal agencies), 21 CFR § 20.88(d) (disclosure to state and local agencies), or 21 CFR 20.89(c) (disclosure to foreign agencies). Any request for non-public information from a federal or state agency must be sent to the Testimony Specialists in the Division of Information Disclosure Policy/Office of Strategic Policy and Operational Planning/ORA at the FDA Outlook address for the *ORA OSPOP Testimony – Info Sharing Team*. See also RPM [Chapter 3 Commissioning > Confidentiality](#). Any request for non-public information from a foreign agency must be sent to the Office of Partnerships International and Federal Engagement staff at the FDA Outlook address for ORA OP DI International and Federal Group.

Other examples of instances in which FDA may share non- public information are set forth below.

1. FDA may share under 21 U.S.C. § 372(a) certain non-public information, including trade secrets, personal privacy, open investigatory, and confidential commercial information, , with federal or state officials commissioned by FDA under law. For questions contact Office of Partnerships at the FDA Outlook address for *ORA State Commissioning* . See also RPM [Chapter 3 Commissioning](#) > *Confidentiality*.
2. FDA may share under 21 CFR § 20.90 certain non-public information with other government officials under agreements or contracts that contain appropriate confidentiality provisions. For questions contact Office of Partnerships at the FDA Outlook address for *ORA OP Feedback*.

10-11-7 Other Requests for Information – Informal Meetings

A person (individual, company, corporation, etc.) might request an informal meeting with an FDA employee to discuss information the employee obtained during the course of his or her employment.

1. If the requester is not an official from another government agency, and if private civil litigation is involved, decline the request and suggest that the requester submit a request for testimony under 21 CFR 20.1. Also, advise the requester that FDA has a long- standing practice against granting one-sided interviews or informal testimony to avoid creating the impression that FDA is biased toward a party.
2. If the requester is not an official from another government agency, and if the request relates to a matter other than private civil litigation (e.g., the requester seeks general information about FDA's activities), advise the requester to submit a written request to FDA, to be handled as general correspondence under routine office procedures.
3. If the requester is an official from another government agency, advise the requester to submit a written request to FDA to be handled under appropriate agency procedures for the sharing of publicly releasable or non-public information under RPM Chapter 3 Commissioning > Confidentiality and in Instructions for ORA employees in 10-12, U. S. Congressional Requests and in 10-13, Requests from State and Federal Officials. Contact OCI's information disclosure senior investigator if the request is from a law enforcement agency and the request is for non-public information.

Consult with DIDP if needed at the FDA Outlook address for the *ORA OSPOP Testimony – Info Sharing Team*.

10-11-8 Definitions

The following list contains definitions of commonly used terms in the context of testimony, subpoenas, or production of records.

Affidavit - A written document signed in the presence of a notary public under a sworn oath that the statement is true. FDA considers an affidavit to be testimony covered by 21 CFR 20.1.

Certification (also known as “certificate”) - A written assurance, or official representation, that some act has or has not been done, or some event occurred, or some legal formality has been complied with. Typically, a requester will ask that FDA certify as to the authenticity of an FDA record as a true copy. FDA processes requests or subpoenas for certification under 21 CFR 20.3.

Declaration - A written statement signed under the penalty of perjury. A declaration can substitute for an affidavit in federal court proceedings. 28 U.S.C. 1746. FDA considers a declaration to be testimony covered by 21 CFR 20.1.

Deposition - The taking and recording of testimony of a witness under oath, in front of a court reporter prior to trial and away from the courtroom. FDA considers an employee's responses in a deposition to be testimony covered by 21 CFR 20.1.

Interrogatories - Written questions sent by one party in a lawsuit to the other party during the discovery process prior to trial. Interrogatories must be answered in writing under oath or under penalty of perjury. FDA considers the employee's response to interrogatories to be testimony covered by 21 CFR 20.1.

Notary Public - A person authorized by the state in which they reside to administer an oath of truth to a person making an affidavit, and to apply their signature and seal or stamp to attest to the oath.

Rogatory Letters - A written request from a judge in one state to a judge in another, asking that the latter take the testimony of a witness. FDA considers testimony in response to rogatory letters to be covered by 21 CFR 20.1.

Subpoena - A court order commanding a witness to appear at a certain time and place to testify on a certain matter. For purposes of this section, a “subpoena” means a subpoena for verbal or written testimony (e.g., an affidavit). A subpoena for testimony also might include a request for records. In that case, FDA would process the subpoena under 21 CFR 20.1 and 20.2.

Subpoena Duces Tecum - A court order commanding a witness to produce documents at a certain time and place. FDA processes these subpoenas, which are intended for the production of records, under 21 CFR 20.2.

Testimony - For purposes of this section, testimony is an individual's statement given in writing (such as an affidavit or a declaration) or by appearance under oath at a proceeding. The statement might be in response to a deposition or interrogatories. Testimony is covered by 21 CFR 20.1.

10-11-9 References

The following list contains references commonly used in the context of testimony, subpoenas, or production of records.

1. "Enforcement Notes," Issue No. 85, September 18, 2002, Testimony, available on ORA's Intranet
2. Staff Manual Guide 1410.21 (General Redelegations of Authority from the Commissioner to other Officers of the Food and Drug Administration)
3. Staff Manual Guide 1410.23 (Certification of True Copies and Use of Department Seal)
4. Staff Manual Guide 1410.24 (Disclosure of Official Records and Authorization of Testimony)
5. Staff Manual Guide 2127.1 (Attendance by FDA Employees at Congressional Hearings)
6. Staff Manual Guide 2127.2 (Requests for Testimony of FDA Personnel in Non-FDA Proceedings)
7. Staff Manual Guide 2460.7 (Procedures for Implementing the Freedom of Information Act) (Not on Intranet)
8. 5 U.S.C. § 552a (Privacy Act); 21 CFR Part 21 (Privacy Act regulations)
9. 5 U.S.C. § 552(b) (Freedom of Information Act (FOIA)); 21 CFR Part 20 (FOIA regulations), particularly 21 CFR 20.1, 20.2, and 20.3
10. 5 CFR § 2635.805 (Standards of Ethical Conduct for Employees of the Executive Branch; Service as an expert witness)
11. 5 CFR § 5501.106 (HHS Supplemental Standards of Ethical Conduct; Outside employment and other outside activities)
12. Information Disclosure Manual on ORA's Intranet Information Disclosure Main Page
13. FDA's FOIA Page on FDA's Intranet

10-12 U. S. CONGRESSIONAL REQUESTS – INSTRUCTIONS FOR ORA EMPLOYEES

Whether any ORA field or headquarters employees may directly answer an inquiry from U.S. Congressional staff (House or Senate) in their district's geographical area or must refer the inquiry to ORA's Executive Secretariat Staff (ESS) depends on the source and subject matter of the inquiry, as detailed below.

1. The following type of U.S. Congressional (House or Senate) inquiries may be answered directly by ORA field or headquarters employees:
 - a. Inquiries from Congressional staff located in a district's geographical area that concern issues of general interest and can be answered using approved information already available to the public (e.g., copies of public documents, FDA publications, talking points, press releases, Federal Register notices, or other published materials).
 - i. ORA employees should refer the Congressional staff located in their district's geographical area to FDA's public websites, where many of these materials are available online.
 - b. Inquiries from Congressional staff located in a district's geographical area that request information about an import entry in "may proceed" status that is "closed" for ORA.
 - i. ORA employees may refer these inquiries to FDA's public website for its import entry system - Import Trade Auxiliary Communication System (ITACS):
<https://itacs.fda.gov/app/welcomeToITACS.jsf>.

Note: "May Proceed" status indicates that the entry has been released without any further action by FDA and is considered "closed."

"May Proceed" status does not include entries in which there was an examination, sampling, detention, etc. Those inquiries must be referred to FDA's Office of Legislation (OL) through ESS.
2. The following types of U.S. Congressional (House or Senate) inquiries *must be* referred to ESS:
 - a. Inquiries that originate from the staff of a Congressional office located in Washington, D.C.

- b. Inquiries involving legislative, policy, or budget issues that are national in scope (e.g., issues that are receiving major press coverage, are the subject of pending Federal legislation, involve FDA expenditures, etc.).
- c. Inquiries regarding FDA inspections, investigations, sample collection/analysis, litigation, or pending product approvals.
- d. Inquiries that involve import entries in any status other than “may proceed,” as defined in section 1(b) above.
- e. Inquiries regarding cases in litigation or pending product approvals.
- f. Any inquiries that require a formal, written response.

Submit the inquiry or refer the requesters to ESS via the FDA Outlook address for the *ORA OCPM Executive Secretariat Staff* within one business day of receiving the inquiry. To ensure the expeditious handling of the inquiry, please include “Congressional Inquiry” in the subject line of your email.

Upon receipt, ESS will refer the inquiry to OL’s Congressional Correspondence Team to collect information/data and issue the official agency response to the requester.

Federal (non-congressional) inquiries are processed by ORA’s Federal-State Health Communications and Relations (FSHCR) program manager. Submit federal (non-congressional) inquiries to the FSHCR program manager at the FDA Outlook address for *DivComm-ORA*’s per [RPM 10-13-3, Procedures for Handling Inquiries from Federal Agencies](#). Additionally, if the federal request is for non-publicly available records, forward the request to the FDA Outlook address for the *ORA OSPOP Testimony – Info Sharing Team* in DIDP/DPB with a copy to the FSHCR program manager at the FDA Outlook address for *DivComm-ORA*.

Inquiries from state, local, tribal, and territorial government officials *must* be processed per [RPM 10-13-4 Procedures for Handling Inquiries from Other State, Local, Tribal, and Territorial Government Officials](#) unless the inquiry concerns non-publicly available information or is solely a records request; in those cases, forward the request to the FDA Outlook address for the *ORA OSPOP Testimony – Info Sharing Team* in DIDP/DPB with a copy to the FSHCR program manager at the FDA Outlook address for *DivComm-ORA*.

If you have any questions regarding U.S. Congressional inquiries, call or email ESS or OL. Contact information below:

Executive Secretariat Staff

Email address: use the FDA Outlook address for *ORA OCPM Executive Secretariat Staff*

Phone: (301) 796-5231

Fax: (301) 827-0963

Office of Legislation

Congressional Correspondence Team

Email address: use the FDA Outlook address for *legislation*

Phone: (301) 796-8900

Fax: (301) 827-8602 or (301) 847-8603

10-13 REQUESTS FROM STATE AND FEDERAL OFFICIALS – INSTRUCTIONS FOR ORA EMPLOYEES

10-13-1 Background

Be aware of changes in 2014 in the handling of inquiries and requests for information and reports (henceforth referred to as inquiries) originating from state government officials and national associations representing state government officials (State government officials include governors, attorneys general, state legislators, and other officials in state, local, tribal, and territorial governments.) Historically, these inquiries were handled by the Office of Partnerships (OP) in ORA. These requests included most inquiries involving actions and matters that were policy-related and operational in nature. In addition, ORA's district and regional offices responded directly to inquiries from state legislatures within their boundaries when the inquiries involved issues of general interest that could be answered using cleared information available to the public.

With the exception of testimony and subpoena requests that fall under 21 C.F.R §§ 20.1, 20.2 and non-public information and records requests that fall under 21 CFR §§20.85, and 20.88 (all of which are managed by DIDP), responsibility for handling and coordinating agency responses to policy-related and operational-type inquiries from these entities was moved from the OP to ORA's Division of Communications in March 2014 as part of ORA's realignment and consolidation of all communications and public affairs staff and functions into a newly established Division of Communications. Under this ORA realignment, the FSHCR program manager in ORA's Division of Communications was charged with handling and coordinating responses to policy-related and operational-type inquiries from state congressional officials, other state, local, tribal, and territorial government officials, and national associations representing state government officials.

In September 2014, FDA's Office of Policy, Planning, and Legislation (OPPL) signed a Service Level Agreement (SLA) with ORA that outlined the responsibilities of ORA and of OPPL's newly created Intergovernmental Affairs (IGA) staff, with new procedures for

handling inquiries from state congressional officials and the national associations that represent state government officials.

1. Under the SLA, IGA is responsible for handling responses to policy-related inquiries from state congressional officials and the national associations representing state government officials. ORA, however, retains responsibility for handling and coordinating operational-type responses to inquiries from those groups.
 - a. Inquiries that are policy-related generally pertain to questions regarding FDA laws, regulations, policies, guidance, and rulemaking.
 - b. Inquiries that are operational in nature usually involve regulatory actions such as FDA investigations and compliance/enforcement activities. Examples include warning letters, embargos, injunctions, seizures, etc.) as well as information on illness outbreaks and injury-related events involving FDA-regulated products.
2. The SLA designates the following as points of contact and liaisons in ORA and OPPL: the director and staff of IGA, which is part of OPPL, and the FSHCR program manager. They are variously responsible for handling and coordinating different kinds of policy-related and operational inquiries from state congressional officials and the national associations representing state government officials.

10-13-2 Procedures for Handling Inquiries from State Congressional Officials and their Staff

In accordance with the SLA, all inquiries, unless solely a request for records or a request for non-public information, that originate from state congressional officials (e.g., state senator, state representative, state assemblyman) and their staff must be referred either to the FSHCR program manager in ORA's Division of Communications or IGA Staff for further processing as detailed below. If solely records are requested, or the release of non-public information is implicated, contact DBP/DIDP at the FDA Outlook address for *ORA OSPOP Testimony – Info Sharing Team*.

1. The FSHCR program manager will handle responses to inquiries that are operational in nature and involve regulatory actions such as FDA inspections, investigations, and compliance/enforcement actions (e.g., warning letters, embargos, injunctions, seizures, inspections, etc.) and activities like work planning, emergency response, and sample collection. This responsibility includes coordinating with the responsible FDA center/office and the Office of Chief Counsel (OCC) to develop and clear the response as required. It also entails coordinating with DBP/DIDP if records are requested or if non-publicly available information may be released pursuant to 21 CFR § 20.88.

- a. ORA field and headquarters employees must refer the inquiry to the FSHCR program manager for further processing within one business day of receipt of the inquiry. To ensure the expeditious handling of the inquiry, "State Congressional Inquiry" should be in the subject line of the email.
 - i. The FSHCR program manager referenced above must contact the requester to acknowledge receipt of the inquiry and provide a projected time frame when a response will be provided.
 - ii. The FSHCR program manager will provide the cleared response to the requestor as expeditiously as possible after receipt of the inquiry. If significant delays are encountered with coordinating or clearing the response, the FSHCR program manager will inform the requestor of the delay, along with a projected date or time frame when the cleared agency response will be provided to them.
2. The IGA staff will handle inquiries that are policy-related and involve FDA legislation, legislative testimony, guidances and rulemaking, FDA-regulated products, and tobacco.
 - a. ORA field and headquarters employees must forward the inquiry to the FSHCR program manager at the FDA Outlook address for *DivComm-ORA* for further processing within one business day of receipt of the inquiry. To ensure the expeditious handling of the inquiry, "State Congressional Inquiry" should be in the subject line of the email.
 - b. The FSHCR program manager will forward the inquiry within one business day of receipt to the IGA Staff to handle and coordinate the response to the inquiry.
3. The IGA staff will handle responses to inquiries that are policy-related and involve pharmacy compounding issues.
 - a. ORA field and headquarters employees must forward the inquiry within one business day of receipt directly to the IGA staff at the FDA Outlook address for the *IGA*, with copies sent to the FSHCR program manager at the FDA Outlook address for *DivComm-ORA* and to the Outlook address for *ORA Compounding ICS*.
4. For inquiries that are a combination of policy-related and operational in nature, the IGA staff and FSHCR program manager will collaboratively review the inquiry to determine who will take the lead in handling and coordinating the response to the inquiry.

5. ORA field and headquarters employees who have questions regarding whether an inquiry is policy-related or operational in nature may forward the inquiry to the [FSHCR program manager](#) to determine how it should be handled.

10-13-3 Procedures for Handling Inquiries from Federal Agencies

With the exception of inquiries from the HHS Office of the Inspector General (OIG) and U.S. Government Accountability Office (GAO), the FSHCR program manager handles all inquiries for publicly available information from other federal agencies sent to any ORA employee. If records are requested or the release of non-public information is contemplated, coordination must be made with the DPB/DIDP to determine if non-publicly available information may be released pursuant to 21 CFR § 20.85. Additionally, OSPOP is responsible for coordinating ORA's response to inquiries involving GAO studies and OIG audits.

1. ORA field and headquarters employees must forward the federal agency inquiry directly to the FSHCR program manager at the FDA Outlook address for DivComm-ORA for further processing within one business day of receipt of the inquiry. To ensure the expeditious handling of the inquiry, "Federal Agency Inquiry" should be in the subject line of the email.
2. For federal inquiries from the HHS OIG and US GAO, ORA field and headquarters employees must forward the inquiry to the FDA Outlook address for the GAO ORA Liaison in ORA's OSPOP with a copy to the FSHCR program manager at the FDA Outlook address for DivComm-ORA within one business day of receipt of the inquiry.
3. If solely records are requested, or the release of non-public information is implicated, the FSHCR must contact DBP/DIDP at the FDA Outlook address for the ORA OSPOP Testimony – Info Sharing Team.

10-13-4 Procedures for Handling Inquiries from Other State, Local, Tribal, and Territorial Government Officials and National Associations

Regarding inquiries from other state, local, tribal, and territorial government officials and the national associations representing these officials: The source and subject matter determine whether the inquiry should be handled by ORA field employees or be referred to the FSHCR program manager or IGA staff for further processing. See details below.

1. The following types of inquiries from non-elected state, local, tribal, and territorial government officials and national associations representing these officials may be answered directly by ORA field and headquarters employees:

- b. Inquiries that deal with issues of general interest that can be answered with approved information and reports available to the public (e.g., copies of public documents, FDA publications, Field Alert Reports, talking points, press releases, Federal Register notices, or other published materials). When applicable, ORA employees should refer the requestor to FDA's public website, where many of the materials are available online.
 - c. Inquiries involving operational matters such as requests for information about pending or recommended compliance/enforcement actions, within five working days of completion of a violative inspection, events related to illness and injury involving regulated products, and emergency situations subject to appropriate information disclosure requirements. If solely records are requested or the release of non-public information is implicated, ORA employees must contact DBP/DIDP at the FDA Outlook address for the *ORA OSPOP Testimony – Info Sharing Team*.
 - d. Field or headquarters employees must provide a cleared response to the requestor as expeditiously as possible after receipt of the inquiry. If significant delays are encountered with coordinating or clearing the response, the requestor must be informed of the delay along with a projected date or time frame when the cleared agency response will be provided to them.
2. The following types of inquiries from elected and high-level other state, local, tribal, and territorial government officials and their staff, as well as the national associations representing these officials, must be referred to the FSHCR program manager or IGA staff for further processing as detailed below:
- a. The FSHCR program manager will handle responses that involve operational issues.
 - i. ORA field and headquarters employees must forward the inquiry to the FSHCR program manager at the FDA Outlook address for *DivComm-ORA* for further processing within one business day of receipt of the inquiry. To ensure the expeditious handling of the inquiry, "State Government Inquiry" should be in the subject line of the email. If solely records are requested or the release of non-public information is implicated, ORA employees must contact DBP/DIDP at the FDA Outlook address for the *ORA OSPOP Testimony – Info Sharing Team* with a copy to FSHCR program manager at the FDA Outlook address for *DivComm-ORA*.

- b. IGA staff will handle responses to inquiries that involve legislative, policy, budget matters, and high interest issues that are national in scope (e.g., issues that are receiving major press coverage, are the subject of pending federal legislation, involve FDA expenditures, etc.) However, send the inquiries to the FSHCR project manager for initial handling.
 - i. ORA field and headquarters employees must forward the inquiry to the FSHCR program manager for further processing within one business day of receipt of the inquiry. To ensure the expeditious handling of the inquiry, "State Government Inquiry" should be in the subject line of the email.
 - ii. The FSHCR program manager will forward the inquiry within one business day of receipt to the IGA Staff at the FDA Outlook address for *IGA* to handle and coordinate the response to the inquiry.
- c. The IGA staff will handle the response to policy-related pharmacy compounding inquiries.
 - i. ORA field and headquarters employees must forward the inquiry within one business day of receipt directly to the IGA staff at the FDA Outlook address for the *IGA* to handle and coordinate the response to the inquiry, with copies sent to the FSHCR program manager at the FDA Outlook address for *DivComm-ORA* and to the Outlook address for *ORA Compounding ICS*. To ensure the expeditious handling of the inquiry, "State Pharmacy Compounding Inquiry" should be in the subject line of the email.

10-14 APPLICATION INTEGRITY POLICY

The Application Integrity Policy (AIP) describes the agency's approach regarding the review of applications that may be affected by wrongful acts that raise significant questions regarding data reliability. FDA published this policy, formally titled, "[Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities; Final Policy](#)" in the Federal Register on September 10, 1991 (56 FR 46191), and in Compliance Policy Guide (CPG) 7150.09. See Sec. 120.100 of the Compliance Policy Guides publication. These documents, procedures to implement the AIP, and AIP information are available on the FDA [Application Integrity page](#).

10-15 EXHIBIT

Exhibit 10-1 – SECTION 414 OF THE FD&C ACT RECOMMENDATION MEMORANDUM

To: Director, Division of Enforcement, Office of Regulatory Affairs

From: Program Division Director or Designee

Date:

Re: Formal Recommendation for Invoking Records Inspection Authority under Section 414 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) [21 U.S.C. § 350c]

Firm Identification #(s): Insert firm name, address, and FEI number (may not be a farm or restaurant)

Dates of Inspection:

Details of Record Refusal: Provide information on the facts of the records refusal and FDA's attempts at obtaining the necessary records or provide the background of past experiences with the firm, if the Division anticipates the firm may refuse to provide access to records.

Section 414 of the FD&C Act Statutory Requirements: Outline evidence supporting why the Division believes the current situation meets the statutory requirements of section 414 of the FD&C Act. This may be done with a bulleted list to describe how the requirements are met under either section 414(a)(1) or 414(a)(2) of the FD&C Act. Examples include but are not limited to: Description of foodborne outbreak; sample results; or inspectional observations.

- Section 414(a)(1) of the FD&C Act: FDA has a reasonable belief that an article of food, and any other article of food that FDA reasonably believes is likely to be affected in a similar manner, is adulterated and presents a threat of serious adverse health consequences or death to humans or animals (SAHCODHA).
- Section 414(a)(2) of the FD&C Act: FDA believes that there is a reasonable probability that the use of or exposure to an article of food, and any other article of food that FDA reasonably believes is likely to be affected in a similar manner, will cause SAHCODHA.

Records to Request: Include a bulleted list of records to request and summarize, in one to two sentences, the rationale for why section 414 of the FD&C Act authorizes FDA to access and copy these records.

- The records should relate to the article in question and to any other article of food believed to be affected in a similar manner.
- The records should be necessary to assist in determining whether the food is adulterated and presents a threat of SAHCODHA, or there is a reasonably probability that use of or exposure to the food will cause SAHCODHA.
- Examples include: Receiving records for raw materials or finished product; production records; sanitation records; testing records; inventory; distribution records; and complaints and adverse event reports.

- Section 414 records inspection authority excludes recipes for food, financial data, pricing data, personnel data, research data, or sales data (other than shipment data regarding sales).

Timeframe for Issuance of Form FDA 482c: Provide a timeframe for when the Division could issue Form FDA 482c, if approved. Include any concerns surrounding issuance (e.g. personal safety during issuance).

Program Division Director or designee Signature Block

Center Concurrence:

As an official delegated with the authority to make determinations under section 414(a) of the FD&C Act, I have determined there is a reasonable belief, based on the information noted above and facts presented to date, that [*an article of food*] [*manufactured, processed, packed, distributed, received, held, or imported*] by [*firm name*] is adulterated and presents a threat of serious adverse health consequences or death to humans or animals (SAHCODHA) or that there is a reasonable probability that use of or exposure to the food will cause SAHCODHA.

I concur with the recommendation to invoke records inspection authority under section 414 of the FD&C Act.

Delegated Official per [SMG 1410.306](#) Signature Block

Regulatory Procedures Manual

Chapter 11 – Glossary

ADDITIONAL SAMPLE: A physical sample collected from a previously sampled lot of either a domestic or imported product. Additional import samples must have the same sample number as the original sample. Additional domestic samples may have another sample number, but it must be flagged as an “ADD” Sample, with the original sample number referenced in the “Related Sample” block on the Collection Record.

ADJUDICATE (ADJUDICATION): To make a final judgment in a lawsuit, the judgment of the court.

AFFIDAVIT: For affidavits provided to FDA -A written statement from a person who has dealt with the goods sampled, knows material facts relating to the movement of the goods or to events affecting their condition, and/or or other fact relevant to the goods in question, which is obtained by an FDA employee. The affidavit is signed and sworn to (affirmed as true) by the affiant and then signed by the FDA employee. See IOM Chapter 4 and affidavit forms in that chapter.

For affidavits provided by FDA - A written statement signed in the presence of a notary public under a sworn oath that the statement is true. FDA considers such affidavits to be testimony covered by 21 CFR 20.1. See RPM Chapter 10, Requests for Testimony.

ALLEGATION: An assertion or statement, made in a pleading, setting forth what its maker intends to prove. A statement of the issues in a written document (a pleading) which a person is prepared to prove in court.

AMERICAN GOODS RETURNED: Goods produced in the United States (U.S.) which, after being exported, are subsequently returned to the U.S. Such goods are considered imports.

AMICUS CURIAE: Literally, “friend of the court.” A person who is not a party in a suit, but is allowed to file a brief to present their views on the matter before the court.

AMS: See Automated Manifest System.

ANSWER: A formal, written statement by the defendant in a lawsuit which answers each allegation contained in the complaint. In a seizure action, after filing a Claim of Ownership, the claimant files an Answer in which he may deny any or all of the allegations of the Complaint for Forfeiture.

APPEAL: The formal review by a higher court of a lower court's disposition of a lawsuit. Also, the review of an agency decision at a higher level within the agency or in a court.

BATF: See Bureau of Alcohol, Tobacco and Firearms.

BILL OF LADING B/L: The written order from a shipper to a carrier to move goods from one place to another. When available, this is the best source of shipping dates, origin, and name of shipper.

BIOLOGICAL PRODUCT: Means any virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product, or arsphenamine or its derivatives (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of diseases or injuries of man.

BIMO: Bioresearch Monitoring Program.

BONA FIDE: Literally, "in good faith." A bona fide document is a genuine one.

BOND: A written promise to pay a certain sum of money in the event agreed upon conditions are not met. For example, section 304(d) of the FD&C Act requires a bond as a condition of the release of condemned articles for salvaging.

BOND ACTION: Action taken by Customs resulting in forfeiture of all or a portion of an entry bond when an importer fails to redeliver merchandise covered by such a bond.

BOND VIOLATION: Failure to redeliver merchandise that is in import status when demanded by Customs. Such failure may result in bond action.

BONDED WAREHOUSE: A warehouse in the U.S. where imported merchandise is stored under Customs bond prior to withdrawal for consumption entry or export.

BREAK-BULK CARGO: Term used to describe cargo that is transported in individual units, i.e., sacks, boxes, bags, or cartons which are not containerized. Also refers to loose (unbound) items such as sugar.

BROKER (CUSTOMS BROKER): Private individual or firm licensed by Customs to represent importers concerning import matters. See Filer.

BROKER'S REFERENCE NUMBER: A number assigned by brokers to identify an entry of imported merchandise. This number is not to be confused with the entry number assigned through Customs.

BUREAU OF ALCOHOL, TOBACCO AND FIREARMS: The Homeland Security Act of 2002 divided the Bureau of Alcohol, Tobacco and Firearms into two new agencies, the Bureau of Alcohol, Tobacco, Firearms, and Explosives, which has moved to the Department of Justice, and the Alcohol and Tobacco Tax and Trade Bureau (TTB),

which remained in the Department of the Treasury. This division was effective January 24, 2003. The newly created TTB will, as ATF did before it, administer and enforce the existing Federal laws and tax code provisions related to the production and taxation of alcohol and tobacco products. A memorandum of understanding (MOU) between FDA and TTB (formerly BATF) clarifies and coordinates the responsibility of each agency with respect to the identification, testing, and recall of adulterated alcoholic beverages. Further, the MOU confirms TTB (formerly BATF) policy with respect to the labeling of ingredients and substances in alcoholic beverages that pose a public health problem.

BURDEN OF PROOF: The necessity or duty of proving a fact or facts in dispute on an issue.

CERTIORARI: "To be informed of". An extraordinary writ issued by a superior court (as the Supreme Court) to call up the records of a particular case from an inferior judicial body (as a Court of Appeals). When the Supreme Court grants certiorari, it has agreed to hear the case. If it denies certiorari, it will not hear the case

CARGO CONTROL: Placement of an entry in a bonded warehouse so that movement of the goods can be controlled and traced. Cargo control may occur in those situations where an importer does not hold shipments pending a suitable release from FDA and introduces the product into domestic distribution.

CBER: Center for Biologics Evaluation and Research.

CDER: Center for Drug Evaluation and Research.

CDRH: Center for Devices and Radiological Health.

CENTRALIZED EXAMINATION STATION (CES): A privately operated facility at which imported merchandise is made available to Customs officers for physical examination. A CES may be established in any port, or any portion of a port, or any other area, under the jurisdiction of a Customs district director.

CERTIFICATE FOR EXPORT: Firms exporting products from the U.S. are often asked by foreign customers or foreign governments to supply a certificate concerning the regulatory status of a product, or the system by which a commodity is manufactured. See Compliance Policy Guide 110.100, 7150.01.

CERTIFICATION: Agreement between the U.S. government and a foreign government specifying the conditions under which FDA may accept the foreign government's certification that the product complies with the Federal Food, Drug, and Cosmetic Act and/or other pertinent Acts.

Also, a written assurance, or official representation, that some act has or has not been done, or some event occurred, or there has been compliance with some legal formality. Typically, a requester will ask that FDA certify as to the authenticity of an FDA record as a true copy. FDA processes requests or subpoenas for certification under 21 CFR 20.3.

CFSAN: Center for Food Safety and Applied Nutrition.

CGMP: Current Good Manufacturing Practice.

CHARGE SHEET: The specification of the violation attached to a Section 305 Notice. It is the proposed statement of charges that, should prosecution ensue, would become the Government's allegation in the Criminal Information.

CHECK ANALYSIS: A second examination of a sample that has been examined and found violative. Check analyses are to be conducted by other than the analyst performing the original analysis.

CITATION: See Section 305 Meeting.

CITEE: One who is cited. See also Section 305 Meeting.

CIVIL MONEY PENALTIES: Monetary penalties that are assessed by FDA for violations of the Federal Food, Drug, and Cosmetic Act (the Act) or the Public Health Service Act (see FD&C Act Section 303(f)).

CIVIL SUIT (Federal Court): A lawsuit brought under the Federal Rules of Civil Procedure. For example, seizure, injunction, and civil contempt are actions initiated under civil rules.

CLAIM: A statement of interest in seized property, affirmed by sworn oath, entered by a person in response to a seizure action.

CMP: Civil Money Penalty (see FD&C Act Section 303(f)).

CODE OF FEDERAL REGULATIONS (CFR): An annual publication which contains regulations of Executive Departments and Agencies of the Federal government. The CFR is divided into 50 titles that represent broad areas subject to Federal regulation. Each title is divided into chapters that bear the name of the issuing agency. Each chapter is further subdivided into parts covering specific regulatory areas. FDA's regulations are in Title 21, Parts 1-1271. U.S. Customs regulations are found under Title 19.

COMMINGLED LOTS: Merchandise arriving off the same carrier with identical markings but covered under two or more entries. Two or more separate shipments of the same product, stored together and bearing no distinguishing marks which enable easy separation. There may be many codes in one shipment.

COMMISSION: A commission is a formal written document granting the power to perform various acts or duties

COMPLIANCE ACHIEVEMENT: The observed repair, modification, or adjustment of a violative condition, or the repair, modification, adjustment, relabeling, or destruction of a

violative product when either the product or condition does not comply with the Acts enforced by the agency.

COMPLIANCE POLICY GUIDES (CPG): Compliance Policy Guides explain the Food and Drug Administration (FDA) policy on regulatory issues related to FDA laws or regulations.

COMPLAINANT: Person registering a complaint, as a consumer complaining about an article. Also, the party who files the complaint in a legal action or proceeding (i.e., the plaintiff).

COMPLAINT FOR FORFEITURE: The document furnished to the United States Attorney for filing with the Clerk of Court to initiate the seizure of an article. (This document was formerly known as a Libel of Information.)

COMPLAINT SAMPLES (FLAGGED "COMPLAINT"): Samples collected from a consumer because of a complaint or injury.

CONFIDENTIALITY AGREEMENT: An agreement not to communicate certain knowledge to others.

CONSENT DECREE OF CONDEMNATION: The document entered by the court in a seizure action based on the claimant's agreement that the article seized is in violation as alleged in the Complaint for Forfeiture and the article is subject to condemnation. It is also a declaration of Claimant's intent to provide a Bond and to recondition the article under supervision of FDA and to pay costs.

CONSENT DECREE OF INJUNCTION: An injunction to which the defendant has agreed and which is filed in court.

CONSIGNEE: Person named in a bill of lading to whom or to whose order the bill promises delivery.

CONSUMER SAFETY INSPECTOR (CSI)/CONSUMER SAFETY OFFICER (CSO): FDA personnel performing inspections, investigations, sample collections, and examinations of imported articles.

CONSUMPTION ENTRY (CE): See Entry.

CONTAINER: Term used to describe a self-contained unit of various dimensions and configurations used for storage and transportation of goods.

CONTEMPT OF COURT: Any act which is calculated to embarrass, hinder, or obstruct a court in the administration of justice, or which is calculated to lessen its authority or its dignity. The willful disobedience of a judge's command or of an official court order is a contempt of court. Civil contempt consists of a failure to do something ordered by the court for the benefit or advantage of another party, and a fine is imposed. Criminal

contempt is an act done in disrespect of the court or its process or which obstructs the administration of justice, and a fine or imprisonment is imposed.

CONTEST: To dispute or challenge the case made by a plaintiff or prosecutor.

CORRECTION: "Correction" means repair, modification, adjustment, relabeling, destruction, or inspection (including patient monitoring) of a product or the promotional materials that cause the product to be violative, without its physical removal to some other location.

COUNT: A statement of a violation of the Act in a Criminal Information or Indictment.

COUNTERCLAIM: A claim presented by a defendant in opposition to the claim of the plaintiff, which claim could have been filed in a separate suit. If asserted in the same suit brought by plaintiff, it is called a counterclaim.

CONTRABAND: Against the law. Prohibited. Goods exported or imported into a country against its laws.

COUNTRY OF ORIGIN: The country of manufacture, production, or growth of any article of foreign origin entering the U.S. (see Customs regulation, 19 CFR Part 134). CPG: See Compliance Policy Guides.

CREDENTIALS: Testimonials, certificates, or diploma something that gives a title to credit or confidence that a person a right to exercise official powers.

CRIMINAL CASE (Federal Court): A criminal prosecution brought under the Federal Rules of Criminal Procedure, whereby the defendant may be punished for having violated the law, or a court order.

CTP: Center for Tobacco Products

CUSTOMS (U.S. CUSTOMS SERVICE): Previously, a Bureau of the Department of the Treasury, whose primary duties included the assessment and collection of duties, taxes, and fees on imported merchandise, and the enforcement of Customs and related laws. Effective March 1, 2003, the U.S. Customs Service moved to the Department of Homeland Security and is no longer a component of the Department of the Treasury. Now referred to as Customs and Border Protection (CBP), it is the primary enforcement agency protecting the nation's borders. It continues to be responsible for regulating and facilitating international trade, collecting import duties, and enforcing U.S. laws.

CUSTOMS ENTRY NUMBER (CEN): The number assigned to an entry document and used by Customs for future references to the entry. The CEN is an 11-character entry number in the format XXX-NNNNNNN-Y. XXX represents an entry filer code assigned by Customs, NNNNNNN is a unique number, which is assigned by the broker or importer, and Y is a check digit computed from the first 10 characters based on a formula provided by Customs. Also referred to as Entry Number.

CVM: Center for Veterinary Medicine.

DALs: See Defect Action Levels.

DATE AVAILABLE: The date supplied by the importer or his/her representative as to when the shipment is available for examination by the agency. Date of availability for examination or sampling will differ based upon the mode of transport of the shipment (i.e., seaports have large facilities for containers and it may be several days before the shipment is available for examination; however, shipments delivered by trucks at the borders are usually available for examination within several hours upon arrival).

DATE COLLECTED: The date a sample is collected.

DATE OF ARRIVAL: The date a carrier transporting imported cargo arrives in the U.S.

DEA: See Drug Enforcement Administration.

DEALER: The term is agency jargon to identify the party from whom a sample was collected; this does not have to be a business concern and often is a private party. Under the Radiation Act, this term is defined slightly differently, as found in 21CFR 1000.3(f).

DEALER STATEMENT (D/S): The written statement taken from the dealer at the time a sample is collected and in which the dealer asserts that the sample obtained was taken from a lot received by him from a certain source and that those documents showing the movement of the lot were furnished for copying.

DEALER VIOLATION: A violation of Section 301(k) of the FD&C Act indicating the doing of some act after shipment in interstate commerce which resulted in the article being adulterated or misbranded.

DECLARATION: A written statement signed under the penalty of perjury. A declaration can substitute for an affidavit in federal court proceedings. 28 U.S.C. 1746. FDA considers a declaration to be testimony covered by 21 CFR 20.1.

DEFAULT DECREE: A Default Decree of Condemnation is a Court Order entered when a seized article is not claimed or defended. The order condemns the article as being in violation of the law and provides for its destruction, donation to charity, sale, or disposal as the Court may elect to decree. When signed by the Court, it signifies the final adjudicatory step in a seizure action.

DEFECT ACTION LEVELS (DALs): Established for specific commodities or products for which filth or extraneous matter is unavoidable and for which a zero tolerance would not be realistic.

DEFENDANT: In civil or criminal cases, the party or parties named in an Information, Indictment, or Complaint, and against whom the Government is proceeding. The article against which a seizure action is brought is also referred to as the defendant.

DE MINIMIS: So minor as to be disregarded; Insignificant or unimportant.

DE MINIMIS NON CURAT LEX: The principle that the law does not concern itself with minor or insignificant matters.

DENATURE: The decharacterization of an article generally through the addition of some foreign substance in sufficient quantity so as to preclude its future use for its original purpose.

DEPTH OF RECALL: "Depth of recall" means the level in the distribution chain to which the recall is to extend. This will depend on the product's degree of hazard and the extent of distribution. Levels are as follows:

1. Consumer or User Level - which may vary with product, including any intermediate wholesale or retail level. Consumer or user may include the individual consumers patients, physicians, restaurants and hospitals.
2. Retail Level - recall to the level immediately preceding the consumer or user level. It includes retail groceries, pharmacies, hospital pharmacies, dispensing physicians, institutions such as clinics and nursing homes, and any intermediate levels.
3. Wholesale level - all distribution levels between the manufacturer and the retailer. This level may not been encountered in every recall situation, i.e., the manufacturer may sell directly to the retailer.

NOTE: In some cases, the user level and the retail level may appear to refer to the same group. Certain devices, radiological products, biologics, drugs are supplied directly to physicians or hospital type environments who will, in turn, use the product in the prescribed manner on/for the consumer. This kind of special environment will be considered as the "user level."

DEPOSITION: The taking and recording of testimony of a witness under oath, in front of a court reporter prior to trial and away from the courtroom. FDA considers an employee's responses in a deposition to be testimony covered by 21 CFR 20.1. Testimony of a witness or a party taken under oath outside the courtroom, the transcript of which may become part of the court's file.

DETENTION (Imports): Administrative act where FDA requires that imported articles that appear violative under the laws FDA administers be held intact. Detained articles are released if brought into compliance with or rendered not subject to the FD&C Act (the Act), or are refused entry if not brought into compliance. (Other types of detention – section 304(g) of the Act-Administrative detention of devices; section 304(h) of the Act-Administrative detention of food.)

DEVANNING: The removal of all articles from a container for examination or sampling purposes. Also known as stripping of containers.

DIRECT ACCOUNTS: "Direct accounts" are those consignees, either domestic or foreign, who received shipments of the recalled products directly from the recalling firm or indirectly from the recalling firm's product source via drop shipment.

DISCHARGING: The unloading of imported merchandise from a carrier.

DISCOVERY: The process of obtaining information concerning the other party's case. Methods of discovery are contained in Rule 16 of the Federal Rules of Criminal Procedure, and Rules 26 through 37 of the Federal Rules of Civil Procedure.

DISMISSAL: An order or judgment that disposes of an action, suit, or motion without a trial on the issues. A legal action may be dismissed by the court for failure to introduce evidence of facts on which relief may be granted.

DIVERSION: A method used to divert products from their intended market. For example, a drug manufacturer ships a drug labeled in Spanish to an authorized distributor in Costa Rica, but the product is diverted by the distributor into the U.S. market.

DOCKET, CIVIL: A book kept by the clerk of court, in which each civil action is entered and assigned a consecutive file number. All papers filed with the clerk, all process issued and returns made thereon, all appearances, orders, verdicts, and judgments are entered chronologically in the civil docket on the folio assigned to the action and marked with its file number.

DOCKS (PIERS): Unloading facilities for vessels.

DOCUMENTARY (DOC) SAMPLE: An official sample where no actual physical product is taken. A DOC sample is collected based upon the documents accompanying the entry such as freight bills, and bills of lading, or any other record or document related to the lot or item involved. DOC samples are collected in situations where an actual physical sample is not practical or where there is little or no need for laboratory analysis. In addition to copies of transportation records, this official sample may consist of labels, photos of the product, drawings, and sketches.

DOCUMENTATION: The collection of documents to support a certain element of proof, i.e., the copying of a Bill of Lading to demonstrate that interstate commerce has been accomplished.

DOMESTIC IMPORT (DI) SAMPLE: A sample of an imported article collected after release from import status (See IOM Chapter 4).

DRUG ENFORCEMENT ADMINISTRATION (DEA): A component of the Department of Justice responsible for enforcing the controlled substances laws and regulations.

EDIFACT: See Electronic Data Interchange for Administration, Commerce, and Transportation.

EEPS: See Electronic Entry Processing System.

EFFECTIVENESS CHECKS: "Effectiveness Checks" are actions taken to verify that all consignees at the recall depth specified by the strategy have received notification about the recall and have taken appropriate action. The method for contacting consignees may be accomplished by personal visits, telephone calls, letters, or a combination of both. These checks are to be conducted by the recalling firm as part of its recall strategy. In the determination of which consignees should be contacted by the firm for effectiveness checks, FDA may consider as acceptable for a portion of the verification of recall effectiveness:

1. The firm's receipt and retention of response cards, e-mails, or letters from consignees in accordance with instructions issued in the recall notification.
2. Signed records or reports of actions accomplished by the firm's own representatives or signed records or reports from direct or sub-accounts.

EFFECTIVENESS CHECK LEVEL: The "Effectiveness Check Level" is an alphabetical term representing the extent to which effectiveness checks will be made within the distribution chain, including consumers or patients where appropriate.

1. Level A--100 percent of the total number of consignees to be contacted (at the specified recall depth).
2. Level B--Some percentage of the total number of consignees to be contacted, which percentage is to be determined on a case-by-case basis, but is greater than 10 percent and less than 100 percent of the total number of consignees to be contacted (at the specified recall depth).
3. Level C--10 percent of the total number of consignees to be contacted (at the specified recall depth).
4. Level D--2 percent of the total number of consignees to be contacted (at the specified recall depth).
5. Level E--No checks.

ELECTRONIC DATA INTERCHANGE FOR ADMINISTRATION, COMMERCE, AND TRANSPORTATION (EDIFACT): A United Nations sponsored initiative to develop international electronic messages including electronic invoices.

ELECTRONIC ENTRY PROCESSING SYSTEM (EEPS): The link to ACS, screening portion of OASIS, and initial user interface.

ENJOIN: To require a person, through a court-ordered injunction, to perform, or to abstain or desist from performing a specified act or course of conduct. See injunction.

ENTRY: Delivery or offer for delivery of merchandise into the Customs Territory of the U.S. from an outside point.

- A. **Consumption entry (CE):** The entry documentation submitted to Customs by the importer when imported merchandise is offered for consumption.

- B. **Formal entry:** As defined by Customs regulations, an entry required to be covered by an entry bond. Currently, most entries with aggregate values of \$2,500 or more (value subject to change).
- C. **Informal entry:** As defined by Customs regulations, an entry whose value is currently less than \$2,500 (value subject to change) and therefore usually not imported under bond. U.S. goods returned (USGR) valued at \$10,000 or less are also considered informal entries. Informal entries may be converted to formal entries, pursuant to Customs regulations.
- D. **Intransit Entry (IT):** An entry document filed with Customs by the importer. It allows the merchandise to move from the port of unloading to its destination under Customs bond without the initial payment of entry fees and allows the importer 30 days to file a consumption entry. FDA usually inspects the merchandise at the destination point (port of entry).
- E. **Mail Entry:** Merchandise offered for entry through the mail. Where the value of the merchandise is less than \$2,500 (the current threshold between formal and informal entries), an entry document is generally not required to be filed with Customs. For mail entries, Customs prepares the appropriate paperwork for the entry, which is typically forwarded to the addressee by the Postal Service, who then collects the duty for Customs.
- F. **Personal Baggage Entry:** Entry of merchandise by personal baggage.
- G. **Transportation and Exportation (T&E):** An entry document (CF-7512) filed with Customs which permits merchandise to be transported through the U.S. and exported intact, without payments associated with entry, to a foreign destination. This does *not* exempt the articles from complying with the FD&C Act. See CPG Manual Section 110.700 (7153.08).
- H. **Warehouse Entry:** An entry document filed by the importer with Customs for storage of goods in a bonded warehouse without the initial payment of entry fees. (Normally, it is filed prior to manipulation or withdrawal for export).

ENTRY BOND: A bond posted by the Importer of Record with Customs, currently in the amount of three times the value of the imported product, to insure redelivery of the product for examination, reconditioning, export, or destruction.

ENTRY DOCUMENT (ENTRY PACKAGE): Documents describing the articles offered for entry which may contain a consumption entry form, commercial invoice, manifest, or other FDA notification.

ENTRY NUMBER: See Customs Entry Number.

ENVIRONMENTAL PROTECTION AGENCY (EPA): The federal government agency responsible for protecting human health and the environment. EPA enforces FIFRA (Federal Insecticide, Fungicide, and Rodenticide Act) and registers pesticides for use in the U.S. on food crops, among other duties.

ESTABLISHMENT: A place of business or residence, including all accoutrements essential to such business or resident.

- A. **Grower:** Raises livestock, raw agricultural products, or aquaculture products for sale (farms, feedlots, dairy farms, and botanicals).
- B. **Manufacturer:** Firm or individual responsible for making a product.
- C. **Packer/repacker:** Packs a product or products into different containers without making any change in the form of the product. Includes packers of raw agricultural products and medical gas repackers.
- D. **Salvage Operation:** An establishment dealing primarily in the reconditioning and resale of damaged goods.
- E. **Shipper:** Firm or individual responsible for introducing merchandise into interstate commerce by way of transport and that does not act as a manufacturer, repacker, distributor.
- F. **Warehouse:** A private or public facility for the storage of consumer products, including products reshipped from the producer or grower to the manufacturer or other customer.

EX PARTE: On one side only. These are cases in which only one side is represented or present. On behalf of only one party, without notice to any other party. For example, a request for a search warrant is an ex parte proceeding, since the person subject to the search is not notified of the proceeding and is not present at the hearing.

EXPORT: The shipment of articles from the U.S. to a foreign country. Articles that comply with the FD&C Act may be exported freely. Section 801(e)(1) contains the requirements for the export of articles that, but for intended export, would be adulterated or misbranded. Section 801(e)(2) provides additional requirements applicable to the export of unapproved medical devices; and Section 801(f)(2) addresses the export of approved drugs for unapproved uses. Section 802 provides provisions for the export of unapproved drugs, biologics, and devices. Also see Re-Export.

EXECUTION OF DECREE: The carrying out of the court's order. For example, the destruction of seized goods by the Marshal, in response to a Default Decree of Condemnation.

FACTORY FOOD SAMPLES: A sample, usually investigational in nature, obtained from an establishment where food is manufactured, processed, or packed, used to show conditions in the establishment. Such samples include in-line samples and require analysis to determine the specific conditions.

FDA ORDERED RECALL: "FDA ordered recall," means a recall initiated by a firm in response to an order for such action. Examples would be: device recalls ordered under section 518(e), Infant Formula recalls ordered under section 412(e)(1) of the act, and human tissue for transplantation ordered under 21 CFR Part 1270.

FDA RECALL AUDIT CHECK PROGRAM: The purpose of FDA audit checks is to determine the adequacy of the firm's performance in assuring that all consignees have received notification of the recall and are taking appropriate action. A FDA audit check program should be determined after evaluating the recalling firm's strategy. The audit

check levels will either be based upon the effectiveness check levels provided in 21 CFR or on other statistically valid plans. The method for conducting audit checks may be personal visits, telephone calls, or a combination thereof. Cooperating federal, state, or local officials may assist FDA in the performance of the audit checks.

FDA REQUESTED RECALL: "FDA requested recall" means a recall initiated by a firm in response to a formal request for such action by the Associate Commissioner for Regulatory Affairs, or the appropriate center director when the authority has been delegated.

FD&C Act/FDCA: The Federal Food, Drug, and Cosmetic Act.

F.D.C. OR INJ NUMBER: The F.D.C. or INJ number is the identification used by the General Counsel's Office to designate FDA cases. On all correspondence pertaining to seizure and prosecution cases, show the F.D.C. number directly under the sample number identification. On injunction cases, show the INJ number the same way.

FEDERAL IMPORT MILK ACT: An Act to regulate the importation of fluid milk and cream into the U.S. for the purpose of protecting the public health (see 21 CFR 1210).

FEDERAL TRADE COMMISSION (FTC): An independent government agency whose goal is to prevent free enterprise from being hampered by monopoly or restraints on trade or corrupted by unfair or deceptive trade practices.

FIARS: FIARS (FDA's Import Alert Retrieval System) is a computerized retrieval system for import alerts. Users navigate FIARS by searching for the import alert number, or by the problem, product, or country keyword, or by utilizing a full text search for a keyword or any other word that may be contained in the system. FDA updates FIARS nightly and the data

is accessible to FDA users via the intranet. A redacted version of the data is also available to the public via the internet.

FILER: A Customs term used to identify the individual or firm responsible for filing an entry, which is usually the broker but may be the importer.

FILTH EXHIBITS: Any material obtained to illustrate a condition. An exhibit is for court use, and is self-explanatory in nature. Usually no confirmatory analysis by the laboratory is required. Exhibits include photographs, rat and rodent pellets and mice nests.

FINAL ORDER: The last order issued by the Court in a lawsuit, which terminates the action.

FIRM INITIATED RECALL: "Firm initiated recall," means a recall that is initiated by a firm on its own volition without a formal request from FDA.

FOOD STANDARDS SAMPLES (PREFIX "F.S."): Samples collected as a direct result of an assignment in connection with food standards development.

FOR CAUSE INSPECTION: An inspection that is carried out in response to specific information that raises questions, concerns, or problems associated with an FDA regulated firm or commodity. This information could come to the attention of FDA from any source, and includes, but is not limited to, the following: the results of a sample analysis, observations made during prior inspections, recall or market withdrawal, consumer or employee complaint, adverse reaction report, or suspicion of fraud.

FOREIGN MAIL DIVISION: A designated location within a post office facility for examination of foreign mail by Customs.

FOREIGN TRADE ZONES: Areas set aside in the U.S. that allow a person to hold or otherwise manipulate goods for an unlimited period of time awaiting a favorable market in the U.S. or nearby countries without being subject to Customs duties, tax, or other charges. See CPG Manual Section 110.200 (7150.11) and Section 110.600 (7150.14).

FORFEITURE OF BOND: Literally, the loss of a bond, as a result of a failure to perform the conditions agreed upon when the bond was made.

FORMAL ENTRY: See Entry.

FP&F (FINES, PENALTIES AND FORFEITURES): Both a module of Customs ACS and a division within Customs which deals with post-entry procedures, i.e., bond actions, liquidated damages, and seizures.

FPLA (THE FAIR PACKAGING AND LABELING ACT): Applies only to retail containers of foods, drugs, cosmetics, and devices.

FREIGHT BILL (F/B): The document stating the transportation charges incurred by the carrier (a bill for the freight charges on a shipment). Next to a B/L, the freight bill is the most authentic document that supports movement of a shipment in interstate commerce.

GAO (GOVERNMENT ACCOUNTABILITY OFFICE): Was previously named the General Accounting Office. GAO, which is independent and nonpartisan, is commonly called the investigative arm of Congress. It studies how the federal government spends taxpayer dollars. GAO evaluates federal programs, audits federal expenditures, and issues legal opinions.

GRAND JURY: A jury of inquiry composed of 16-23 citizens whose duty it is to determine whether probable cause exists that a crime has been committed and whether an indictment (true bill) should be returned for such a crime. If the grand jury determines that probable cause does not exist, it returns a "no bill." The grand jury is an accusatory body; it does not determine guilt.

GREY MARKET: Generally used to describe diversion of regulated commodities purchased from foreign suppliers and introduced into the U.S. through a source other than the authorized U.S. dealer. It is also used to describe situations where a product manufactured by a foreign subsidiary of a U.S. firm is not identical to the U.S. manufactured product yet the product is shipped to the U.S. for marketing. The products may be imported by a third party from a dealer in a country other than the country of origin.

GROWER: See Establishment.

GUARANTY: A formal and signed agreement between buyers and sellers in which the latter verifies the goods he sells are not in violation of the FD&C Act when shipped. A guaranty that meets the conditions in section 303(c)(2) of the Act protects a good faith purchaser from criminal prosecution based on violations of sections 301(a) or 301(d).

HARMONIZED TARIFF SCHEDULE (HTS): Ten-digit international tariff codes that replaced TSUSA codes on January 1, 1989. This system identifies products for classification purposes. Once the classification is determined, the rates of duty, value-added tax, quota limits, and visa requirements can be obtained.

HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP): A prevention-based food safety system by which food processors and importers evaluate the kinds of hazards that are reasonably likely to occur and could adversely affect the safety of their products, institute controls necessary to keep these hazards from occurring or reduce the hazard to an acceptable level, monitor the performance of these controls, and maintain records of this monitoring as a matter of routine practice.

HEALTH FRAUD: The promotion, advertisement, distribution, or sale of products, that are represented as being effective to diagnose, prevent, cure, treat, or mitigate disease or other conditions, or to provide a beneficial effect on health, but which have not been proven safe and effective. Such practices may be intended to defraud or mislead.

HEALTH HAZARD EVALUATION: A "health hazard evaluation" is an evaluation by FDA scientists of the threat to health presented by a product, including its labeling and/or promotional materials, that is being recalled or considered for recall. It takes into account, but is not limited to, the following:

1. Deaths, diseases, injuries or other adverse reactions that have already occurred from the use of the product.
2. Existing conditions that could contribute to a clinical situation that could expose humans or animals to a health hazard.
3. Assessment of population who may be at greatest risk (age, physical condition.)
4. Assessment of degree of seriousness of the health hazard to the population at greatest risk.
5. Assessment of the likelihood of the occurrence of the health hazard.
6. Assessment of long range or immediate consequences of the hazard. See 21 CFR 7.41(a) for a full description of these factors.

HEARING: The opportunity for a party to present views. In imports, the importer may explain why his goods should not be refused entry and returned to the shipper. Many types of administrative hearings are provided for in various sections of the CFR.

HEARING RESPONDENT: Individuals who respond to the "Notice of Detention and Hearing."

HOLD OF SHIP: Portion of a vessel where cargo is stored for transportation.

HOME DIVISION: The Division in whose program the alleged violation of the Act occurs, or in whose program the firm or individual responsible for the alleged violation is included. The original point from which the article was shipped, or offered for shipment - as shown by the interstate records - is usually considered the point where the violation occurred; and the shipper of such article, as shown by such records, is usually considered to be the alleged violator.

For actions based on goods which became violative after interstate shipment was made, or after reaching their destination (such as 301(b) and 301(k) violations), the dealer in whose possession the goods are sampled is usually considered the violator and the location of this dealer determines the "Home Division."

If both the shipper and the dealer are legally responsible for the violation, and are located in different Divisions, the records and correspondence shall be processed, routed, and distributed in accordance with the needs of each Division.

IMMEDIATE DELIVERY (ID): An entry document (CF-3461) filed with Customs by the importer. An ID allows the importer to take immediate possession of the goods and allows him/her 10 days to file the Consumption Entry (CE) documentation.

IMMEDIATE DELIVERY (ID) ADVANCE NOTICE: The filing of an ID by the importer prior to the arrival of the goods at the point of entry.

IMMEDIATE EXPORT (IE) NOTICE: A document that is filed with U.S. Customs by a broker on behalf of the importer for refused merchandise prior to exportation.

IMPORTS: Products brought into the U.S. from foreign countries. Such products include American manufactured goods that are being returned to the United States. Once such products are entered (admitted by FDA and the bond is liquidated by Customs) into the United States, they are no longer considered to be in import status. Under certain limited conditions, released articles may be reverted back to import status.

IMPORT ALERTS: Information to the FDA Division offices concerning unusual or new problems affecting imports which gives background and compliance guidance information for each product and problem.

IMPORT BULLETINS: Informational bulletins that generally provide only information on a problem affecting imported products.

IMPORTER OF RECORD: The individual responsible for assuring that imported goods are in compliance with all laws affecting the importation. While the importer may authorize others to carry out certain tasks such as filing, the importer of record holds the bond and is ultimately responsible for the entry.

IMPORT RECORD DOCUMENT EXAMINATION: The examination of import records to determine if goods should be sampled and examined.

IMPORT REGULATIONS: Regulations written under the authority of specific acts administered by FDA for the regulation of imported articles: (1) foods, drugs, cosmetics, and medical devices - see 21 CFR Sections 1.83 - 1.99; (2) electronic products - see 21 CFR Part 1005; (3) Imported milk - see 21 CFR Part 1210; (4) banked human tissue for transplantation - see 21 CFR Part 1270, among others.

IMPORT SAMPLE COLLECTION: The collection of samples of articles still in import status. Sample collections may be either an actual physical collection of the product with a subsequent analysis or examination, or a documentary sample where the sample evaluation is based upon the documents accompanying the import.

IMPORT SAMPLES: Samples of commodities collected from shipments made by foreign firms into the U.S. Samples are collected by an FDA Investigator or by Customs officials for FDA.

IMPORT SECTION (801): The current section of the Federal Food, Drug, and Cosmetic Act (Chapter VIII) containing Import/Export Provisions (see 21 USC 381).

IMPORT STATUS: The status of an imported article prior to FDA admission and Customs entry. Liquidation should not occur until FDA has released the shipment for domestic distribution.

IMPORT SUPPORT AND INFORMATION SYSTEM (ISIS): The primary user interface, operational support, and reporting portion of OASIS.

IMPORTING VESSEL: Vessel used to transport articles offered for entry into the U.S.

INDICTMENT: The formal statement of the charges against an individual or entity presented by a grand jury.

The United States Attorney (with witnesses deemed necessary) appears before a grand jury and presents evidence. If at least 12 jurors concur that an offense has been committed, the grand jury returns an indictment (referred to as a "true bill") to the court and the matter is then entered on the court docket.

INFORMAL ENTRY: See entry.

INFORMATION: The formal statement of the charges against an individual for some criminal offense, issued by the U.S. Attorney, and not by a grand jury. It may always be used in misdemeanor prosecutions, and may be used in felony prosecutions only if the defendant waives his right to be indicted.

INJUNCTION: An order issued by the Court requiring a defendant to perform an act which he is obligated to perform but refuses to do, or forbidding him from doing a specified act which he is threatening or attempting to do.

IN PERSONAM: Against the person.

IN REM: Against the thing.

INTERROGATORIES: Written questions sent by one party in a lawsuit to the other party during the discovery process prior to trial. Interrogatories must be answered in writing under oath or under penalty of perjury. FDA considers the employee's response to interrogatories to be testimony covered by 21 CFR 20.1.

INTERSTATE (IS) COMMERCE: Commerce between one state or territory and anyplace outside thereof, or commerce within the District of Columbia or within any other territory. Section 201(b) of the Act.

INTRAGENCY AGREEMENTS (IAGs): Agreements between different parts of the same agency.

INTRANSIT ENTRY (IT) ADVANCE NOTICE: The filing of an IT by the importer prior to the arrival of the merchandise at the port of entry.

INTRANSIT SAMPLES (FLAGGED "IN-TRANSIT"): Samples collected from a lot after delivery for introduction in Interstate Commerce or while on the way to a consignee. Such samples may be on a manufacturer's shipping dock, in a conveyance, or in a terminal.

INTRASTATE: Within a state.

INVESTIGATIONAL SAMPLES (PREFIX "INV."): Samples collected for purposes of general information when regular sample number identification is necessary. Interstate documentation is not required at the time of collection. Should interstate documentation be possible and it is obtained at a later date (for example, after analysis shows the product is violative) such samples would then be converted to "official" samples.

INVOICE (Imports): A document that accompanies imported merchandise and contains at least the following information: (a) port of entry or merchandise destination; (b) local consignee, foreign shipper; (c) description of merchandise including any marks; (d) quantity, (e) purchase price, (f) country of origin of the merchandise.

ISIS: See Import Support and Information System.

JUDICIAL DISTRICT: Physical parameters, set by Congress, designating the counties under the jurisdiction of a United States District Court.

LABEL and LABELING: These words are defined in the FD&C Act in Sections 201(k) and 201(m).

LACF (LOW ACID CANNED FOOD): Any thermally processed foods in hermetically sealed containers, other than alcoholic beverages, with a finished equilibrium pH greater than 4.6 and a water activity (aw) greater than 0.85. Tomatoes and tomato products having a finished equilibrium pH less than 4.7 are not classed as low-acid foods. All manufacturers of low acid canned foods and acidified low acid canned foods must be registered with FDA and have a food canning establishment (FCE) number and the manufacturing process specific for the product and can size on file with FDA. See 21 CFR 108, 113, and 114.

LD-3: Airline containers used to transport imported articles.

LEGAL STATUS: The legal organization or constitution of a business enterprise; for example, as a corporation, partnership, cooperative, or sole-ownership.

LIB: Laboratory Information Bulletin

LICENSE: Means authorization issued by CBER, which is required by the PHS Act for individuals or companies who introduce or deliver for introduction into interstate commerce any biological product. Biologics license applications for human use are approved on the basis of a demonstration that the biological product is safe, pure, and potent; and that the facility in which the biological product is manufactured, processed, packed, or held meets

the standards designed to assure that the biological product continues to be safe, pure, and potent. Biological products intended for veterinary use are regulated separately.

LINE ITEM: Each portion of an entry that is listed as a separate item on an entry document. An importer may identify merchandise in an entry in multiple portions; however, an item in the entry having a different tariff description must be listed separately.

LINE RELEASE: Customs - An automated bar code system of identifying and processing "repetitive and low-risk" entries that involve a combination of the same importer, filer (broker), product, or manufacturer.

LIQUIDATED DAMAGES: A monetary claim against a person, company and surety for violations of a Customs bond.

LIQUIDATING AN ENTRY: Customs liquidates an entry when duty has been paid and the product has been determined to be admissible into the U.S.

LITIGATION: The act or process of carrying on a lawsuit.

LOT: An amount of a product produced during a period of time indicated by a specific code, or some other unique identifying characteristic. Also, an import entry, group of entries, or a portion of an entry of merchandise that can be clearly defined as appropriate for FDA sampling and examination purposes.

MAGISTRATE (U.S. Magistrates): A judicial officer of federal district courts who has some but not all of the powers of a federal district judge. They may conduct many of the preliminary or pre-trial proceedings in both civil and criminal cases; and perform certain other duties of the court, such as issuing inspection warrants.

MAIL ENTRY: See Entry.

MANDAMUS: A command that a superior court issues to a lower court or a person (including a government agency) ordering it to do its duty.

MANIFEST: An itemized listing of a vessel's cargo, with other particulars, for the facility of the customs officers. A document issued by the carrier describing the contents of merchandise being transported.

MANUFACTURER: See Establishment.

MARKET WITHDRAWAL: "Market withdrawal" means a firm's removal or correction of a distributed product which involves a minor violation for which FDA would not initiate legal action, or which involves no violation. These include normal stock rotation practices, routine equipment adjustments and repairs, and product improvement. Replacement of device components which fail or wear out after a reasonable life span will be considered a market withdrawal unless a violation of the FD&C Act has occurred and can be supported. Recovery of investigational products are normally considered a market withdrawal unless the product has been sold in domestic commercial distribution or a significant health hazard is involved necessitating classification and publication of the action as a recall.

The removal of products from the market as a result of actual or alleged tampering with individual units, and where there is no evidence of manufacturing or distribution problems will be considered a market withdrawal.

MARKS: Words or symbols, usually including the country of origin, marked on cartons, bags, and other containers of imported merchandise for identification purposes. See Customs requirements in 19 CFR Part 134.

MEDICAL DEVICE SAFETY ALERT: A medical device Safety Alert is a notification to device users that, under certain circumstances, use of or exposure ¹ to the device may pose a risk of harm.

¹ The exposure mentioned in this definition excludes electronic product radiation exposure. See 21 CFR Subchapter J.

MEMORANDUM OF UNDERSTANDING (MOU): This is a formal agreement between the Food and Drug Administration and another Government Agency (Federal, State, local) or an **informal** agreement with foreign governments or other foreign institutions. See Staff Manual Guides (SMG) 2820.1 and 2830.1. The agreement does not involve a transfer of personnel, or a transfer of funds or real property (Agreements calling for transfer of personnel, funds, or real property are considered Interagency Agreements, see SMG 2810.1).

MIS: Management information system.

MODUS OPERANDI: Manner of operating.

MOTION: A written or oral application to a court or judge, which requests a ruling or order in favor of the applicant.

MUTUAL RECOGNITION AGREEMENT (MRA): A type of memorandum of understanding that provides for the mutual assessment of the comparability of specific FDA programs or activities with those of a foreign regulatory authority. An MRA is suitable as an equivalence agreement when it can be determined that FDA's controls and the foreign regulatory authority's controls are comparable and are designed to provide the same level of protection. With respect to MRAs for good manufacturing practices (GMPs), this term means that the agency has determined that another country's regulatory system for GMPs (i.e., regulations, inspection procedures and enforcement) provides at least the same level of consumer protection as FDA's system.

NAI: No action indicated.

NCBFAA: National Customs Brokers & Forwarders Association of America, Inc.

NO-TOBACCO-SALE ORDER: An agency order that temporarily or permanently prohibits an individual retail outlet from selling tobacco products. All permanent orders shall include provisions that allow the outlet, after a specified period of time, to request that the agency compromise, modify, or terminate the order (see FD&C Act Section 303(f)).

NOTARY PUBLIC: A person authorized by the state in which they reside to administer an oath of truth to a person making an affidavit, and to apply their signature and seal or stamp to attest to the oath.

OASIS: Operational and Administrative System for Import Support.

ODNR: See Originally Detained Now Released.

OFFICIAL COMPENDIA: See FD&C Act Section 201(g)(1)(A).

OFFICIAL SAMPLES: A sample taken from a lot for which Federal jurisdiction can be established. If violative, the official sample provides a basis for administrative or legal action. Official samples generally, but not always, consist of a physical portion of the lot

sampled. See 21 CFR 2.10 for requirements regarding official samples of food, drugs, or cosmetics collected for analysis.

ORA: Office of Regulatory Affairs.

ORDER: A formal written statement from a Court, requiring action or simply stating a ruling.

ORIGINALLY DETAINED NOW RELEASED (ODNR): Notice to importer that detained merchandise has been satisfactorily shown to be in compliance with the law and is now released.

PACKER/REPACKER: See Establishment. **PACKING LIST:** Inventory of contents.

PDMA: Prescription Drug Marketing Act.

PENALTY: Damages assessed against an importer or broker, usually connected with failure to redeliver merchandise.

PENALTY CASE: See Bond Action.

PERMANENT INJUNCTION: A Decree of Permanent Injunction may be entered at any time after the complaint is filed, either following a hearing or as a result of a negotiated settlement. Defendants in an injunction proceeding may consent to a Decree of Permanent Injunction just as they consent to a Consent Decree of Condemnation in a seizure action.

Should the defendant not consent to such a decree, a trial is held in which, to prevail, the government must prove each element of its case by a preponderance of the evidence. As its name implies, a Decree of Permanent Injunction remains in effect until it is dissolved by an order of the court.

A Decree of Permanent Injunction perpetually restrains the defendants from engaging in specified violative practices and remains in force until termination.

PERSONAL BAGGAGE ENTRY: See Entry.

PLAINTIFF: The party who institutes the lawsuit; the opposite of the defendant. The government is the plaintiff in all the actions it initiates. When the Government is sued, the suing party is the plaintiff in the action.

PLANT PROTECTION AND QUARANTINE (PPQ): A division within USDA's Animal and Plant Health Inspection Service (APHIS) that prohibits or restricts the entry of foreign pests and plants, plant products, animal products and byproducts, and other materials that may harbor pests or disease. Other responsibilities include the inspection and certification of domestic commodities for export, regulation of the import and export of endangered plant species, and ensuring that imported seed is free of noxious weeds.

PLEADINGS: The papers filed in court to initiate and defend a suit, such as the Complaint, and Answer, setting forth the allegations and defense in the case. The written statements of fact and law filed by the parties to a lawsuit.

PORT (POINT) OF ENTRY: The Customs locations where the consumption entry is made. This may or may not be at the Port of Unloading.

PORT OF LOADING: The location where the final Bill of Lading is issued prior to shipment to the U.S. This may or may not be the country of origin.

PORT (POINT) OF UNLOADING OR DISCHARGING: The location where the merchandise is unloaded from the carrier. This may or may not be at the Port of Entry.

POST-SEIZURE SAMPLES (PREFIX "P.S."): A representative sample collected under court order from goods under seizure.

PPQ: See Plant Protection and Quarantine.

PRELIMINARY INJUNCTION: Court order requiring action or forbidding action until a decision can be made whether to issue a permanent injunction. Whether or not a Temporary Restraining Order (TRO) has been obtained, a Motion for Preliminary Injunction is subject to a full hearing in which (1) evidence by affidavit, and/or (2) testimony of witnesses is presented, depending on the practice of the court. Once the motion is granted, or the defendants consent to the entry of a decree, the preliminary injunction is in effect.

A preliminary injunction may stand indefinitely on the court record until the case is settled or a permanent injunction has been entered, after trial. A preliminary injunction may be dismissed, or the court, at the request of either party, may set a trial for permanent injunction at any time.

PREPONDERANCE OF EVIDENCE: The common standard of proof in civil cases. To prevail, the party bearing the burden of proof must present evidence which is more convincing than that presented by the opposing party; and which as a whole shows that the fact to be proven is more probable than not.

PRE-SENTENCE INVESTIGATION: Many courts request an investigation of convicted parties prior to the imposition of sentence. These investigations are conducted by the U.S. Probation Officer, and are governed by Rule 32(c) of the Federal Rules of Criminal Procedure.

PRE-TRIAL CONFERENCE: A meeting between the Court and the attorneys for the parties in preparation for trial. One use of a pre-trial conference is to consider ways to limit the issues for trial through admissions or agreements of counsel.

PRIMA FACIE EVIDENCE: Evidence sufficient to establish the allegations in the Complaint unless refuted by some evidence to the contrary.

PRIOR NOTICE: The FDA policy of notifying an individual or firm of a violation of the Federal FD&C Act, or other acts, when voluntary correction is an appropriate initial response to the violation. This policy is also commonly referred to as "Prior Warning."

PRIVATE LABORATORIES: Independent laboratories providing analytical services to importers, customhouse brokers, and others.

PRODUCT PROBLEM AREAS (PPAS): Also known as import targeting. This term is used to describe a program where FDA targets (samples and analyzes) specific imported products over a specific period. It can also include investigating certain import-related practices over a specified period of time.

PRO FORMA: As a matter of form. Provided or made in advance to describe items or projections. Example: a *pro forma* invoice.

PRO FORMA INVOICE: Importer's statement of value or the price paid in the form of an invoice.

PROCEDURE IN ADMIRALTY: Seizure actions taken pursuant to the FD&C Act are (per Section 304(b)) to be in conformity with the procedure in admiralty, which means the Government may initiate confiscation of articles it deems to be contraband without having to first show proof of the allegation or responsibility for the violation.

PROMULGATE: To publish; to announce officially, e.g., to promulgate new regulations pursuant to the FD&C Act.

PROSECUTION: The institution of a criminal proceeding against a person.

QUICK COLOR TEST (QCT): A field screening technique used by FDA personnel to detect lead in ceramicware.

RARE DISEASE OR CONDITION: A rare disease or condition is one that affects less than 200,000 persons in the United States or that affects more than 200,000 persons in the United States, but the drug sponsor has no reasonable expectation of recovering development costs through U.S. sales. (Section 526 of the Act.)

RCHSA: Radiation Control for Health and Safety Act covers radiation emitting electronic products and devices. These include x-ray machines, TVs, compact disc players, microwave ovens, and tanning beds. See Sections 531- 542 of the Act.

REBUTTAL: An answer or response to a statement. To refute, oppose, or contradict that which has been stated. Evidence disproving other evidence previously given or reestablishing the credibility of challenged evidence.

RECALL: A "recall" is a firm's removal or correction of marketed products, including its labeling and/or promotional materials, that FDA considers to be in violation of the laws it administers. The agency would initiate legal action for example, seizure or other

administrative or civil actions available to the agency if the product was not recalled. Recall does not include market withdrawal or a stock recovery.

RECALL CLASSIFICATION: "Recall classification" is a numerical designation, I, II, or III, that is assigned by FDA to a particular product recall that indicates the relative degree of health hazard.

1. Class I is a situation in which there is a reasonable probability (strong likelihood) that the use of, or exposure to, a violative product will cause serious adverse health consequences or death.
2. Class II is a situation in which the use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.
3. Class III is a situation in which the use of, or exposure to, a violative product is not likely to cause adverse health consequences.

RECALL COMPLETED/RECALL TERMINATED: Recall completed is the classification status used for monitoring purposes when the recall action reaches the point at which the firm has actually retrieved and impounded all outstanding product that could reasonably be expected to be recovered, or has completed all product corrections.

Recall terminated is the monitoring classification used to indicate that FDA has determined that all reasonable efforts have been made to remove or correct the violative product in accordance with the recall strategy, and proper disposition has been made according to the degree of hazard.

RECALLING FIRM: "Recalling firm" means the firm that initiates a recall or, in the case of an FDA requested recall, the firm that has primary responsibility for the manufacture and (or) marketing of the product to be recalled.

RECALL NUMBER: A "recall number" is the number assigned to the recall of one product regardless of package size, lot numbers, or private buyers' labels, provided the labels are otherwise identical. If a manufacturer requests a wholesaler, distributor, or relabeler to extend the recall to a lower level (assuming no change of the product has occurred), the same recall number assigned to the manufacturer will be used. If the recalled product has undergone a change due to further processing or use as an ingredient or component in a new product, or has had the directions or indications for use changed, it will be considered a different product and its recall will be the responsibility of the firm responsible for the change. FDA will then assign a separate recall number.

RECALL STRATEGY: The planned course of action to be carried out by the firm in the achievement of its recall goals. The strategy will normally be developed by the recalling firm following 21 CFR, Part 7, Subpart C, Recalls. For FDA requested recalls, the agency will recommend a strategy to the recalling firm.

RECONDITION: The process of reworking a lot of goods under seizure pursuant to a Consent Decree of Condemnation, in an attempt to bring the goods into compliance with the Act.

RECONDITIONING: A process by which the importer of record, owner, or consignee may submit to FDA a written application requesting permission to bring into compliance any article, adulterated, misbranded, or in violation of Section 505 by relabeling or other action, or by rendering it other than a food, drug, device, or cosmetic.

REDELIVERY BOND: See Entry Bond.

REEFER CARGO: Refrigerated cargo.

RE-EXPORT (RE-EXPORTATION): A term used to identify goods shipped out of the U.S. after being offered for entry. This is not the same as an export of U.S. manufactured goods and is not covered by the restrictions in Section 801(e) of the FD&C Act.

RELABELING: The application of different labels to a product.

RELEASE WITH COMMENT: FDA Release Notice advising the importer the goods offered for entry are released but appear to have minor violations which the agency, in the exercise of its enforcement discretion, has refrained from enforcing at this time, and that future entries violating the Act may be detained.

RELEASED WITHOUT EXAMINATION: Form FDA-717 amended. A notice to the importer that FDA is releasing an entry for which a Notice of Sampling was issued, and the sample was collected but was not examined.

RES: Things, includes real and personal property.

RES JUDICATA: A matter finally decided on its merits by a court having competent jurisdiction and not subject to litigation again between the same parties. For example, if a product has been seized for misbranding and adjudicated by order of a Court, the same article with the same labeling containing the same misbranding may be seized subsequently and summary judgment obtained without a trial.

RESPONDENT: One who answers; as in Notice of Hearing, the response is given by the party to whom notice is given - he then is the respondent. In an appeal, the party who contends against the appeal, the appellee.

RETURN DATE: After a lot has been seized by the U.S. Marshal, the court allows a period of time so that a claimant may appear. The date this interval expires is known as the "return date". This date varies according to judicial district. If no one appears as claimant before expiration of the return date in the proceedings, the U.S. Attorney will secure a default decree of condemnation, forfeiting and disposing of the article.

RETURN OF SERVICE: The person serving the process shall make proof of service to the court.

REVERSAL: The act of a higher court in setting aside or revoking a lower court order or verdict; i.e., an appellate court may reverse a decision, rendered by a district court.

REVOCATION: Is the cancellation of a license and the withdrawal of the authorization to ship a biological product for sale, barter, or exchange in interstate commerce either at the request of the manufacturer or when grounds exist for the agency to initiate such an action.

REVOCATION OF PROBATION: If a person convicted of a criminal charge is placed on probation by the Court, the probation may be revoked if, during the period of probation, the person violates the law or the conditions of probation.

RFDD: Regional Food and Drug Director.

ROGATORY LETTERS: A written request from a judge in one state to a judge in another, asking that the latter take the testimony of a witness. FDA considers testimony in response to rogatory letters to be covered by 21 CFR 20.1.

RPM: Regulatory Procedures Manual.

SAIL: State Action Information Letter.

SALVAGE OPERATION: See Establishment.

SAMPLE JACKET: The file containing the investigational, analytical, and compliance or regulatory recommendation and legal documents on any civil or criminal case.

SECTION 305 MEETING: A meeting prior to consideration of criminal proceedings that is provided pursuant to Section 305 of the Act.

SEGREGATION: See Recondition.

SEIZURE: An action brought against an FDA-regulated product because it is adulterated and/or misbranded within the meaning of the FD&C Act. The purpose of such an action is to remove specific violative goods from commerce.

SELECTIVITY: U.S. Customs' entry screening mechanism. Criteria can include information concerning the importer, filer (broker), manufacturer, country, or Harmonized Tariff Schedule (HTS) code.

SENTENCE: The judgment formally pronounced by the court upon the defendant after his conviction in a criminal prosecution.

SERVICE: The delivery of a writ, summons, subpoena, or other notice to the party named in the document, thereby officially notifying him of some action or step which he is commanded to take or not to take.

SHIP-TO-SHIP COVERAGE: An import coverage approach providing for placing of FDA inspectors and analysts at a point of cargo discharge for the purpose of sampling and examination of merchandise as it is being unloaded from a carrier.

SHIPPER: See Establishment.

SPLIT SAMPLES: A sample that is divided into two or more portions for analysis by two or more laboratories.

SPONSOR: The sponsor of a work-sharing agreement is the FDA office assigned primary responsibility in the proposed agreement.

STANDARDS: The term applied to formal statements of Definitions and Standards for Foods promulgated pursuant to Section 401, FD&C Act.

STATUTE OF LIMITATIONS: This is the period in which any criminal action contemplated must be brought. In all FDC matters, the period is five (5) years; if no prosecution is filed within that time, FDA may not proceed. 18 U.S.C. 3282.

STOCK RECOVERY: "Stock recovery" means a firm's removal or correction of a product that has not been marketed or that has not left the direct control of the firm. The product is located on premises owned by, or under the control of, the firm and no portion of the lot has been released for sale or use.

STRIPPING (OF CONTAINERS): The removal of all articles from a container for examination or sampling purposes. This is also known as "devanning."

SUB-ACCOUNTS: "Sub-accounts" are consignees, either domestic or foreign, who received shipments of the recalled product from other than the recalling firm. This includes wholesalers, assemblers, and other distributors.

SUBPOENA: A court order commanding a witness to appear at a certain time and place to testify on a certain matter. For purposes of this section, a "subpoena" means a subpoena for verbal or written testimony (e.g., an affidavit). A subpoena for testimony also might include a request for records. In that case, FDA would process the subpoena under 21CFR 20.1 and 20.2.

SUBPOENA DUCES TECUM: A court order commanding a witness to produce documents at a certain time and place. FDA processes these subpoenas, which are intended for the production of records, under 21 CFR 20.2.

SUMMARY JUDGMENT: A judgment given to one party or the other without the necessity of a formal trial. This may be done when the record before the court shows there are no genuine issues of fact that are in dispute.

SUMMARY AND RECOMMENDATION (S&R): The written justification from the Division in its request for institution of a criminal prosecution.

SUMMONS: In a civil suit, a document that is served upon the defendant along with the complaint, advising him that a case has been filed against him, and requiring him to appear and answer the complaint within a specified time.

SUPERVISORY CHARGES: The charges for supervising the reconditioning and examination of articles that an importer, owner, or consignee attempts to bring into compliance after detention (See 21 CFR 1.99).

SURVEY SAMPLES: Samples obtained during a survey that is a planned operation in which the primary objective is to gather information on labeling, production, or marketing practices regarding a certain product or class of products.

Injury, poisoning, and complaint investigation samples where there is no interstate documentation available.

Samples collected in connection with Civil Defense activities.

General investigational samples collected to provide information of interest to the Administration, such as methods development and interpretation.

SUSPENSION: Means the immediate withdrawal by FDA of the authorization to introduce or deliver for introduction into interstate commerce a biological product. Suspension is a summary action taken by the agency when there is a reasonable belief that any of the grounds for revocation of a license exist and by reason thereof there is a danger to health.

TEMPORARY ABEYANCE (TA): The holding of samples in abeyance for possible future regulatory action.

TEMPORARY RESTRAINING ORDER (TRO): Temporary restraining orders are court-enforced cease and desist orders that are brought to control an emergency situation. A TRO seeks immediate, temporary relief (for a period of 10 days, which may be extended for 10 additional days) prior to the hearing for preliminary injunction.

FDA recommends a TRO when the agency believes that the violation is so serious that it must be controlled immediately. A request for a TRO also has the effect of expediting review of the underlying injunction case by the court. An inadequately documented TRO request may result in the court viewing the entire injunction action as lacking credibility.

At the court's discretion, the TRO request may be subjected to a hearing, but usually the court hears the matter ex parte by reviewing the documents and questioning government counsel, the FDA investigator, the Division compliance officer, or other FDA personnel.

An emergency remedy of brief duration issued by a court only in exceptional circumstances, usually when immediate or irreparable damages or loss might result before the opposition could take action.

TESTIMONY: For purposes of this section, testimony is an individual's statement given in writing (such as an affidavit or a declaration) or by appearance under oath at a proceeding. The statement might be in response to a deposition or interrogatories. Testimony is covered by 21 CFR 20.1.

TOBACCO RETAIL COMPLIANCE CHECK INSPECTIONS: Inspections of tobacco product retailers conducted by FDA or FDA-commissioned personnel to determine a retailer's compliance with the Federal Food, Drug, and Cosmetic Act, as amended by the Family Smoking Prevention and Tobacco Control Act and its implementing regulations, with regard to tobacco products.

TRANSPORTATION AND EXPORTATION (T&E): See Entry.

TRANS-SHIPMENT: Merchandise transferred from one conveyance to another form of conveyance while enroute to the port of unloading or discharging.

USDA: U.S. Department of Agriculture.

VAI: voluntary action indicated.

VALUE OF ENTRY: The value of an entry used by Customs to determine the rate of duty and entry bond amount.

VENUE: The proper location for the trial of a case.

VERDICT: The decision of a jury after a trial.

WALK-BY EXAMINATION: A rapid inspection of imported articles conducted by FDA field personnel. Although the inspection is rapid, it should be thorough enough to determine whether a sample should be collected. The examination usually consists of a visual examination for water damage, and breakage.

WAREHOUSE: See Establishment.

WAREHOUSE ENTRY: See Entry.

WARRANT (FOR ARREST): A writ, directed to the marshal or other proper officer, requiring him to arrest the defendant or article named and bring him before the court or U.S. magistrate.

WAYBILL: This record accompanies the shipment during transit.

WHARF EXAMINATION: The examination of a product in import status, sufficient in scope to determine whether the product is in compliance with the Acts enforced by FDA.

WITNESS: A person who will appear to present evidence as testimony in any proceeding in a lawsuit. An expert witness is one who is skilled in some art, science, trade, profession, or other human activity, and may give opinions while under oath. A fact witness may not express opinions while testifying.

WORKSHEET: A document on which the analyst records his analytical work and findings.

WRIT: An order of the court.

WORK-SHARING: This term describes any arrangement between FDA and state or local agencies in which the parties agree to assume a portion of the activities necessary to fulfill common responsibilities. These arrangements are usually with state agencies having regulatory responsibilities that are essentially the same as FDA's. Ideally, these arrangements should be formalized by written memoranda.