FDA U.S. FOOD & DRUG ADMINISTRATION

FDA FOODS AND VETERINARY MEDICINE PROGRAM STRATEGIC PLAN

FISCAL YEARS 2016–2025

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LETTER FROM THE DEPUTY COMMISSIONERS

WE ARE PLEASED TO PRESENT the Food and Drug Administration (FDA) Foods and Veterinary Medicine (FVM) Program's Strategic Plan Fiscal Years (FY)[1] 2016–2025, which outlines our goals and objectives for the next 10 years. This is an exciting time for the FVM Program. The congressionally-mandated modernization of the FDA's regulatory framework for preventing foodborne illness is one of the most challenging initiatives in FDA's history and will have significant public health and economic benefits. We also have many opportunities to promote and facilitate healthy food choices for the population and enhance the health of animals. It is imperative that we continue driving toward a more proactive, preventive, risk-informed approach to food and feed safety, nutrition, and animal health that makes excellent use of our scarce resources. This is essential to meet the challenges of:

- Persistent foodborne illness;
- An unacceptably high prevalence of diet-related chronic disease leading to excessive health care costs;
- Increasing globalization and complexity of the food and feed supply;
- Rapid advances in science and technology that pose both challenges and opportunities for achieving our public health goals; and
- High expectations for all of our activities among the consuming public, the industry, Congress, and a wide range of other important stakeholders.

The FVM Program[2] is responsible for a wide range of activities to meet these challenges. Our mission is to promote public health by preventing foodborne illness, fostering good nutrition, and improving the safety and efficacy of animal health products. We also

[1] "Fiscal Year" covers the period from October 1st through September 30th

[2] Includes the Office of Foods and Veterinary Medicine (OFVM), the Center for Food Safety and Applied Nutrition (CFSAN), and the Center for Veterinary Medicine (CVM), as well as the related activities under the Office of Global Regulatory Operations and Policy and the Office of Regulatory Affairs (GO/ORA)

ensure FDA regulations and guidance provide clear and reliable direction and assistance to industry, both inside and outside the United States, with a goal to obtain high rates of compliance with standards necessary to protect public health and meet consumer and stakeholder expectations.

The FDA Food Safety Modernization Act (FSMA) enacted in 2011 is based on congressional recognition of the unique challenges faced by FDA in the area of food safety in the 21st century. This FVM Program Strategic Plan takes this statutory framework into account, places high priority on the implementation of FSMA, and focuses on how FDA plans to modernize its food safety work. This includes:

- An increased focus on obtaining compliance with preventive control standards rather than finding and responding to violations after an illness or outbreak has occurred;
- Strengthening FDA technical expertise and capacity to support FDA and industry in implementing the new prevention standards;
- Furthering federal, state, local, and territorial partnerships, and investing in training and capacity to ensure efficient, high quality, and consistent oversight nationwide; and
- Broadening interaction with foreign partners and increasing oversight of importers, who will have more responsibility for the safety of imported foods.

Beyond FSMA implementation, the FVM Program Strategic Plan for FY 2016–2025 provides greater focus on important public health goals and objectives in the areas of nutrition and chemical safety that will drive us toward our vision of protecting and enhancing the health of people and animals. Organizational excellence will remain a central strategic priority for our program to make the best use of all available resources and to continue to invest in our workforce.

FSMA MANDATES:

- A comprehensive set of prevention-oriented food safety standards across the food system;
- A domestic inspection frequency, based on risk, to ensure high rates of compliance;
- A nationally integrated food safety system based on full partnership with states; and
- A new import safety system based on food safety accountability for importers, increased foreign presence, and increased collaboration with foreign governments.

The success of this plan depends on FDA working seamlessly across internal organizations; federal, state, local, tribal, and territorial regulatory partners; and international borders—as well as engaging a wide range of consumer, industry, public health, and scientific stakeholders and partners. We will continue to build the FVM program for the benefit of the people we serve. To that end, we welcome comments on this strategic plan, and we plan biannual reviews that will allow us to incorporate what we learn through our experience and from our stakeholders as we do our work in the coming years.

Stephen Ostroff
Deputy Commissioner for Foods and Veterinary Medicine

Howard R. Sklamberg
Deputy Commissioner for Global Regulatory Operations and Policy

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FDA FOODS AND VETERINARY MEDICINE PROGRAM STRATEGIC PLAN FRAMEWORK, FY 2016-2025

VISION

Protecting and enhancing the health of people and animals.

MISSION

Promoting public health by preventing foodborne illness, fostering good nutrition, and improving the safety and efficacy of animal health products.

FOOD SAFETY

Protect America's consumers and animals from foreseeable hazards.

OUTCOME

Reduce the incidence of illnesses and deaths attributable to preventable contamination of FDA-regulated food and feed products.

OBJECTIVES

- Establish and gain high rates of compliance with science-based preventive control standards across the global farm-to-table continuum.
- Improve prevention, detection, and response to foodborne illness outbreaks and other food and feed safety incidents.
- Strengthen the ability of consumers to play a proactive role in minimizing food safety risks.
- Enhance the safety of food and feed additives and dietary supplements.
- Strengthen existing partnerships with international, federal, state, local, tribal, and territorial agencies to improve the effectiveness and efficiency of the FDA's food safety program for government and industry.

NUTRITION

Foster an environment to promote healthy and safe food choices.

OUTCOME

Reduce risk factors for and the incidence of nutrition-related chronic disease.

OBJECTIVES

- Provide and support accurate and useful nutrition information and education so consumers can choose healthier diets consistent with the Dietary Guidelines for Americans and other evidence-based recommendations.
- Monitor and assess emerging nutrition science as well as changes in the composition of foods in the marketplace in relation to the nutritional and health status of Americans.
- Encourage and facilitate new products and product reformulation to promote a healthier food supply.

ANIMAL HEALTH

Protect human and animal health by enhancing the safety and effectiveness of animal health products.

OUTCOME

Reduce human and animal illness and death from FDA-regulated animal health products.

OBJECTIVES

- Improve access to safe and effective animal drug products.
- Reduce risks in the manufacturing, production, distribution, and use of FDA-regulated animal health products.
- Strengthen detection and surveillance of problems with FDA-regulated animal health products.

ORGANIZATIONAL EXCELLENCE

Continuously improve the leadership, management, staffing, and organizational capacity of the FVM program to protect public health.

OUTCOME

Enable the FVM Program to optimize public health gains by making the best use of available resources.

OBJECTIVES

- Achieve optimal risk-informed resource allocation throughout the FVM Program.
- Optimize the development and deployment of the FVM Program's scientific expertise and organizational capacity to better understand and detect hazards and devise preventive interventions.
- Attract, retain, and optimally deploy the skilled workforce required to lead, manage, and execute the FVM Program's public health mission.

Note: A text version of this graphic is in Appendix B.

GUIDING PRINCIPLES

- Public health is the first priority.
- Partnerships are the key to success.
- Scientific expertise and research are the foundations of the FVM Program's work.
- Operating openly and transparently is a core principle.

INTRODUCTION

THE AMERICAN PUBLIC has high expectations of Food and Drug Administration (FDA) and its Foods and Veterinary Medicine (FVM) Program. Consumers expect that the food they purchase at the marketplace will be safe, and that FDA, Centers for Disease Control and Prevention, U.S. Department of Agriculture, and Environmental Protection Agency, as well as federal, state, local, territorial, and tribal regulatory and public health authorities, will work together to ensure food and product safety and support a healthier food supply.

Industry has similarly high expectations that FDA will provide clear rules and guidance to support industry in meeting its own responsibilities for producing safe foods, veterinary medicine products, and cosmetics. For example, food processors and producers expect that FDA's regulations and guidance will serve as an effective and practical standard for food safety, and the agriculture industry expects that the drugs they use to keep animals healthy will be safe and effective for their intended use.

The FVM Program—encompassing the Office of Foods and Veterinary Medicine (OFVM), the Center for Food Safety and Applied Nutrition (CFSAN), the Center for Veterinary Medicine (CVM), related activities under the Office of Global Regulatory Operations and Policy, and the Office of Regulatory Affairs (GO/ORA)—is responsible for a wide range of activities to meet these expectations.

While the environment surrounding the FVM Program is increasingly challenging and complex, stakeholders rely on FDA to continue to uphold effective safety standards to protect health and maintain the confidence of consumers worldwide. Science and technology advancements, impacts from globalization, new congressional mandates and authorities, constraints on local and state budgets, as well as fluctuating federal budgets, all have substantial influence on the strategic direction and accomplishments of the FVM Program, creating the need for greater clarity and focus of the FVM Program over the long term.

For instance, the agency's funding and staffing levels for the FVM Program's activities have fluctuated since the September 11, 2001, terrorist attacks. Initially, funding and staffing levels increased; however, they began to decline in 2004. From 2008 through 2010, these levels again rose in response to illness outbreaks and growing concerns about the safety of imported food. For the FDA's field force in the GO/ORA, the additional resources directly supported FSMA's foundation by increasing the inspection staff sufficiently to accommodate the domestic inspection frequency mandate. This also permitted FDA to conduct more foreign inspections—from fewer than 100 inspections in FY 2007 to about 1,400 inspections in FY 2014. Funding has yet to catch up, however, with the many other FSMA mandates and growing demands in the FVM Program's many other areas of responsibility.

In addition to FSMA implementation, the FVM Program conducts many other important food and feed safety, nutrition, and animal health activities fundamental to the safety and quality of the food supply and to consumer confidence. These include a wide range of standard-setting and premarket oversight activities involving chemical safety (encompassing food and feed additives, dietary supplements, food packaging, chemical contaminants in food, and cosmetics); nutrition (including the expansion of nutrition labeling to menus, food quality standards, and food fortification); and animal health (grounded in our responsibility for premarket review and licensing of animal health

products and medicated animal feed). To be successful in these areas, FDA must invest in the expert staff needed to perform these complex functions, as well as the research and data collection needed to provide the strongest possible scientific foundation for its decisions.

The FVM Program's premarket activities are backed by the field-based surveillance, inspection, and compliance activities carried out by GO/ORA in conjunction with CFSAN and CVM to enforce standards, oversee imports, respond to and contain foodborne illness outbreaks, remove harmful and illegal products from the market, and collect data needed to inform future policymaking and standard setting.

The FVM Program performs unique functions and plays a key leadership role in all these areas, but the complexity of the issues in today's global food system and the scarcity of resources make it more crucial than ever that we leverage the expertise, resources, and efforts of others outside of FDA and the FVM Program. We do this through active engagement with our industry and consumer, public health and scientific stakeholders, and active partnership with our counterparts in federal, state, local, territorial, tribal, and foreign governments. A central feature of the FVM Program's collaboration strategy—and FSMA mandate—is to work with our government partners at all levels to build the national Integrated Food Safety System (IFSS), which envisions a fully operational partnership to deliver the comprehensive, well-coordinated implementation of FSMA.

The FVM Program Strategic Plan FY 2016–2025 charts a path forward to meeting our broad stakeholder expectations by establishing a longer term outlook, with an eye on achievable public health outcomes.

A new vision and mission statement for the FVM Program has been developed, critical goal areas have been established, and key objectives with supporting strategies have been set in place to advance food safety, nutrition, and animal health in the years to come.

It is imperative to recognize that our ability to implement the strategies outlined in the FVM Program Strategic Plan is contingent upon the receipt of adequate resources.

Several guiding principles were considered in the development of this plan:

PUBLIC HEALTH IS THE FIRST PRIORITY: All FVM Program activities are carried out with the end goal of protecting consumers and promoting public health.

PARTNERSHIPS ARE THE KEY TO SUCCESS: The FVM Program must partner and collaborate with a wide array of stakeholders in all of its program areas to ensure that roles and responsibilities are clear, that standards are scientifically sound and workable across our diverse food system, and that high rates of compliance and good public health outcomes are achieved.

SCIENTIFIC EXPERTISE AND RESEARCH ARE THE FOUNDATIONS OF THE FVM PROGRAM'S WORK: Because food, animal health, and nutrition science drive much of what the FVM Program does, maintaining the quality and credibility of the FVM Program's science base is a central priority.

OPERATING OPENLY AND TRANSPARENTLY IS A CORE PRINCIPLE: The FVM Program is committed to open communication and engagement to inform rule making and other activities, generate high levels of compliance with public health standards, and build the public confidence that is critical to the FVM Program's success.

Strategic Planning Process

The FVM Program Strategic Plan FY 2016–2025 identifies the Goals, Objectives, and Strategies necessary for achieving its Mission and Vision over a 10-year timeframe. Additionally, Public Health Outcomes are identified, enabling the FVM Program to direct its efforts towards accomplishing meaningful, measurable results. This strategic plan will be followed by an implementation plan.

The FVM Implementation Plan will identify the specifications that OFVM, CFSAN, CVM, and GO/ORA will implement over a shorter timespan in order to realize the strategies and ultimately accomplish the objectives identified in the FVM Program Strategic Plan. The implementation plan will prioritize and sequence these actions based on anticipated resources and other practical constraints. In addition, the implementation plan will identify initial and intermediate outcomes, as well as the performance metrics required to monitor the FVM Program's performance. Performance will be reviewed regularly through FDA's agency-wide performance management system FDA-TRACK, which is a Quarterly Performance Review process.

In addition, the FVM Program will utilize monthly program reviews, as well as periodic senior leadership reviews, to monitor performance and ensure progress against the strategic goals.

We chose a 10-year timeframe for the FVM Program Strategic Plan because some of the strategic change initiatives, such as FSMA Implementation and Program Alignment,[3] require sustained focus and commitment over an extended period. Meanwhile, our role in our other activities is more fluid since expectations and mandates from Congress are dynamic, and new legislation can be considered at any time. As such, the Strategic Plan will be reviewed and approved by the designated FVM governance body every two years at a minimum. More frequent reviews may be necessary as a result of changes in the FVM Program environment. The FVM Implementation Plan will be reviewed annually, updated as appropriate, and approved by the designated FVM governance body.

FDA Mission

FDA is charged with protecting the public health by ensuring the safety, effectiveness, and security of human and veterinary drugs, biological products, and medical devices; ensuring the safety of foods, and radiation-emitting products; and regulating tobacco products.

Specifically, FDA is responsible for advancing the public health by:

- Helping to speed innovations that make foods safer and make medicines and devices safer and more effective;
- Ensuring the public has accurate, science-based information they need to use medicines, devices, and foods to improve their health;
- Regulating the manufacturing, marketing, and distribution of tobacco products and reducing tobacco use by minors; and
- Addressing the nation's counterterrorism capability and ensuring the security of the supply of foods and medical products.

FVM Vision

Protecting and enhancing the health of people and animals.

FVM Mission

Promoting public health by preventing foodborne illness, fostering good nutrition, and improving the safety and efficacy of animal health products.

FVM Public Health Outcomes

- Reduce the incidence of illnesses and deaths attributable to preventable contamination of FDA-regulated food and feed products.
- Reduce risk factors for and the incidence of nutrition-related chronic disease.
- Reduce human and animal illness and death from FDA-regulated animal health products.
- Enable the FVM Program to optimize public health gains by making the best use of available resources.

* See Appendix A for the alignment of the objectives between the FVM Program and FDA Strategic Plan.

[3] FDA Program Alignment is a multi-year process initiated in FY 2015 to modify FDA's functions and processes by transitioning to commodity-based and vertically-integrated regulatory programs in order to address new regulatory challenges, including the impact of globalization on the food supply chain. Critical actions are being taken between FDA's Centers and ORA to jointly fulfill FDA's mission in the key areas of specialization, training, work planning, compliance policy and enforcement strategy, imports, laboratory optimization, and information technology.

GOAL 1: FOOD SAFETY
PROTECT AMERICA'S CONSUMERS AND ANIMALS FROM FORESEEABLE HAZARDS

Ensuring that the food people and animals eat is safe and protected from contamination is an essential element of promoting human and animal health, as is helping to ensure that people are protected from any contaminants that originate in animals and pass on to become health concerns for humans. Foodborne illness is a preventable and underreported public health problem. It presents a major challenge to both general and at-risk populations.

PUBLIC HEALTH OUTCOME

Reduce the incidence of illnesses and deaths attributable to preventable contamination of FDA-regulated food and feed products.

Each year, millions[4] of illnesses in the United States can be attributed to contaminated foods. Many factors determine the safety of the nation's food supply, including how food is grown, processed, transported, and stored. Improper handling, preparation, and storage practices in retail settings and homes may also result in cases of foodborne illness. Thus, working collaboratively with a wide range of partners and stakeholders, the FVM Program will work to prevent foodborne illness by establishing and ensuring compliance with appropriate, prevention-oriented standards at each step in the commercial process of food production and marketing to minimize the risk of contamination. These standards will be grounded in the latest food safety research and science, and be practical across the diversity of the food system. The goal is to foster a food safety culture of continuous improvement based on evolving best practices and thus ensure everything that reasonably can be done in the commercial food chain to provide safe food is being accomplished. In addition, the FVM Program will elevate the role of consumer education in its prevention strategy.

Objectives

1.1: Establish and gain high rates of compliance with science-based preventive control standards across the global farm-to-table continuum.

The FVM Program will establish and maintain up-to-date, science-based, preventive control standards for chemical and microbiological hazards in food and feed products and use a wide range of tools to foster compliance.

Strategy 1.1a: Develop and implement a robust communication, training, and technical assistance plan for preventive control standards.

Strategy 1.1b: Utilize innovative inspection and compliance strategies, backed by administrative and judicial enforcement tools to foster compliance with preventive control standards.

[4] http://www.cdc.gov/foodborneburden/estimates-overview.html. CDC website estimates roughly 48 million people per year.

GOAL 1: FOOD SAFETY

Strategy 1.1c: Evaluate and improve the effectiveness of preventive control standards.

Strategy 1.1d: Evaluate and mitigate the risks of chemical exposures in food and feed products that pose public health or regulatory concerns.

Strategy 1.1e: Evaluate and mitigate the risks of microbiological hazards in food and feed products.

1.2: Improve prevention, detection, and response to foodborne illness outbreaks and other food and feed safety incidents.

Based on a philosophy of continuous improvement, the FVM Program will enhance its efforts to prevent, promptly detect, and contain outbreaks, and take appropriate enforcement actions. This includes an enhanced effort to assess the root cause of outbreaks and ensure that knowledge gained from these assessments is incorporated in future prevention efforts. To support continuous improvement across the food safety system, the FVM Program will enhance data collection, analysis, sharing, and communication with regulatory partners and collaborators at all levels, as well as with animal health and public health agencies.

Strategy 1.2a: Improve data analysis and collaboration with food and feed safety partners, including industry, academia, and other domestic and foreign regulatory bodies.

Strategy 1.2b: Improve risk prediction and prioritization to focus FVM resources and the efforts of regulatory partners on high-risk commodities and firms.

Strategy 1.2c: Utilize knowledge gained from previous outbreaks and other incidents to better inform risk modeling, identify best practices, and increase compliance through voluntary corrective actions.

Strategy 1.2d: Improve collaboration and communication within the agency and among external stakeholders in order to improve the efficiency and effectiveness of FVM compliance actions.

1.3: Strengthen the ability of consumers to play a proactive role in minimizing food safety risks.

Consumers rightfully expect that those in the commercial chain of food production, processing, distribution, and sales have done everything they reasonably can to provide the consumer with safe food. It is widely recognized, however, that consumers have a role to play in minimizing food safety risks through their food choices and food handling practices. Consumers are part of the farm-to-table prevention paradigm. The FVM Program, working with an array of partners, will elevate the food safety awareness and knowledge of consumers and the effectiveness of food safety education in improving consumer practices that can help reduce foodborne illness.

Strategy 1.3a: Increase research, data analysis, and systematic evaluation to improve the effectiveness of food safety education in changing unsafe consumer food handling behaviors.

Strategy 1.3b: Increase consumer-based communications and outreach regarding safe food handling practices, including leveraging a variety of community-based education programs.

Strategy 1.3c: Enhance communication to consumers during and following illness outbreaks.

GOAL 1: FOOD SAFETY

1.4: Enhance the safety of food and feed additives and dietary supplements.

The FVM Program is committed to promoting a safe and healthy food supply for American consumers. The FVM Program will continue executing a science-based regulatory program to improve the congressionally-mandated safety oversight of additives in human and animal food and feed, including Generally Recognized as Safe (GRAS) substances. Key to achieving this goal will be the strengthening of both pre- and postmarket oversight of food additives, as well as postmarket oversight of dietary supplements, focusing on enhanced Good Manufacturing Practices (GMP) compliance and adverse event reporting.

Strategy 1.4a: Implement innovative regulatory and compliance strategies to improve premarket oversight and safety evaluation of food and feed additives, GRAS substances, and FDA's ability to verify that substances added to the food supply meet applicable safety standards.

Strategy 1.4b: In collaboration with external stakeholders, including regulatory and scientific partners, improve data-driven, postmarket surveillance of substances added to the food supply to understand and assess changing use and intake patterns, emerging toxicological data, and adverse event reports.

Strategy 1.4c: Make innovative use of FDA resources and collaborative initiatives with regulatory partners and industry to achieve the goals of FDA's dietary supplement GMP regulation and other standards related to the safety, quality, identity, and integrity of dietary supplements.

Strategy 1.4d: Expand consumer and healthcare provider education regarding safe use of dietary supplements.

1.5: Strengthen existing partnerships with international, federal, state, local, tribal, and territorial agencies to improve the effectiveness and efficiency of the FDA's food safety program for government and industry.

Ensuring the safety of the food supply and protecting public health require seamless coordination and cooperation among regulatory and public health agencies. The FVM Program is committed to working with domestic and international food safety regulatory and public health partners to continue building a national IFSS. Such a system will allow partners to build mutual reliance and leverage resources through joint work-planning, shared data, and targeted risk-informed inspections in order to increase the safety of the food supply and drive widespread compliance with food safety standards.

Strategy 1.5a: Enhance leveraging of food safety efforts with domestic and international regulatory and public health partners.

Strategy 1.5b: Increase engagement and partnerships with domestic and international intergovernmental organizations to strengthen food safety capacity building and food safety standards development.

Strategy 1.5c: Utilize the Partnership for Food Protection (PFP)[5] and its FY 2015-2020 Strategic Plan to continue to build the national IFSS domestically.

[5] http://www.fda.gov/downloads/ForFederalStateandLocalOfficials/FoodSafetySystem/PartnershipforFoodProtectionPFP/UCM423834.pdf

GOAL 2: NUTRITION
FOSTER AN ENVIRONMENT TO PROMOTE HEALTHY AND SAFE FOOD CHOICES

The FVM Program plays an important role in reducing the prevalence of nutrition-related risk factors for chronic disease and improving nutritional status in humans and animals, including supporting growth and development among infants and children. It does so by improving the way human and animal nutrition information is communicated to and understood by consumers so they can make healthier dietary choices, by monitoring the composition of the foods in the marketplace and consumption by the U.S. population, and by facilitating new products and the reformulation of existing products to be healthier and more nutritious. As evidence-based approaches for improving nutrition for humans and animals are strengthened, new strategies will be identified to promote improved health and well-being in humans and animals.

PUBLIC HEALTH OUTCOME

Reduce risk factors for and the incidence of nutrition-related chronic disease.

Objectives

2.1: Provide and support accurate and useful nutrition information and education so consumers can choose healthier diets consistent with the Dietary Guidelines for Americans and other evidence-based recommendations.

The FVM Program will use its best available tools, including surveillance, research, education, regulations and guidance, and other options to best convey nutrition information on food labels, restaurant menus, vending machines, and pet food labels. It will continue to work with stakeholders, including industry, consumer, and public health groups, to implement these strategies.

Strategy 2.1a: Improve the availability and accuracy of nutrition information provided to consumers by modernizing nutrition and supplement fact labels, and by implementing the expansion of nutrition labeling to menus in restaurants, other retail establishments, and vending machines.

Strategy 2.1b: Promote collaboration to advance the science underlying dietary guidance statements, medical food disease claims, and nutrition-related claims.

Strategy 2.1c: Enhance understanding of how consumers notice, understand, and act on labeling and nutrition information, including nutrition facts labels, nutrition product claims, front-of-package nutrition labels, and dietary recommendations.

Strategy 2.1d: Promote collaboration with stakeholders, including industry, consumer, and public health groups, to enhance consumer nutrition education directed towards age and demographic groups with specific needs.

2.2: Monitor and assess emerging nutrition science as well as changes in the composition of foods in the marketplace in relation to the nutritional and health status of Americans.

The FVM Program will advance its understanding of emerging food technologies and nutrition science, along with the changing composition of the food supply, to better

GOAL 2: NUTRITION

implement FVM Program nutrition initiatives and evaluate their impact on the nutrition and health status of the U.S. population.

Strategy 2.2a: Enhance the FVM Program's capacity to gather and analyze information about the composition and labeling of foods in the marketplace.

Strategy 2.2b: Collaborate with federal partners who conduct food intake surveys to monitor overall intake of nutrients and food-related components in the U.S. population, and assess the effect of FVM initiatives on population intake (overall and in subpopulations of interest), risk factors for chronic disease, and health outcomes.

Strategy 2.2c: Enhance the FVM Program's capacity to review and respond to emerging scientific and technological issues in food and nutrition.

2.3: Encourage and facilitate new products and product reformulation to promote a healthier food supply.

The FVM Program will promote and facilitate the reformulation of food toward healthier products. FVM will enhance and support healthful reformulation by using regulatory or other mechanisms such as nutrition labeling, voluntary guidelines, research into healthful ingredient substitutes, and stakeholder collaboration.

Strategy 2.3a: Improve the nutritional profile of foods through mechanisms such as labeling, voluntary industry guidelines, and utilizing additional regulatory authorities where appropriate.

Strategy 2.3b: Collaborate with stakeholders to encourage research into healthful ingredient substitutes to support development and reformulation of healthier food options.

GOAL 3: ANIMAL HEALTH

PROTECT HUMAN AND ANIMAL HEALTH BY ENHANCING THE SAFETY AND EFFECTIVENESS OF ANIMAL HEALTH PRODUCTS

The FVM Program protects human and animal health by conducting timely evaluation of the safety, efficacy, and quality of animal health products, oversight of the supply chain, and postmarket surveillance activities. The challenges posed by innovative new technologies and increased globalization require a regulatory review process that draws together both pre- and postmarket functions, helps prioritize and manage risk, and optimizes the use of agency resources. Moreover, antimicrobial resistance is considered a serious public health threat, and the FVM Program is committed to informing the public and helping shape public policy regarding the judicious use of medically important antimicrobial drugs in food-producing animals. The FVM Program is also concerned about the number of unapproved animal drug products—particularly compounded animal drugs—that are being illegally marketed and sold to animal owners and veterinarians. It is working to decrease the prevalence of these drug products marketed in the United States and to reduce unsafe use of legally-marketed animal drugs.

PUBLIC HEALTH OUTCOME

Reduce human and animal illness and death from FDA-regulated animal health products.

Objectives

3.1: Improve access to safe and effective animal drug products.

The FVM program reviews animal drug applications for new and generic drugs intended for animals that produce food, for companion animals, and for minor species such as fish, sheep, goat, game birds, and exotic pets. When the drug is for use in food-producing animals, not only must the safety to the animal be demonstrated, but also the safety of food products derived from the treated animals that are intended for human consumption. To meet the therapeutic and production needs of animals, the FVM Program will expeditiously approve safe, effective, quality manufactured, and properly labeled new animal drug products through a science-based approach in a regulatory environment.

Strategy 3.1a: Identify and develop new scientific methods, models, and tools to improve the quality, safety, predictability, and efficiency of new animal drug development.

Strategy 3.1b: Optimize rigorous science-based premarket review to ensure that animal drugs marketed to the public are safe and effective.

Strategy 3.1c: Collaborate with stakeholders, including other regulatory bodies, in the exchange of information to facilitate the efficient evaluation of new animal drug products.

Strategy 3.1d: Facilitate the introduction of innovative products and processes by enhancing the predictability of regulatory evaluation processes of animal drug products.

GOAL 3: ANIMAL HEALTH

3.2: Reduce risks in the manufacturing, production, distribution, and use of FDA-regulated animal health products.

The increasingly complex global drug supply chain, from raw source materials to finished products, presents multiple opportunities for the products to be contaminated, diverted, or otherwise adulterated. The FVM Program will minimize risks that arise anywhere along the supply chain continuum, from oversight of a product's manufacture to sale and distribution of animal health products and actual use. The FVM Program will develop and implement new monitoring and enforcement tools to help ensure the authenticity, integrity, and quality of animal health products and the safety of the global supply chain.

Strategy 3.2a: Increase coordination with federal, state, local, tribal, and private partners, and enhance monitoring of antimicrobial drug use practices and resistance data to support efforts to foster judicious use of medically important antimicrobials in food-producing animals.

Strategy 3.2b: Increase access, sharing, and use of data from foreign, federal, state, local, and private sources to aid in the assessment of risks related to animal health products.

Strategy 3.2c: Support research to better understand the emergence, persistence, and spread of antimicrobial resistance.

Strategy 3.2d: Enhance risk-informed regulatory frameworks and enforcement tools to reduce the availability of unapproved animal drugs, including unapproved compounded animal drugs.

3.3: Strengthen detection and surveillance of problems with FDA-regulated animal health products.

Although a new animal drug product is carefully tested before it is marketed, problems not evident during the pre-approval stage may appear after the product is approved and marketed commercially and over time. Therefore, the assessment of the safety of a new drug is a continuing process that takes place throughout the development and marketing of a drug. The FVM Program will enhance its efforts to promptly detect, monitor, and learn from problems experienced with FDA-regulated animal health products in order to prevent marketing of unsafe products, including veterinary devices, and to undertake enforcement actions against products associated with adverse events.

Strategy 3.3a: Advance surveillance systems for adverse events for approved animal drugs, unapproved animal drugs, and veterinary devices, to identify safety signals and effectiveness issues of concern.

Strategy 3.3b: Foster development of tools and models to assess the safety of unapproved animal drugs, including compounded animal drugs.

Strategy 3.3c: Collaborate with federal and state agencies to identify and address illegal drug residues in animal-derived food.

Strategy 3.3d: Ensure stakeholder awareness of animal drug quality and integrity issues through effective education.

GOAL 4: ORGANIZATIONAL EXCELLENCE
CONTINUOUSLY IMPROVE THE LEADERSHIP, MANAGEMENT, STAFFING AND ORGANIZATIONAL CAPACITY OF THE FVM PROGRAM TO PROTECT PUBLIC HEALTH

Advancing the FVM Program's public health mission depends on an infrastructure of expert institutional knowledge, a world-class workforce, integrated and agile management systems, and meaningful engagement with stakeholders. It also requires responsible stewardship of resources, including both taxpayer dollars and user fees from industry. Faced with scarce resources and a rapidly evolving regulatory landscape, FVM will promote an adaptive, risk-informed, and cost-effective management system and infrastructure to support organizational excellence, performance, and accountability.

PUBLIC HEALTH OUTCOME

Enable the FVM Program to optimize public health gains by making the best use of available resources.

Objectives

4.1: Achieve optimal risk-informed resource allocation throughout the FVM Program.

The FVM Program will strengthen operational effectiveness through integrated planning and risk-informed decision making, supported by robust and adaptive process management and information technology systems. Evidence-based risk priorities will inform strategic planning and resource allocation, and performance metrics linked to public health outcomes will drive continuous improvement. The FVM Program remains committed to transparency in these planning and prioritization efforts and will encourage input from both internal and external stakeholders to help define and meet our regulatory and administrative goals. By clearly defining priorities and aligning workforce efforts to most efficiently achieve them, the FVM Program will enhance quality, productivity and transparency for mission-critical business processes.

Strategy 4.1a: Fully implement a risk-informed resource allocation framework, linking risk-informed program priorities to spend plans and budget execution.

Strategy 4.1b: Leverage information technology systems and processes to support risk-informed decision making, evaluation of public health impact, and strategic resource planning.

Strategy 4.1c: Improve efficient use of resources to enhance productivity while maintaining program integrity.

Strategy 4.1d: Expand comprehensive data-informed planning models that connect performance measures and outputs to public health outcomes.

Strategy 4.1e: Develop and implement a vertically-integrated management structure for the FVM Program, with organizational delayering and streamlined work processes across OFVM, CFSAN, CVM, and GO/ORA.

Strategy 4.1f: Advance strategic alignment of program activities both across the FDA and within the FVM Program to foster coordination and avoid duplication of efforts.

Strategy 4.1g: Inform and engage all stakeholders through effective internal and external communication.

GOAL 4: ORGANIZATIONAL EXCELLENCE

4.2: Optimize the development and deployment of the FVM Program's scientific expertise and organizational capacity to better understand and detect hazards and devise preventive interventions.

A core responsibility of the FVM Program is to protect consumers by applying the best possible science to the regulation of food and animal health products. Rapid advances in science and technology will continue to support both regulatory science and product innovation. To protect and promote public health, the FVM Program must keep pace with, and utilize, these scientific advances. Expanding internal scientific expertise, acquiring state-of-the-art equipment, and leveraging existing knowledge from our stakeholders and partners will enable broader understanding and adoption of emerging technologies that have the potential to significantly improve regulatory science, including genomics and rapid detection methodologies. Timely evaluation and response to changes in regulated products, such as the use of nanotechnology in food and cosmetics, will require enhanced market surveillance, a laboratory infrastructure that can rapidly adapt to emerging analytical needs, and proactive communication with internal and external stakeholders. By continually striving to identify and understand advances in scientific knowledge and technology, the FVM Program will be able to reliably and promptly respond to emerging priority areas.

Strategy 4.2a: Adopt innovative, risk-informed approaches to ensure scientific research is directed at mitigating priority hazards and advancing public health.

Strategy 4.2b: Establish collaborative arrangements with the public health community, including academia, industry, and other regulatory agencies, to leverage existing knowledge and improve innovation in areas including product development, food safety, and analytic methods.

Strategy 4.2c: Improve cosmetic safety through oversight and increased efforts to fill gaps in scientific knowledge on the safety of cosmetic ingredients.

Strategy 4.2d: Foster the development of rapid and advanced technologies to accurately identify biological and chemical hazards through expansion of FVM Program scientific expertise and laboratory capacity.

Strategy 4.2e: Promote proactive and ongoing communication with internal and external stakeholders about FVM Program efforts to understand and ensure the healthfulness and safety of novel products and innovations.

4.3: Attract, retain, and optimally deploy the skilled workforce required to lead, manage, and execute the FVM Program's public health mission.

The capacity for the FVM Program to effectively advance safety and health relies on our ability to attract and retain a talented and diverse workforce. To that end, the FVM Program will foster a culture of excellence through leadership and collaboration with external stakeholders. Integrated programs for career development, performance management, and strategic workforce planning will ensure a strong, unified, and high-performing organization. In an increasingly complex and globalized environment, however, the advancement of public health cannot be accomplished in isolation. Collaborations with partner organizations at local, national, and international levels will improve workforce readiness and community capacity.

GOAL 4: ORGANIZATIONAL EXCELLENCE

Strategy 4.3a: Recruit, develop, train, and strategically manage a talented and diverse workforce by investing in leadership and human capital infrastructures.

Strategy 4.3b: Promote an organizational culture of quality, cooperation, innovation, and accountability by enhancing open communication, encouraging creativity, and supporting employee recognition.

Strategy 4.3c: Enhance leadership development through continuous learning, performance management, and effective succession planning.

Strategy 4.3d: Increase leveraging of resources through collaboration with external stakeholders, including academia, industry, and other regulatory bodies.

APPENDIX A

CROSSWALK OF OBJECTIVES BETWEEN FVM PROGRAM AND FDA STRATEGIC PLANS

FY 2016–2025 FVM Program Strategic Objectives	FY 2014–2018 FDA Strategic Objectives
1.1: Establish and gain high rates of compliance with science-based preventive control standards across the global farm-to-table continuum.	**1.1:** Increase the use of regulatory science to inform standards development, analysis, and decision-making. **1.2:** Reduce risks in the manufacturing, production, and distribution of FDA-regulated products. **1.3:** Strengthen detection and surveillance of problems with FDA-regulated products.
1.2: Improve prevention, detection, and response to foodborne illness outbreaks and other food and feed safety incidents.	**1.3:** Strengthen detection and surveillance of problems with FDA-regulated products. **1.4:** Improve response to identified and emerging problems with FDA-regulated products.
1.3: Strengthen the ability of consumers to play a proactive role in minimizing food safety risks.	**3.3:** Improve safety and health information provided to the public.
1.4: Enhance the safety of food and feed additives and dietary supplements.	**1.1:** Increase the use of regulatory science to inform standards development, analysis, and decision-making. **2.1:** Increase regulatory science capacity to effectively evaluate products. **2.2:** Improve the effectiveness of the product development process. **2.3:** Improve predictability, consistency, transparency, and efficiency of the review process. **3.2:** Improve patient and provider access to benefit-risk information about FDA-regulated products.
1.5 Strengthen existing partnerships with international, federal, state, local, tribal, and territorial agencies to improve the effectiveness and efficiency of the FDA's food safety program for government and industry.	**1.2:** Reduce risks in the manufacturing, production, and distribution of FDA-regulated products. **1.3:** Strengthen detection and surveillance of problems with FDA-regulated products.
2.1: Provide and support accurate and useful nutrition information and education so consumers can choose healthier diets consistent with the Dietary Guidelines for Americans and other evidence-based recommendations.	**3.1:** Strengthen social and behavioral science to help patients, consumers, and professionals make informed decisions about regulated products. **3.3:** Improve safety and health information provided to the public.

Note: A text version of this graphic is found immediately following this table.

APPENDIX A

CROSSWALK OF OBJECTIVES BETWEEN FVM PROGRAM AND FDA STRATEGIC PLANS

FY 2016–2025 FVM Program Strategic Objectives	FY 2014–2018 FDA Strategic Objectives
2.2: Monitor and assess emerging nutrition science as well as changes in the composition of foods in the marketplace in relation to the nutritional and health status of Americans.	**3.1:** Strengthen social and behavioral science to help patients, consumers and professionals make informed decisions about regulated products. **3.3:** Improve safety and health information provided to the public.
2.3: Encourage and facilitate new products and product reformulation to promote a healthier food supply.	**3.1:** Strengthen social and behavioral science to help patients, consumers, and professionals make informed decisions about regulated products.
3.1: Improve access to safe and effective animal drug products.	**2.1:** Increase regulatory science capacity to effectively evaluate products. **2.2:** Improve the effectiveness of the product development process. **2.3:** Improve predictability, consistency, transparency, and efficiency of the review process.
3.2: Reduce risks in the manufacturing, production, and distribution of FDA-regulated animal health products.	**1.2:** Reduce risks in the manufacturing, production, and distribution of FDA-regulated products.
3.3: Strengthen detection and surveillance of problems with FDA-regulated animal health products.	**1.3:** Strengthen detection and surveillance of problems with FDA-regulated products. **1.4:** Improve response to identified and emerging problems with FDA-regulated products. **3.2:** Improve patient and provider access to benefit-risk information about FDA-regulated products.
4.1: Achieve optimal risk-informed resource allocation throughout the FVM Program.	**4.2:** Improve the overall operation and effectiveness of the FDA.

APPENDIX A

CROSSWALK OF OBJECTIVES BETWEEN FVM PROGRAM AND FDA STRATEGIC PLANS

FY 2016–2025 FVM Program Strategic Objectives	FY 2014–2018 FDA Strategic Objectives
4.2*: Optimize the development and deployment of the FVM's scientific expertise and organizational capacity to better understand and detect hazards and devise preventive interventions.	**4.3:** Invest in infrastructure to enhance productivity and capabilities.
4.3: Attract, retain, and optimally deploy the skilled workforce required to lead, manage, and execute the FVM Program's public health mission.	**4.1:** Recruit, develop, retain, and strategically manage a world-class workforce.

* Includes activities related to FVM Program priority areas not covered under FVM Goals 1–3.

APPENDIX A

CROSSWALK OF OBJECTIVES BETWEEN FVM PROGRAM AND FDA STRATEGIC PLANS

(OPTIMIZED FOR SCREEN READERS)

FY 2016–2025 FVM Program Strategic Objectives / FY 2014–2018 FDA Strategic Objectives

1.1: Establish and gain high rates of compliance with science-based preventive control standards across the global farm-to-table continuum.

- **1.1:** Increase the use of regulatory science to inform standards development, analysis, and decision-making.
- **1.2:** Reduce risks in the manufacturing, production, and distribution of FDA-regulated products.
- **1.3:** Strengthen detection and surveillance of problems with FDA-regulated products.

1.2: Improve prevention, detection, and response to foodborne illness outbreaks and other food and feed safety incidents.

- **1.3:** Strengthen detection and surveillance of problems with FDA-regulated products.
- **1.4:** Improve response to identified and emerging problems with FDA-regulated products.

1.3: Strengthen the ability of consumers to play a proactive role in minimizing food safety risks.

- **3.3:** Improve safety and health information provided to the public.

1.4: Enhance the safety of food and feed additives and dietary supplements.

- **1.1:** Increase the use of regulatory science to inform standards development, analysis, and decision-making.
- **2.1:** Increase regulatory science capacity to effectively evaluate products.
- **2.2:** Improve the effectiveness of the product development process.
- **2.3:** Improve predictability, consistency, transparency, and efficiency of the review process.
- **3.2:** Improve patient and provider access to benefit-risk information about FDA-regulated products.

1.5 Strengthen existing partnerships with international, federal, state, local, tribal, and territorial agencies to improve the effectiveness and efficiency of the FDA's food safety program for government and industry.

- **1.2:** Reduce risks in the manufacturing, production, and distribution of FDA-regulated products.
- **1.3:** Strengthen detection and surveillance of problems with FDA-regulated products.

APPENDIX A

CROSSWALK OF OBJECTIVES BETWEEN FVM PROGRAM AND FDA STRATEGIC PLANS

(OPTIMIZED FOR SCREEN READERS)

2.1: Provide and support accurate and useful nutrition information and education so consumers can choose healthier diets consistent with the Dietary Guidelines for Americans and other evidence-based recommendations.

- **3.1:** Strengthen social and behavioral science to help patients, consumers, and professionals make informed decisions about regulated products.
- **3.3:** Improve safety and health information provided to the public.

2.2: Monitor and assess emerging nutrition science as well as changes in the composition of foods in the marketplace in relation to the nutritional and health status of Americans.

- **3.1:** Strengthen social and behavioral science to help patients, consumers and professionals make informed decisions about regulated products.
- **3.3:** Improve safety and health information provided to the public.

2.3: Encourage and facilitate new products and product reformulation to promote a healthier food supply.

- **3.1:** Strengthen social and behavioral science to help patients, consumers, and professionals make informed decisions about regulated products.

3.1: Improve access to safe and effective animal drug products.

- **2.1:** Increase regulatory science capacity to effectively evaluate products.
- **2.2:** Improve the effectiveness of the product development process.
- **2.3:** Improve predictability, consistency, transparency, and efficiency of the review process.

3.2: Reduce risks in the manufacturing, production, and distribution of FDA-regulated animal health products.

- **1.2:** Reduce risks in the manufacturing, production, and distribution of FDA-regulated products.

3.3: Strengthen detection and surveillance of problems with FDA-regulated animal health products.

- **1.3:** Strengthen detection and surveillance of problems with FDA-regulated products.
- **1.4:** Improve response to identified and emerging problems with FDA-regulated products.
- **3.2:** Improve patient and provider access to benefit-risk information about FDA-regulated products.

APPENDIX A

CROSSWALK OF OBJECTIVES BETWEEN FVM PROGRAM AND FDA STRATEGIC PLANS

(OPTIMIZED FOR SCREEN READERS)

4.1: Achieve optimal risk-informed resource allocation throughout the FVM Program.

4.2: Improve the overall operation and effectiveness of the FDA.

4.2*: Optimize the development and deployment of the FVM's scientific expertise and organizational capacity to better understand and detect hazards and devise preventive interventions.

4.3: Invest in infrastructure to enhance productivity and capabilities.

4.3: Attract, retain, and optimally deploy the skilled workforce required to lead, manage, and execute the FVM Program's public health mission.

4.1: Recruit, develop, retain, and strategically manage a world-class workforce.

* Includes activities related to FVM Program priority areas not covered under FVM Goals 1–3.

APPENDIX B

FDA FOODS AND VETERINARY MEDICINE PROGRAM STRATEGIC PLAN FRAMEWORK, FY 2016–2025

(OPTIMIZED FOR SCREEN READERS)

Vision

Protecting and enhancing the health of people and animals.

Mission

Promoting public health by preventing foodborne illness, fostering good nutrition, and improving the safety and efficacy of animal health products.

Food Safety

Protect America's consumers and animals from foreseeable hazards.

Outcome

Reduce the incidence of illnesses and deaths attributable to preventable contamination of FDA-regulated food and feed products.

Objectives

- Establish and gain high rates of compliance with science-based preventive control standards across the global farm-to-table continuum.
- Improve prevention, detection, and response to foodborne illness outbreaks and other food and feed safety incidents.
- Strengthen the ability of consumers to play a proactive role in minimizing food safety risks.
- Enhance the safety of food and feed additives and dietary supplements.
- Strengthen existing partnerships with international, federal, state, local, tribal, and territorial agencies to improve the effectiveness and efficiency of the FDA's food safety program for government and industry.

Nutrition

Foster an environment to promote healthy and safe food choices.

Outcome

Reduce risk factors for and the incidence of nutrition-related chronic disease.

Objectives

- Provide and support accurate and useful nutrition information and education so consumers can choose healthier diets consistent with the Dietary Guidelines for Americans and other evidence-based recommendations.

- Monitor and assess emerging nutrition science as well as changes in the composition of foods in the marketplace in relation to the nutritional and health status of Americans.
- Encourage and facilitate new products and product reformulation to promote a healthier food supply.

Animal Health

Protect human and animal health by enhancing the safety and effectiveness of animal health products.

Outcome

Reduce human and animal illness and death from FDA-regulated animal health products.

Objectives

- Improve access to safe and effective animal drug products.
- Reduce risks in the manufacturing, production, distribution, and use of FDA-regulated animal health products.
- Strengthen detection and surveillance of problems with FDA-regulated animal health products.

Organizational Excellence

Continuously improve the leadership, management, staffing, and organizational capacity of the FVM program to protect public health.

Outcome

Enable the FVM Program to optimize public health gains by making the best use of available resources.

Objectives

- Achieve optimal risk-informed resource allocation throughout the FVM Program.
- Optimize the development and deployment of the FVM Program's scientific expertise and organizational capacity to better understand and detect hazards and devise preventive interventions.
- Attract, retain, and optimally deploy the skilled workforce required to lead, manage, and execute the FVM Program's public health mission.

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