[DA ADMINISTRATIVE ORDER NO. 138 S. 1990, December 10, 1992]

DOH ADMINISTRATIVE ORDER NO. 100 s. 1990

REGULATION FOR THE LICENSING OF VETERINARY DRUG AND PRODUCT ESTABLISHMENTS AND OUTLETS

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. 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 requirements for the licensing of veterinary drug and product establishments and outlets are hereby promulgated for the information, guidance and compliance of all concerned.

In accordance with the above laws, any organization company or business establishment in the veterinary drugs and products industry shall fall under the following general classification:

I. **Veterinary Drug and Product Establishment** refers to any organization or company involved in the manufacture, importation, repacking, labelling, advertising or distribution of veterinary drugs and products. This is covered by **Chapter I** below.

II. **Veterinary Drug Outlet** refers to drugstore, pharmacy, livestock and poultry supply store, and other business establishments selling veterinary drugs and products. This is covered by **Chapter II** below.

Chapter I
Veterinary Drug and Product Establishments

1. *Definition of Different Types of Veterinary Drug and Product Establishments*

1.1 **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, labelling, advertising, storage distribution or sale of the veterinary drug product: provided that for the purpose of this regulation the compounding and filling of prescription by drugstores shall not be considered as production operations.

1.2 **Veterinary Drug and Product Trader** 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 sub-contracts the manufacture of such veterinary drug and product to a licensed manufacturer. In addition, a trader may also engage in distribution, and marketing of its veterinary drugs and products.

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

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

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

2. *Standards and Requirements for License to Operate (LTO)*

2.1 **General Requirements**

2.1.1 Application — any person desiring to operate or establish a veterinary drug and product establishment shall file with the BFAD/BAI an application supported by the following documents:

2.1.1.1 A standard petition form containing among others the name, age, citizenship, and a passport-size picture (5 x 5 cm) of the petitioner and other pertinent circumstances pertaining to the proposed veterinary drug and product establishment including the place where it is to be established.

2.1.1.2 Proof of registration as an establishment, *i.e.*:

a) For single proprietorship; an authenticated photocopy of the Certificate of Business Name Registration issued by the Bureau of Domestic Trade (BDT) of the Department of Trade and Industry.

b) For partnerships, corporations and other juridical persons, authenticated photocopies of the Certificate of Registration issued by the Securities and Exchange Commission (SEC) and the Articles of Incorporation or Partnership.

2.1.1.3 A valid Certificate of Registration of the establishment's Filipino Veterinarian issued by the Professional Regulation Commission (PRC).

2.1.1.4 A valid Certificate of Registration of the establishment's Filipino Pharmacist issued by the Professional Regulation Commission

(PRC).

2.1.1.5 A valid credential of the establishment's Filipino Microbiologist in case of veterinary biological manufacturer and trader.

2.1.1.6 A certificate of Attendance at a BFAD/BAI sponsored/accredited Seminar on Licensing of Veterinary Drug and Product Establishments;

2.1.1.7 An affidavit of undertaking providing that the applicant shall:

a) change the establishment's name if there is already a validly registered name similar to it.

b) display the duly approved LTO in a conspicuous place within the establishment.

c) notify BFAD/BAI in case of any change in the circumstances described in the application, among others; change of location, change of veterinarian, change of pharmacist, change in veterinary drugs and products.

2.1.1.8 An authenticated photocopy of Contract of Lease for the space to be occupied if the applicant does not own it.

2.1.2 A certificate of continuing compliance with specific technical requirements (to be specified by BFAD/BAI according to Section 2.2 below).

2.1.3 A Batch Distribution Record Book duly registered with BFAD/BAI.

2.1.4 A contingency plan or procedure for a systematic, effective and prompt recall in case any of its products is found violative and ordered recalled from the market by BFAD/BAI.

2.1.5 An orderly and secure system of filing up-to-date invoices from suppliers and buyers identifying lot numbers or batch numbers of manufacturers stock pursuant to BFAD Memo Circular No. 001 s. 1983.

2.2 **Specific Requirements** — An entity applying for a LTO as a veterinary drug and product manufacturer or veterinary drug and product trader or veterinary drug and product distributor shall be required to demonstrate its capacity to perform adequately as such in a manner that satisfactorily assumes the safety, efficacy, and quality of its veterinary drugs and products. It shall be required to conform with the following relevant standards and requirements specific for each category, in addition to the above general requirements.

2.2.1 Veterinary Drug Manufacturers —

2.2.1.1 Guidelines on Current Good Manufacturing Practices (GMP) provided for under A.O. No. 220 s. 1974, as amended including location, building and floor plans, and any additional guidelines issued by BFAD.

2.2.1.2 Minimum standards for pharmaceutical manufacturing equipment/machines owned by the manufacturers described in Annex A*

2.2.1.3 Minimum standards for quality control facilities owned by the manufacturers described in Annex B*

2.2.1.4 If importing raw materials, active ingredients and/or finished products for use in manufacture of veterinary drug and products, a certificate that the manufacturer is registered in the country of origin, duly authenticated by the territorial Philippine Consulate, and evidence that the manufacturer meets BFAD/BAI standards for local manufacturers. If inspection of the foreign manufacturer by BFAD/BAI is necessary, the cost of inspection shall be borne by the applicant establishment. However, in lieu of the above, a Certification Scheme from WHO or from an acceptable equivalent drug regulatory agency or organization.

2.2.2 Veterinary Biological Manufacturers —

2.2.2.1 Guidelines on Current Good Manufacturing Practices (GMP) provided for under A.O. No. 220 s. 1974, as amended including location, building and floor plans, and any additional guidelines issued by BFAD, Administrative Order No. 9, issued by BAI and other guidelines as required by NDC and other agencies.

2.2.2.2 Minimum standards for veterinary biological manufacturing equipment/machine described in Annex C*.

2.2.2.3 Minimum standards for quality control facilities described in Annex D*.

2.2.2.4 If importing raw materials, active ingredients and/or finished products for use in manufacture of veterinary drug and products, a certificate that the manufacturer is registered in the country of origin, duly authenticated by the territorial Philippine Consulate, and evidence that the manufacturer meets BFAD/BAI standards for local manufacturers. If inspection of the foreign manufacturer by BFAD/BAI is necessary, the cost of inspection shall be borne by the applicant establishment.

2.2.3 Veterinary Medicated Feeds, Medicated Feed Premix, Medicated Feed Supplement, Medicated Feed Additive and Medicated Water Additive Manufacturer - Medicated Feed refers to any feed which contains drug ingredients intended or represented for the cure, mitigation, treatment or prevention of diseases of animals other than man or which contains drug ingredients intended to affect the structure or any function of the body of animal other than man.

2.2.3.1 Relevant Guidelines on Current Good Manufacturing Practices (GMP) provided for under A.O. No. 220 s. 1974, as amended including location, building and floor plans, and any additional guidelines issued by BFAD and Administrative Order No. 35 issued by BAI.

2.2.3.2 Minimum standards for Veterinary Medicated Feed Manufacturing equipment/machines described in Annex E.*

2.2.3.3 Minimum standards for quality control facilities described in Annex F* whether owned or contracted by the manufacturer provided the contracted quality control facility is accredited by BAI.

2.2.3.4 If importing raw materials, active ingredients, or finished products for use in manufacture of veterinary drugs and products, a certificate that the manufacturer is registered in the country of origin, duly authenticated by the territorial Philippine Consulate, in the absence of the Consulate any equivalent government regulatory agency and evidence that the manufacturer meets BFAD/BAI standards for local manufacturers. If inspection of the foreign manufacturer by BFAD/BAI is necessary, the cost of inspection shall be borne by the applicant establishment.

2.2.4 Veterinary Drug and Product Traders —

2.2.4.1 A valid contract of agreement with a BFAD/BAI licensed manufacturer containing a stipulation that both the veterinary drug trader and the manufacturer are jointly responsible for the quality of the veterinary drug and product;

2.2.4.2 If importing raw materials, active ingredients, or finished products for use in the manufacture of veterinary drug and product, a certificate that the manufacturer is registered with the country of origin, duly authenticated by the territorial Philippine Consulate, any equivalent regulatory government agency and evidence that the manufacturer meets BFAD/BAI standards for local manufacturers. If inspection of the foreign manufacturer by the BFAD/BAI is necessary, the cost of inspection shall be borne by the applicant establishment.

2.2.4.3 A description of the production process and quality control procedures to be followed by the contracted manufacturer, jointly certified by the owner and the pharmacist of the veterinary drug and product establishment.

2.2.5 Veterinary Drug and Product Distributors —

2.2.5.1 Importers;

2.2.5.1.1 Foreign Agency Agreement between the Philippine importer and foreign supplier duly authenticated by the territorial Philippine Consulate, in the absence of the Consulate, any equivalent regulatory government agency.

2.2.5.1.2 A certificate that the manufacturer of the raw material, active ingredient, or finished product is registered in the country of origin, duly authenticated by the territorial