

**[ JOINT DOH AND DA ADMINISTRATIVE ORDER  
NO. 2013-0026, September 24, 2013 ]**

**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
  - 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;