[BAI ADMINISTRATIVE ORDER NO. 15, July 11, 1991]

REQUIREMENTS AND GUIDELINES FOR THE ESTABLISHMENT AND OPERATION OF VETERINARY BIOLOGIC MANUFACTURING AND REPACKING INSTITUTIONS IN THE PHILIPPINES

Pursuant to Republic Act No. 3101, Republic Act No. 3720, Republic Act No. 1071, and A.O. No. 9, Series of 1982, A.O. No. 138 Series of 1990 the following guidelines, criteria, standards and requirements governing the establishment and operation of veterinary biologic manufacturing and repacking institution in the Philippines are hereby promulgated for the guidance of all concerned.

Article I
General Provisions

SECTION 1. Title - This order shall be known as the Philippine Rules and Regulations on the Establishment and Operation of Veterinary Biologics Manufacturing and Repacking Institutions of 1991

SECTION 2. Scope - This order shall apply to all establishments, public or private which manufacture, produce or repack, rebottle or reconstitute any veterinary biologics either for sale, experiment and distribution for the purpose of treating, preventing and diagnosing livestock and poultry diseases in the Philippines.

SECTION 3. Objectives - This order shall have the following objectives.

a. Set standards and criteria for the production or manufacture and repacking of veterinary biologics in the Philippines.

b. Provide criteria and guidelines on the establishment of operation of veterinary biologics manufacturing and repacking concerns and institutions in the Philippines.

c. Ensure the veterinary biologics manufactured, repacked or otherwise processed in the Philippines are safe and of high quality.

SECTION 4. Definition of Terms - For the purpose of this order the following terms and phrases as herein used shall mean:

a. **Veterinary Biologic Establishment License** refers to an establishment license issued by the BAI authorizing the use of the designated premises for production of biological products specified for one or more unexpired, unsuspended and unrevoked product licensed establishment.

b. **Veterinary Biological Product License.** A document referred to as a product license issued to the holder of an establishment license which authorizes production

of a specified biological product in the license establishment.

c. **Veterinary Biological Product.** These words also referred to as veterinary biologics or biological products shall mean all viruses, bacteria, live microorganisms, killed microorganisms, components or product of microorganisms, antisera and other similar substances whether of natural or synthetic origin, intended for use in the diagnosis, therapy for prophylaxis of diseases of animals, prevention, or for identification of the causative organisms of a disease of animals.

d. **Microorganism** - also referred to as organisms, shall mean any virus , bacteria, protozoa, and other minute parasites which cannot be seen by naked eye and have the capability of causing or disseminating disease in animals.

e. **Preparation of microorganisms veterinary for veterinary use** - also referred to as "preparation" or production" means the processes through which an organism is rendered innocuous and made usable for the treatment, diagnosis and prophilaxis of animal diseases.

f. **Animals** refers to horses, mules, cattle, carabao, buffaloes, sheep, goats, swine, cats, dogs, poultry; wild animals such as deer, wild hogs, zoo animals; show and circus animals; household pets; specialty pets; aquatic animals; laboratory animals use for diagnostic and experimental purposes; and other species not including humans, wherein biological products are used.

g. **Autogenous Biologic** - also referred to as autogenous vaccine or autogenous biological product means any vaccine processed or manufactured from microbial isolates from a specific animal source and/or the infected tissues of the same, and thereafter used as treatment or prophylaxis for the same disease conditions) of animals belonging to the same farm herd of flock as the original source of the products and for exclusive use of the farm and not for sale or commercial distribution. Autogenous biological is classified as experimental biological product.

h. **Experimental Biological Product** refers to new biological product which is being evaluated to substantiate an application for a product license, the composition of which is different from that of already licensed biological product.

i. **Pure or purity** - refers to the quality of a biological product prepared in its final form of being free of extraneous microorganisms or other materials (organic or inorganic), as determined by quality control test.

j. **Safe or safety** refers to a quality of a biologic of being free from properties that cause undue local or systemic reactions when used as recommended or in standard Quality Control test.

k. **Sterile or sterility** refers to freedom from viable contaminating microorganisms as demonstrated by standard procedures and criteria of LSD Quality Control.

l. **Potent or potency** refers to the relative strength of a biological product as measured by standard Quality Control test of the LSD.

m. **Efficacious or efficacy** refers to specific ability or capability of biological product to effect or produce the result for which it is offered when used under

conditions recommended by the manufacturer.

n. **Stable or stability** refers to the quality of a biological product of maintaining an assured degree of potency and efficacy within a specified amount of time after the production date, usually defined as its viable shelf life. Stability is usually measured under normal storage conditions; however, stability under room temperature and at 37 C may also be required.

o. **Identity** refers to the quality of biological product of containing only the specifically declared organisms or antigens, as determined by the quality control tests. This can be analogous to purity in some instances.

p. **Duration of immunity** refers to the length of time that a certain vaccine given to an animal according to recommended conditions would afford sufficient protection against virulent challenge of homologous or specifically related organisms.

q. **Consistency of production** refers to the quality of a biological product which has been processed through the same procedures, or having relatively the same degree of stability, safety, efficacy, potency and general physical properties.

r. **Batch** - the total quantity of completed product which has been thoroughly mixed in a single container and identified by a batch number.

s. **Batch number** - number or numbers and letters used to identify and distinguish one serial from another.

t. **Manufacturing process** refers to the complete chain of procedural events which a biological preparation undergoes starting from the propagaton from seed stock up to the final packaging.

u. **Repacking orrepackaging** - also referred to as rebottling means the filling and bottling procedures used with regards to biological preparation that was previously processed and standardized in another establishment other the Biological Establishment presently handling it. This process could essentially involve reconstitution of the processed product.

v. **Quality control** refers to the test and services performed in the Biological Standards Section of the Laboratory Services Division to determine and ascertain the purity, safety, sterility, potency, efficacy and other desirable characteristics of the biologics.

w. **Standard requirements** refer to the test, methods procedures and criteria established or prescribed by the LSD in evaluating the various qualities and characteristics of a biological product to ensure its purity, safety, potency, and efficacy and to determine that such product is not worthless, contaminated, adulterated dangerous or harmful to animals as construed in the provisions of this Order and others related to it.

x. **Establishment** refers to the buildings and premises or place where veterinary biological products are being produced, manufactured, stored, or processed or any place where the object of business is veterinary biological products.

y. **Director** refers to the Director of the Bureau of Animal Industry.

z. **Laboratory Services Division (LSD)** refers to the Laboratory Services Division of the Bureau of Animal Industry.

Article II
Licensing Requirements and Procedures

SECTION 5. Persons Qualified to Apply for Licenses - No person shall be granted license for the handling repacking or manufacture of any veterinary biological product in the Philippines unless he meets the following qualifications and conditions.

a. He must be a Filipino Citizen or a permanent resident of the Philippines.

b. He has no records of previous violations of Bureau of Animal Industry regulations or similar regulations of other government agencies regarding production, manufacture, handling, distribution or marketing of veterinary biologics or similar products in the Philippines.

c. He has no court record of previous conviction for illegal production, manufacture, handling, distribution or marketing of veterinary biologics or similar products in the Philippines.

d. His establishment or place of business is in accordance with the standard and criteria prescribed by the BAI and it shall be operated under the direction and supervision of a licensed veterinarian or microbiologist sufficiently trained in the prescribed techniques for preparation and testing of such veterinary products specified in the application for registration; and

e. If he operates a branch, subsidiary or franchised establishment of a foreign-based company, such person shall have a valid contract or memorandum of agreement with the foreign mother company.

SECTION 6. Licenses - Every person who intends to prepare or repackage veterinary biological products shall make a written application to the Director of Animal Industry for a Veterinary Biologics Establishment License and a Veterinary Biologics Products License for each individual product.

a. Veterinary Biologic Establishment License

i. Initial application for a Veterinary Biologics Establishment License shall be accompanied by a request for a Veterinary Biological Product License including all document requirements for both, as outlined in this set of guidelines of an Application for Veterinary Biologics Establishment License.

ii. No establishment license shall be granted until at least one biological product prepared therein meets all required standards of BAI.

iii. When a person operates more than one establishment a separate application shall be made for each establishment. A new application shall also be made

when a change of ownership, operation or location of an establishment occurs.

iv. When partnerships of different establishment are involved in single operation, or if one establishment operates as a subsidiary of another, copies of formal contracts between said establishment should be submitted with the other requirements.

v. A Veterinary Biologics Establishment License expires at the end of the year and can be renewed 90 days but not less than 30 days before expiration in accordance with Section 9 of BAI, A.O. No. 9, subject to the results of an annual inspection and examination of other requirements set by the BAI.

b. Veterinary Biological Product License

i. An establishment that prepares or repackages biological products shall hold an unexpired, unsuspended and unrevoked Veterinary Biologics Establishment License and at least one Vet. Biologics Product License issued by the Director of Animal Industry.

ii. A Veterinary Product License shall specify authorization for production or repacking of a single biological product. This is renewed on a yearly basis upon approval of the BAI Director, based on recommendation of authorized BAI personnel. Renewal can be applied for anytime before the license expiry date. This license will not be issued without prior or simultaneous issuance of a Veterinary Biological Establishment License. A processing fe shall be collected upon filing of Application for Veterinary Biological Product License.

iii. A change or modification of the method of production of a particular product shall be a cause for requiring a separate product license for such a product.

iv. any establishment that wishes to prepare an autogenous biologic must have at least one licensed non-autogenous biological product.

v. When a licensee no longer holds a product license authorizing preparation of non-autogenous biological product, any establishment license and any product license(s) for autogenous biologic shall be considered terminated and will be submitted to the BAI office for cancellation.

SECTION 7. Supporting Documents - The following are the supporting documents required before issuance of licenses for manufacturing establishment, or a biological product, is considered. Documents will be treated confidential.

a. Documents for Veterinary Biologics Establishment License

i. Preliminary plot plans, blueprints and legends shall be submitted at least in duplicate, clearly indicating functions performed in each building electrical outlets, water outlets, drains, doors and windows in designated establishment address. A standard specified scale should be used, which should be clearly indicated in the drafts. Date of preparation and signature of the responsible officer of the firm shall be indicated.

ii. Suggested alteration in preliminary drawings will be indicated by the authorized LSD personnel, and these shall be returned for subsequent revision.