[BAI DEPARTMENT OF AGRICULTURE ADMINISTRATIVE ORDER NO. 39, S. 1991, October 15, 1991]

DEPARTMENT OF HEALTH ADMINISTRATIVE ORDER NO. 111-B, S. 1991

RULES AND REGULATIONS TO IMPLEMENT PRESCRIBING REQUIREMENTS FOR THE 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 Act", R.A. No. 6675, otherwise known as the "Generics Act of 1988", R.A. 382 known as the "Veterinary Practice Act", R.A. 5921 known as the "Pharmacy Act", R.A. 6425 known as the "Dangerous Drugs Act of 1972" as amended, 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 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 are hereby promulgated for the information, guidance and compliance of all concerned:

SECTION 1. Definition of Terms —

1.1. **Prescription** refers to the written order and instruction to the pharmacist by a duly-licensed veterinarian for the use of a specific veterinary drug and product for a specific species of animal. For the purpose of these Rules and Regulations, the Veterinary Drug Order (VDO) for the use of specific drug(s) shall be considered a prescription.

1.2 **Generic Prescribing** refers to the prescribing of veterinary drugs and products or medicines using their generic name(s) or generic terminology.

1.3 **Dispensing** refers to the act by a duly-licensed pharmacist and/or veterinarian of filling a prescription or veterinary drug order.

1.4 **Generic Dispensing** refers to dispensing the client's/buyer's choice from among generic equivalents.

1.5 **Generic Name or Generic Terminology** refers to the identification of drugs and medicines by their scientifically and internationally recognized active ingredients or by their official names as determined by the Bureau of Food and Drugs of the Department of Health and the Bureau of Animal Industry of the Department of Agriculture.

1.6 **Veterinary Drugs** refer to: (1) articles recognized in the current official United States Pharmacopoeia (USP), National Formulary (NF), official homeophatic pharmacopeia of the United States, official Philippine National Veterinary Drug Formulary (PNVDF), or any supplement to any of them; and (2) articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in terrestrial and aquatic animals; and (3) articles (other than food) intended to affect the structure or function of the animal body; and (4) articles intended for use as a component of any article specified in clauses (1), (2) or (3) but do not include devices or their components, parts or accessories.

1.6.1 **Prescription or Ethical Veterinary Drugs and Products** 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. Such preparation are labelled Rx. The general list of prescription or ethical veterinary drugs and products is found in List C (Annex C).

1.6.2 **Non-prescription Veterinary Drugs or Over-the-Counter Veterinary Drugs (OTC) or Self-Service Veterinary Drugs (SS)** refer to drug preparations that can be approved for animal use, even without the written order of a duly-licensed veterinarian.

1.7 **Veterinary Drug Products** refer to the finished forms that contain the active ingredient(s), generally, but not necessarily in association with inactive ingredients.

1.8. **Dangerous Drugs** refer to either prohibited drugs or regulated drugs which require a special prescription from, the use of which is monitored by the Dangerous Drugs Board.

1.8.1. **Prohibited Drugs** refer to opium and its derivatives such as heroin and morphine; coca leaf and its derivatives, principally cocaine, alpha and beta eucaine; hallucinogenic drugs, such as mescaline, lysergic acid diethylamide (LSD) and other substances producing similar effects; Indian hemp and its derivatives; all preparations made from any of the foregoing and other drugs, whether natural or synthetic, with the physiological effects of a narcotic drug.

1.8.2. **Regulated Drugs** refer to sleep-inducing sedatives, such as secobarbital, phenobarbital, barbital, amobarbital and other drugs which contain a salt or derivative of a salt, isomer or salt of an isomer of amphetamine, such as benzedrine or dexedrine, or any drug which produces a pharmacologic action similar to amphetamine; and hypnotic drugs such as methaqualone, or any other compound producing similar pharmacologic effects.

1.9 Definitions of different types of veterinary drug and product outlets:

1.9.1 Drugstores, pharmacy and **botica** are drug outlets where registered veterinary drugs and products, chemical products, active principles, proprietary medicines or pharmaceutical specialties are compounded and/or dispensed and sold excluding

veterinary hospitals, clinic and farm storage areas where drugs and products are stored for their exclusive use.

1.9.2 **Veterinary and Agricultural Supply Store, Livestock and Poultry Supply Store** are outlets selling prescription veterinary drugs and products.

1.9.3 **Retail-outlet for non-prescription drugs** including non-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 smaller quantities not in their original containers.

Standards and requirements for License to Operate (LTO) a veterinary drug and product outlet are found in D.A. A.O. No. 138 and DOH A.O. No. 100 Regulations for the Licensing of Veterinary Drug and Product Establishments and Outlets.

1.10 **Veterinarian-Client-Patient Relationship (VCPR)** (Annex F)* the VCPR is a written agreement between the client and veterinarian wherein the following conditions have been met:

a. The veterinarian has assumed the responsibility for making clinical judgments regarding the health of the animal(s) and the need for medical treatment, and the client has agreed to follow the veterinarian's instructions.

b. The veterinarian has sufficient knowledge of the animal(s) to initiate at least a general or preliminary diagnosis of the medical condition of the animal(s). This means that the veterinarian has recently seen and is personally acquainted with the keeping and care of the animal(s) by virtue of examination of the animal(s) or by medically appropriate and timely visits to the premises where the animal(s) are kept.

c. The veterinarian is readily available for follow-up evaluation in the event of adverse reactions or failure of the treatment regimen.

1.11 **Veterinary Drug Order** (Annex F) is a written instruction (prescription) to pharmacists or of veterinary drug establishment to fill a veterinary prescription of large quantities a specific veterinary drug and product provided that there is an accompanying VCPR letter (see Annex F) from the prescribing veterinarian. VCPR is required when prescribing for ten (10) or more animal units.

SECTION 2. Guidelines on Prescribing Based on Prior Laws — Prior to the Generics Act of 1988, the following general guidelines on prescribing have been operative. In order to have an integrated implementation of all relevant guidelines on prescribing, these guidelines based on prior laws are restated hereunder:

2.1 Only duly-licensed veterinarians, whether in private practice or employed in a private institution/corporation or in the government, are authorized to prescribe drugs. Prescribing by unauthorized persons constitutes illegal practice of veterinary medicine punishable under R.A. 382 or the Veterinary Practice Act.

2.2 In accordance with R.A. 5921, or the Pharmacy Act as amended, all prescriptions (Annex G)* must contain the following information: name of prescriber, office and address. In addition to the above requirements the following shall be included: professional registration number, professional tax receipt number, patient's/client's name, date of prescription, species and number of animal treated and: name (in generic), strength, unit size and quantity of the veterinary drug product to be delivered/dispensed.

2.3 For drugs in List A (Annex A) containing the list of Prohibited Drugs and Regulated Drugs as approved by the Dangerous Drugs Board (DDB), the following are required:

2.3.1 The prescriber must have an S-2 license.

2.3.2 The special DDB prescription form must be used.

2.3.3 A recording system following pertinent DDB regulations must be observed.

SECTION 3. Additional Guidelines on Prescribing — In addition to the guidelines contained in section 2, the following shall specifically guide prescribing under the Generics Act of 1998;

3.1 Generic names shall be used in all prescriptions.

3.1.1 For veterinary drugs and products with a single active ingredient, the generic name of that active ingredient shall be used in prescribing.

3.1.2 For drugs with two or more active ingredients, the generic name as determined by BFAD/BAI shall be used in prescribing.

3.2 The generic name must be written in full but the salt or chemical form may be abbreviated.

3.3 The generic name of the veterinary drug and product ordered must be clearly written on the prescription immediately after the Rx symbol.

3.3.1 If written on a prescription pad, the brand name enclosed in parenthesis may be written after the generic name.

3.4 In prescribing veterinary drugs and products enumerated in List B (Annex B) which need strict precaution in their use, the prescriber must comply with the following:

3.4.1 After the Rx symbol but before the generic name, he must write clearly "(list B)".

3.4.2 He must ensure that the following informations are accurately written on the prescription: