



Republic of the Philippines  
Department of Agriculture  
**BUREAU OF ANIMAL INDUSTRY**  
Visayas Avenue, Diliman, Quezon City  
TIN : 300000746316

## APPLICATION FOR LICENSING OF VETERINARY BIOLOGICAL PRODUCT ESTABLISHMENT

Under Republic Act No. 1071 of 1954. An act to regulate the Sale of Veterinary Biologics and Medical Preparations  
ACT 3101, AO 9 and 15

Type of Application:  Initial  Renewal  CIC Date \_\_\_\_\_

Name of Establishment: \_\_\_\_\_

Office Address : \_\_\_\_\_

Nature of Business : \_\_\_\_\_  
(Veterinary Biological Product Manufacturer/ Importer/ Distributor/ Wholesaler/ Exporter/ Indentor/ Retailer)

Telephone No : \_\_\_\_\_ Mobile No: \_\_\_\_\_ Email address: \_\_\_\_\_

Business Organization: \_\_\_\_\_  
(Sole Proprietorship / Corporation and Partnership/ Cooperative)

Plant Address: \_\_\_\_\_

Laboratory/ Warehouse/ Cold Storage Address : \_\_\_\_\_

### Principal Officers or Partners

	Name	Title	Business Address
1.			
2.			
3.			
4.			
5.			

\_\_\_\_\_  
Signature Over Printed Name of Applicant or  
Authorized Representative

\_\_\_\_\_  
Designation

**REQUIREMENTS FOR THE LICENSING OF VETERINARY BIOLOGICAL AND PRODUCT (INITIAL/RENEWAL)**

**General Requirements:**

1. Application letter addressed to the Director
- \*2. Duly accomplished and notarized Application Form # RF FVDB-03. For items not applicable, please indicate Not Applicable or NA.
3. For business organization: (select only what is applicable)
  - a. **for Sole Proprietorship:** Photocopy of Registration from the Department of Trade and Industry (DTI);
  - b. **for Corporations:** Photocopy of Registration and Articles of Incorporation and By-Laws from the Securities and Exchange Commission (SEC);
  - c. **for Cooperatives:** Photocopy of Registration from the Cooperative Development Authority (CDA);
  - d. **for Partnership and Corporation:** Copy of Articles of Partnership, duly registered with the Security and Exchange Commission (SEC);
- \*4. Contract of Lease of the space (if rental) or Proof of ownership of the building occupied;
5. Reference Books and Documents:
  - a. RA 3101, An Act authorizing the Director of Animal Industry to promulgate regulation for the preparation, sale, traffic in and shipment, and importation of viruses, serum, toxins, or analogue products used for the treatment of domestic animals and relevant IRR.
  - b. RA 1071, An Act to regulate the sale of veterinary biologics and medicinal preparation and relevant IRR.
6. Location Map and Building Layout;
- \*7. Inspection Report (Copy of Inspection and Evaluation Report to be attached by the Inspector);
- \*8. Original copy of License To Operate (LTO) Veterinary Biological Product Establishment( RF FVDB-09);
- \*9. Business / Mayor's Permit;
- \*10. Notarized Joint Affidavit of Undertaking between the duly-licensed Veterinarian and Owner or General Manager, with Photocopy of valid PRC License and PTR of Veterinarian; and
- \*11. Attendance to Orientation Seminar

**Additional Requirements for Veterinary Biologics:**

**INITIAL REGISTRATION**

- \*1. Photocopy of Environmental Compliance Certificate (ECC) from the Environmental Management Bureau (EMB) or Permit to Operate (PTO) and from the Laguna Lake Development Authority (LLDA). For plants outside Metro Manila, a corresponding valid PTO issued by the Department of Environment Natural Resources (DENR) Provincial Environment and Natural Resources Officer (PENRO);
2. SOP on storage of Veterinary Biological Products should be itemized such as – For finished product, for quarantine, released, rejected returned, recall, disposal;
3. SOP on cleaning of cold storage-should be suitably clean and maintained in accordance to its written program cleaning record;
4. SOP on packing product for dispatched  
Products should not come in contact with dry ice or subject to freezing
  - Temperature monitor or record (2-8°C)
  - Correct usage of insulated repacking cases/ container/ Styrofoam box / ice cooler;
5. SOP on picking and dispatching
  - Use of FIFO (first in first out) and or FEFO (first expiry first out)
  - Transport condition, use of ref van/refrigerant materials, temp monitor, record (2-8°C);
  - Condition of the product for damage container, cleanliness, broken seal, evidence of tampering and contaminated, expiry;
6. Veterinary Biologics Product List/Record
  - Name of Product
  - Manufacturer
  - Description of the product
  - Receiving date
  - Name of Supplier
  - Serial Number
  - Expiry Date
  - Stock reconciliation-compare with actual and recording;
7. List of technical officials and employees
  - Enough Trained personnel on good storage practice and or Good Warehouse Practice;
  - Trained to maintain regulatory requirement and photocopy of valid PRC License of Veterinarian;
8. List of facilities and equipment for the manufacture, production, handling, distribution and shipment of biologics (generator, refrigerator, outside and inside thermometer, waste disposal equipment, ect.
9. Contract agreement with the supplier;
10. Back-up power supply- generator set, refrigerant; and
11. Calibration record for temperature and monitoring equipment.

**CHANGE IN CIRCUMSTANCES (CIC):**

1. Official letter requesting change in address/ownership/business name/veterinarian/pharmacist/chemist, etc.
2. Application form RF FVDB-03 reflecting needed change/s;
3. Surrender Original copy of LTO;
4. Mayor's Permit in case of change of address or business name or ownership;
5. SEC or DTI in case of change of address or business name or ownership;
6. Deed of Sale/Transfer of Rights in case of change of ownership;
7. Notarized Joint Affidavit of Undertaking between the duly-licensed Veterinarian and Owner or General Manager, Photocopy of valid PRC License of Veterinarian; and

**\*\*F. SCHEDULE OF FEES**

<u>Establishment</u>		<u>Initial</u>	<u>Renewal</u>
Manufacturer	PHP	12,000.00	12,000.00
Distributor/ Wholesaler	PHP	4,400.00	4,400.00
Importer/ Exporter /Indentor	PHP	4,400.00	4,400.00
Retailer	PHP	500.00	500.00
CIC	PHP	100.00	

**Surcharge:** An additional 50% of the amount due shall be levied on every expired LTO.

\* To be submitted upon renewal

\*\* Fees to be paid upon satisfactory compliance of all general and additional requirements. Fees are non-refundable and shall be charged in full for the entire validity of LTO

DO NOT USE DUE TO ONLINE LTO APPLICATION (FOR REFERENCE ONLY)