[DA ADMINISTRATIVE ORDER NO. 11, April 15, 1991]

REQUIREMENT FOR LABELLING MATERIALS OF VETERINARY DRUGS AND PRODUCTS [*]

Pursuant to R.A. 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 preparation and R.A. 3101, an Act authorizing the Director 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 labelling 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 this Regulation the terms:

1.1 **Labelling materials** refer to the label on the immediate container and package and other printed materials that are made available with the veterinary drug and product at the time of purchase and/or where the veterinary drug and product is used, such as the outer wrapper cartons, leaflet/package insert accompanying the product, which provide the accurate and necessary detailed information for the identification and proper use of the veterinary drug and product.

1.2 **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 behavior.

1.3 **Brand Name** refers to the proprietary/trade name assigned to the veterinary drugs and products by the veterinary drug and product establishment.

1.4 **Generic Terminology** refers to the identification of veterinary drugs and products by their scientifically and internationally recognized active ingredient as determined by the Bureau of Food and Drugs of the DOH/Bureau of Animal Industry of the DA. In case of feed products containing veterinary drugs and products, **generic name** refers to the internationally recognized technical name of the feeds as determined by the Bureau of Animal Industry of the Department of Agriculture.

1.5 **Philippine National Veterinary Drug Formulary (PNVDF)** refers to the classification and listings of the veterinary drug and product.

1.6 **Formulation** refers to the name(s) and amount(s) of ingredients per unit quantity expressed in the metric system.

1.7 **Indication** refers to the approved clinical and non-clinical use of the veterinary drug and product in terrestrial and aquatic animals based on substantial scientific evidence of the safety and efficacy in the given dosage form.

1.8 **Dosage Form** refers to the pharmaceutical form of the preparation based on an official pharmacopoeia.

1.9 **Mode of Administration** refers to the site and manner by which the product is to be introduced to animal.

1.10 **Warning** refers to statements regarding the withdrawal period of the product before the animal is slaughtered for food and/or the occurrence of potential hazard and side effects associated with the use of the product and the limitation of its use.

1.11 **Contraindications** refer to statements of conditions under which veterinary drug and product should not be used.

1.12 **Caution** refers to the instructions and special procedures required in the use and handling of the veterinary drug and product to avoid undesired effects and to ensure the safety and effective use of the veterinary drugs and products.

1.13 **Antidote** refers to a specific substance or combination of substances that would counteract the effect of any undue reaction and overdosage.

1.14 **Veterinary Prescription or Ethical Drugs** refer to any drug preparation that is to be dispensed only upon written order of a duly-licensed veterinarian for the treatment of a condition or a diagnosed disease of animals.

1.15 **Medicated Feed** refers to any feed which contains drug ingredients intended or represented for the cure, mitigation, treatment or prevention of diseases of animal other than man or which contains drug ingredients intended to affect the structure or any function of the body of animal other than man.

1.16 **Medicated Feed Premix** refers to a uniform mixture of one or more drug micro-ingredients with diluent and/or carrier. Premixes are used to facilitate uniform dispension of the micro-ingredients in a larger mix.

1.17 **Medicated Feed Supplement** refers to a drug ingredient or mixture of drug ingredients intended to supply the deficiencies in a ration

or improve the nutritive balance or performance of the total mixture. It is intended to be:

a. fed undiluted as a supplement to other feeds;

b. offered free choice with other parts of the ration separately available; and

c. further diluted and mixed to produce a complete feed.

1.18 **Medicated Feed Additive** refers to a drug ingredient or combination of drug ingredients added to the basic feed mix or parts thereof to fulfill a specific need. Usually mixed in micro quantities and requires careful handling and mixing.

1.19 **Medicated Water Additive** refers to a drug ingredient or combination of drug ingredients added to basic drinking water or parts thereof to fulfill a specific need.

1.20 **Date of Manufacture of Veterinary Drugs and Products other than Veterinary Biological Products and Medicated Feeds** refers to the month and year during which the processing of the bulk product, from which the processing of the bulk product, from which the veterinary drug and product are packaged, is completed. Bulk product refers to the batch of the finished product.

1.21 **Batch Number** refers to any distinctive combination of letters and/or numbers, assigned to a particular batch herein defined as any product produced during a given cycle of manufacture.

1.22 **Lot Number** refers to any distinctive combinations of letters and/or numbers assigned to a particular lot, herein defined as a portion of batch.

1.23 **Expiration or Expiry date** refers to the date after which the product is not expected to retain its claimed safety, efficacy, quality and potency and after which it is not permissible to sell, distribute or use said products.

1.24 **Net Content** refers to the total amount/quantity/number of the dosage form in a certain container of a veterinary drug and product expressed in metric system.

1.25 **Storage Conditions** refer to the specified temperature, humidity and other environmental factors within which optimal stability of the veterinary drug and product is ensured.

1.26 **Principal display panel** refers to the part of the label that is most likely to be displayed, presented, shown or examined under customary conditions of display for retail sale.

1.27 **Area of the principal display panel** refers to the area of surface

of the container/package where the principal display panel is located.

1.28 **Primary Pack** refers to the first pack sustaining the individually wrapped products, strip or blister packs.

1.29 **Information Panel** refers to that part of the label other than the principal display panel.

SECTION 2. General Requirements

2.1 The minimum mandatory information that shall be included in the labelling materials is:

- 2.1.1 Name of the product (Generic name alone or with Brand name, as the case may be) For veterinary use only.
- 2.1.2 Dosage form and strength
- 2.1.3 Pharmacologic category
- 2.1.4 Rx symbol, in case of prescription drugs
- 2.1.5 Name and complete address of manufacturer and when applicable the trader.
- 2.1.6 Registration number (BFAD and/or BAI)
- 2.1.7 For veterinary use only
- 2.1.8 Net content
- 2.1.9 Formulation
- 2.1.10 Indication(s)
- 2.1.11 Contraindication(s)
- 2.1.12 Precaution(s)
- 2.1.13 Warning(s)
- 2.1.14 Antidote (if any)
- 2.1.15 Mode of administration/direction for use
- 2.1.16 Batch and lot number
- 2.1.17 Expiry/expiration date and date of manufacture
- 2.1.18 Storage conditions
- 2.1.19 For Rx products, Foods, Drugs and Devices and Cosmetics Act prohibits dispensing without prescription of a duly licensed Veterinarian

2.2 All information required to appear on the label must be:

- 2.2.1 Written in English or Filipino.
- 2.2.2 Readable with normal vision without straining. The color contrast, the position and spacing of the information must be taken into consideration in complying wit the labelling requirements.

2.3 The principal display panel must:

- 2.3.1 Contain the particulars required under 2.1.1 to 2.1.8
- 2.3.2 Comprise 40% of the total surface of the container, except in the case of a rectangular container where the total area of the principal display panel must be equal to the product of the height and width of the entire side of the container. For any other shaped container presenting an obvious principal display panel such as

the top of a triangular or circular container, the size of the area shall consist of the entire top surface.

2.4 On the Information panel of the label the following shall appear:

2.4.1 Formulation

2.4.2 Indication(s)

2.4.3 Mode of administration/direction for use

2.4.4 Batch and lot number

2.4.5 Expiry/expiration date and date of manufacture

2.4.6 Storage conditions

2.4.7 (For Rx) Foods, Drugs and Devices and Cosmetics Act prohibits dispensing without prescription by a licensed veterinarian.

2.4.8 Warning/caution statements (if necessary)

2.5 Other information and additional details shall (i.e. warning(s), precaution(s) and antidote(s)) appear on the other labelling materials such as inserts/leaflets or wrapper cartons.

SECTION 3. Specific Requirements

3.1 Name of the product

3.1.1 In all cases, the generic name shall be the prominently printed element on the label, defined as the one with the highest point size among the various printed elements on the label. It shall be enclosed exclusively by an outlined box rendered in the same color as the generic name. The background color inside the box, against which the generic name is rendered, should be the same color as the background color outside the box, against which the brand name is rendered.

3.1.2 In all cases, the generic name shall be printed in full, not abbreviated and in accordance with the International Non-proprietary Name (INN). In case the salt is to be indicated this must be included inside the box but in smaller point size.

3.1.3 If a product is identified by generic name together with its brand name the following shall be required in addition to 3.1.1 and 3.1.2.

3.1.3.1 The generic name and brand name shall be rendered using the same typeface, boldness, font and color, with the generic name appearing immediately above the brand name and rendered in a point size bigger than the brand name.

3.1.3.2 If a brand name is presented using a special typeface exclusively designed and used for it, the generic name shall be rendered in Helvetica or Universe typeface while complying with the other pertinent provisions above.