Republic of the Philippines
Department of Health
Department of Agriculture

SEP 2 4 2013

**JOINT DOH and DA ADMINISTRATIVE ORDER**
**No. 2013 – 0026**

**SUBJECT: RULES ON THE REGULATION OF VETERINARY DRUGS AND PRODUCTS, VETERINARY BIOLOGICAL PRODUCTS, AND VETERINARY DRUG ESTABLISHMENTS**

## I. RATIONALE

Republic Act No. 9711 or the "Food and Drug Administration Act of 2009" which further amended Republic Act No. 3720 otherwise known as the "Food, Drugs and Devices and Cosmetics Act", as amended by Executive Order No. 175 was enacted by Congress on August 18, 2009 with the objective of, *inter alia,* enhancing and strengthening the administrative and technical capacity of the Food and Drug Administration (FDA) in the regulation and monitoring of establishments and products under its jurisdiction including veterinary drugs and other health products.

Whereas, on September 25, 1991, a Memorandum of Agreement (MOA) was executed between the Department of Health –Bureau of Food and Drugs (now FDA) and Department of Agriculture- Bureau of Animal Industry (BAI) defining the functions of both agencies in the regulation of manufacture, distribution and registration of veterinary drug and products covered under Republic Act No. 3720, as amended.

Cognizant of the authority of the FDA to call upon the assistance of any department, office or agency under Section 30, paragraph 5 of RA 3720 as amended by RA 9711, the FDA and BAI agree and recommend to continue their partnership under the MOA to maintain the effectiveness of regulating existing establishments manufacturing, distributing and/or selling veterinary drugs and products and ensure efficient supply thereof in the market following the guidelines set forth herein.

## II. OBJECTIVES

1. To facilitate the licensing and registration and for the effective regulation of the manufacture, distribution, and monitoring of veterinary drugs and products, veterinary biological products, and establishments selling the same to avoid overlapping of regulatory functions of the FDA and BAI;

2. To set a policy direction in the licensing and registration of veterinary drugs and products, veterinary biological products and establishments selling the same used either exclusively for veterinary use or both for veterinary and human use.

## III. SCOPE

This Order shall cover veterinary drug and products, and veterinary biological products under the regulatory mandate of FDA and the establishments manufacturing, importing or distributing the same.

## IV. DEFINITION OF TERMS

For purposes of this Order, words, terms and phrases as used herein shall have the same definition as provided for under RA 3720 as amended by Republic Act No. 9711, Republic Act No. 1556, Republic Act No. 1071, and other existing laws, rules and regulations including but not limited to the following:

1. "Registration" refers to the process of approval for the manufacture, importation, exportation , sale, offer for sale, distribution, labeling, advertising or transfer of veterinary drugs and products obtaining active ingredient(s) of known chemical structures and properties determined to be safe, efficacious, and of good quality according to standards of Bureau of Foods and Drugs (BFAD)/Bureau of Animal Industry (BAI).

2. "Veterinary Drugs and Products" refer to any substance, including biological products, applied or administered to food producing, companion, aquatic, laboratory and exotic animals, whether used for therapeutic, prophylactic or diagnostic purposes or for modification of physiological functions or behaviors.

3. "Veterinary Drug and Product Establishment" refers to any organization or company involved in the manufacture importation, repacking, labeling, advertising and/or distribution of veterinary drugs and products.

3a. Veterinary Drug and Product Manufacturer refers to any establishment engaged in operations involved in the production of a drug including propagation, processing, compounding, finishing, filling repacking, labeling, advertising, storage, distribution or sale of the veterinary drug products proving that

for the purpose of this regulation the compounding and filling of prescription by drugstores shall not be considered as production operations.

3b. Veterinary Drug and Product Traders refers to any establishment which is a registered owner of the drug product, procures the raw materials and packaging components, and provides the production monographs, quality control standards and procedures, but subcontracts the manufacture of such veterinary drug and product to a licensed manufacturer. In addition a trader may also engage in distribution, and/or marketing of its veterinary drugs and products.

3c. Veterinary Drug and Product Distributor/Importer refers to any veterinary drug and product establishment that imports raw materials, active ingredients and/or finished products, for its own use or for wholesale or distribution to other drug establishments or outlets.

3d. Veterinary Drug and Product Distributor/Exporter refers to any veterinary drug and product establishment that exports raw materials, active ingredients and/or finished products to another country.

3e. Veterinary Drug and Product Distributor, Wholesaler refers to any veterinary drug and product establishment that procures raw materials, active ingredients and/or finished products from local establishments for local distribution on wholesale basis.

4. Veterinary Drug Outlet refers to drugstore, pharmacy, livestock and poultry supply store and other business establishments selling veterinary drugs and products

4a. Drugstore, Pharmacy and Botica and drug outlets where registered veterinary drugs and products, chemical products, active pharmaceutical, proprietary medicines or pharmaceutical specification are compounded and/or dispensed and hold executive veterinary hospitals, clinic and farm storage store where drugs and products are stored for their exclusive use.

4b. Veterinary and agricultural supply store, livestock and poultry supply stores and any other outlets selling prescription veterinary drugs and products.

4c. Retail outlet for non-prescription drugs including the traditional outlets such as supermarkets and stores means a drug outlet where registered non-prescription or over-the-counter (OTC) or self-service (SS) veterinary drugs and products are sold in their original packages, bottle or containers or in mail quantities nor in their original containers.

5. "Dosage Form" refers to the pharmaceutical form of the preparation based on an official pharmacopoeia.

## V. GENERAL GUIDELINES

The FDA shall continue to register veterinary drugs in pharmaceutical dosage forms except those intended for feeds and license the establishments manufacturing, distributing, importing, exporting, and selling the same.

The BAI shall continue to register veterinary drugs and products, veterinary biological products, intended solely for animal use and license the establishments manufacturing, distributing, importing, exporting, and selling the same.

## VI. SPECIFIC GUIDELINES

The functions of the Food and Drug Administration and Bureau of Animal Industry under this Order are specified as follows:

### A. Food and Drug Administration

A.1 Registration of Veterinary Drugs and Products:

The Food and Drug Administration (FDA) shall regulate the registration of the following veterinary drug and products:

A.1.1 Finished pharmaceutical dosage forms such as but not limited to:

a. Oral Dosage Forms such as; capsules, tablets, bolus, paste, powder for suspension, granules for suspension, powder, suspension, solutions, syrups, emulsions;

b. Injectables such as; solutions, suspensions, powder for injections, granules for injections, parenterals;

c. External Preparations such as; topical suspension, creams, ointments, lotions, aerosols, spray, pastes, gels, powders,

medicated soaps and shampoo, solutions, medicated collars and the like; and

d. Ophthalmic or otic creams, ointments, solutions or suspensions.

A.1.2 Active pharmaceutical ingredients and excipients intended for use as a component in the manufacture of the products mentioned in A.1.1.

A.2 Licensing of Veterinary Establishments:

The FDA shall regulate the licensing of manufacturers, traders, and/or distributors (importers, exporters, wholesalers) of the products classified in A.1 above.

A.3 Monitoring of Veterinary Drug and Products and Establishments

The FDA shall monitor the products and establishments identified in A.1 and A.2, respectively, except veterinary drug outlets.

A.4 Import Permit for Raw Materials and/or Active Pharmaceutical Ingredient (API)

The FDA shall issue import permits for imported active pharmaceutical ingredients and other raw materials intended for use as a component in the manufacture of the products mentioned in A.1.

**B. Bureau of Animal Industry**

B.1 Registration of Veterinary Drug Products

B.1.1 The Bureau of Animal Industry (BAI) shall regulate the following veterinary drugs and products:

a. Pre–mixes, water soluble powder and other preparations (but not limited to solution, suspension, granules, powder, emulsions) added to feeds or water, feed supplements, feed additives and other drinking / dipping solutions intended for mass medication for terrestrial and aquatic animals;

b. Veterinary vaccines, diagnostic kits and reagents, veterinary medical devices and other biological products;

c. Non-medicated soap and shampoo, toothpaste, colognes, conditioners, talc /dusting powder, coat shine oil, breath

freshener (dental sticks), plaque remover, mouth wash, coat deodorants (spray), beddings (ex. disposable litter paper, adsorbents, etc) and other grooming products;

d. Dips for animals and eggs;

e. Disinfectants that are intended for veterinary and aquaculture use including their environment or surroundings, facilities and equipments; and

f. Probiotics that are intended for animal facilities and/or environment including pond or pond water or deodorizer, absorbent, disinfectant, sanitizer, etc.

B.1.2. Active pharmaceutical ingredients and other raw materials intended for use as a component in the manufacture of the products mentioned in B.1.1 exclusively intended for veterinary use.

B.2 Licensing of Veterinary Establishment

The BAI shall regulate the veterinary drug manufacturers, traders, importers distributors, exporters, wholesalers and outlets of the products classified in B.1 above in compliance with existing applicable rules and regulations.

B.3 Monitoring of Veterinary Drug and Products and Establishments

The BAI shall monitor the products identified in B.1 and establishments under B.2 carrying the same. The BAI shall also be responsible for the regulation of veterinary outlets whether or not the same carries products classified in B.1.1.

B.4 Import Permit

The BAI shall issue import permits for all veterinary products classified in B.1 enumerated above and their respective API.

**C. Procedure And Requirements**

The DA-BAI shall adopt and use the existing rules of procedure and requirements or standards currently implemented by DOH-FDA for licensing and registration of veterinary drugs and products including applicable regulations related to generic labeling of veterinary drug products.

In the absence of applicable requirements, procedure or standards, the BAI shall provide for the technical input necessary and recommend the same to the FDA for the subsequent issuance of guidelines and policies.

**D. Continuing Collaboration of FDA and BAI**

The FDA and BAI through the Technical Working Groups (TWG) shall conduct activities and perform functions necessary for the effective implementation of this Order including the periodic review as provided in Item XI.

## VII. ADMINISTRATIVE ACTIONS AND PENALTIES

The BAI is called on to assist the FDA in the conduct of investigation and hearing of cases for any violations committed involving the manufacture, importation, distribution and sale of products and/or the establishments covered by this Order. For the effective implementation of any of the provisions in this Order, the FDA and BAI shall formulate within thirty (30) days the procedures following the Rules of Procedure provided in the Rules and Regulations Implementing Republic Act No. 9711.

The penalties imposable involving the products within the scope of this Order shall be as provided under Republic Act No. 9711.

## VIII. SUPPLETORY CLAUSE

The provisions of all existing and applicable laws shall be deemed suppletory to this Order.

## IX. REPEALING CLAUSE

This Order supersedes the previous Memorandum of Agreement between DOH-BFAD and DA-BAI executed on September 25, 1991.

## X. SEPARABILITY CLAUSE

Should any part of this Order be declared unconstitutional, all other remaining portions not so declared shall remain valid and in effect.

## XI. EFFECTIVITY AND DURATION

This Order shall take effect immediately after publication in a national newspaper of general circulation and filing with the UP Law Center. This

Order shall remain in force for a period of five (5) years or until sooner terminated by consensus of the parties. For the effective implementation of this Order periodic review shall be undertaken by the TWG for recommendations of any appropriate and future action.

## XII. TRANSITORY PROVISION

The current system and procedure of the respective agencies with respect to the licensing of establishments and registration of the products within the scope of this Order shall still be operative until such time that definite guidelines, rules and regulations have been established for the full implementation of this Order.

Department of Agriculture

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