[DA DEPARTMENT OF AGRICULTURE ADMINISTRATIVE ORDER NO. 33 S. 1991, October 07, 1991]

DEPARTMENT OF HEALTH ADMINISTRATIVE ORDER NO. 111-A s. 1991

RULES AND REGULATIONS ON REGISTRATION OF VETERINARY DRUGS AND PRODUCTS

Pursuant to R.A. No. 3720, as amended by Executive Order No. 175 otherwise known as the "Foods, Drugs and Devices, and Cosmetics, R.A. No. 6675, otherwise known as the "Generics Act of 1988", R.A. 1556, otherwise known as the "Livestock and Poultry Feeds Act", R.A. 1071, an act to regulate the sale of veterinary biologics and medicinal preparations and R.A. 3101, an Act authorizing the Director of the Bureau of Animal Industry, subject to the approval of the Secretary of Agriculture and Natural Resources to promulgate regulations for the preparation, sale, traffic in, shipment, and importation of viruses, sera, toxins, or analogous products used for the treatment of domestic animals, the following requirements for the registration of veterinary drugs and products are hereby promulgated for the information, guidance and compliance of all concerned:

SECTION 1. Definition of Terms — For purposes of these Rules and Regulations, the following definitions are adopted:

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

1.2 **Veterinary Drugs and Products** refers 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 purpose or for modification of physiological functions or behaviors.

1.3 **Veterinary Drug for General Use** refers to a veterinary drug approved for sale for animal use without restriction other than the usual.

1.4 **Veterinary Drug for Restricted Use** refers to a veterinary drug approved for sale for animal use under certain conditions.

SECTION 2. General Standards —

2.1 Establishments applying to register a veterinary drug and product are required

to fully disclose all pertinent documentation and information regarding the veterinary drug and product. Failure to fully disclose material information about the veterinary drug and product is a ground for disapproval of registration application and one of the bases for withdrawal of the establishment's license to operate.

2.2 Action on registration application shall be based on the complete set of specifications of the veterinary drug and product proposed to appear on the label, *i.e.* formulation, dosage form, strength, therapeutic indications and manufacturer. Any change in any of the above specifications shall require a new registration.

2.3 Action on registration application shall include the classification of the veterinary drugs and products among each of the classification categories defined in *Section 3* below. Any change in classification shall require a new registration. However, any change in the name of the same manufacturer shall require proper notification of BFAD/BAI.

2.4 The standards of veterinary drug and product registration as well as the methods of evaluation are subject to revisions. Any major change shall be made after proper consultation with the parties concerned. Revised standards and evaluation methods shall be made applicable to all covered veterinary drugs and products as appropriate.

2.5 Only establishments with valid license to operate, required under joint Administrative Orders No. 100 Department of Agriculture, and No. 186, Department of Health, series 1990 can apply to register veterinary drug and products.

SECTION 3. Classification — All veterinary drugs and products shall be evaluated and registered on the basis of specific requirements and standards pertinent to the classification of such veterinary drugs and products. All registered veterinary drugs and products shall be classified in terms of each of the following categories.

3.1 **Number of active ingredients**

3.1.1 Single active ingredient

3.1.2 Fixed-dose combination of two or more active ingredients

3.2 **Available scientific and product's evidence and experience on the veterinary drug use.**

3.2.1 **Investigational Veterinary Drugs and Products** refers to any new chemical or structural modification of Tried and Tested or Established Veterinary Drug and Product proposed to be used for a specific therapeutic indication. Investigational veterinary drug and product need further clinical pharmacology studies (Phase I, II, or III) to determine their safety and efficacy, and meet the requirements of new veterinary drugs and products.

3.2.2 **New Veterinary Drug and Product** refers to any new chemical or structural modification of Tried and Tested or Established Veterinary Drugs and Products proposed to be used for a specific therapeutic indication, which have undergone adequate clinical

pharmacology Phase I, II, and III studies but which need further Phase IV Clinical Pharmacology studies before they can be given regular registration.

3.2.3 **Tried and Tested Veterinary Drugs and Products** refers to any veterinary drug and product which has been used for at least five (5) years.

3.2.4 **Established Veterinary Drug and Product** refers to veterinary drug and product, the safety and efficacy of which have been demonstrated through long years of general use and can be found in current official USP-NF, and other internationally-recognized pharmacopeias.

3.2.5 **Pharmaceutical or Therapeutic Innovation of Tried and Tested or Established Veterinary Drug and Product** includes any or all of the following:

3.2.5.1 An innovation involving use for new indication(s)

3.2.5.2 An innovation involving a new mode of administration

3.2.5.3 An innovation involving a new dosage form

3.2.5.4 An innovation involving a new fixed dose combination of two or more ingredients.

3.3 Pharmacologic/therapeutic category as specified in the Philippine National Veterinary Drug Formulary (See Joint A.O. DOH-No. 100 and DA-No. 138 s. 1990).

3.4 **Source of circumstance of veterinary drug and product production**

3.4.1 Imported as finished

3.4.2 Locally manufactured from imported materials

3.4.3 Locally manufactured from local materials

3.5 Brand identification and patent protection of the veterinary drug and product.

3.5.1 Branded and patented

3.5.2 Branded and off-patent

3.5.3 Unbranded and off-patent (generic veterinary drug and product)

3.6 Prescribing and dispensing regulations applicable

3.6.1 Over-the-counter (OTC) Veterinary Drugs and Products or Non-prescription/Veterinary Drugs and Products or Self Service (SS) Veterinary Drugs and Products.