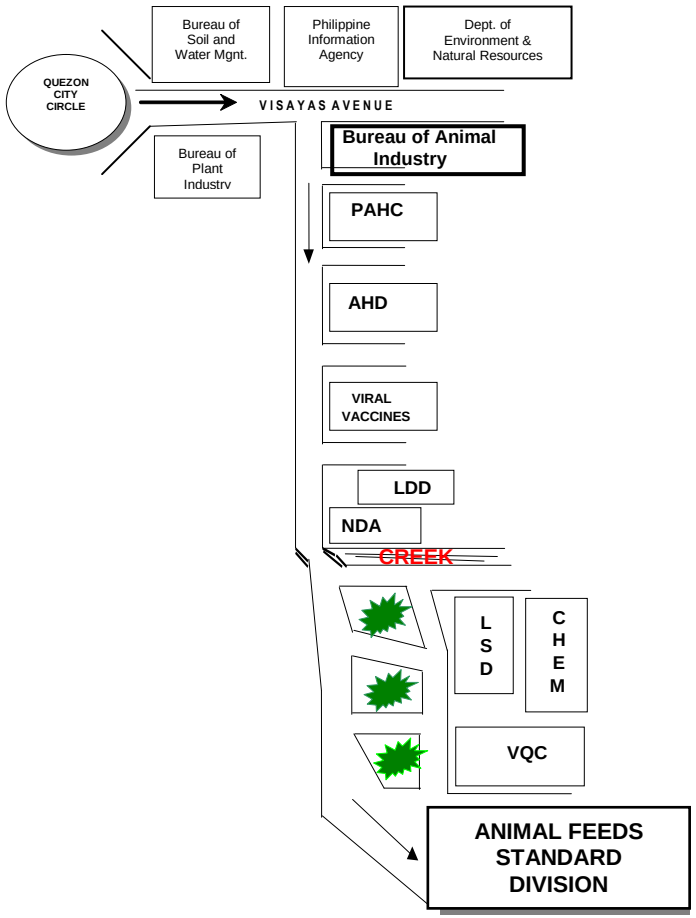
LOCATION MAP



For inquiries, contact or visit:

Animal Feeds Standard Division
BAI Compound, Visayas Ave., Diliman, Quezon City
Telephone Nos.: (632) 928-2837/920-1764
Tel/Fax: (632) 924-7954

Contact Persons:

Angel Antonio B. Mateo, DVM,MSc.
Officer-In-Charge
Animal Feeds Standard Division

Marilou Esterlina D. Arifalo
Chief, Animal Feeds Registration and Evaluation Section

Ma. Corazon G. De Leon
Chief, Veterinary Drugs and Products Registration & Licensing Section

Esterlita E. Karganilla
OIC, National Compliance Monitoring Section

Feeds & Veterinary Drugs and Products Quality Control Program

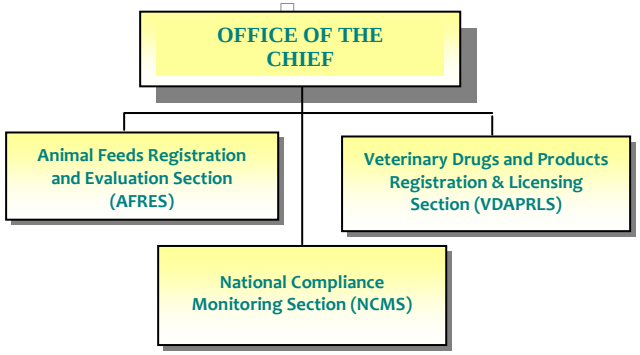
VISION

"A dynamic and ethical feed and veterinary drug industry that conforms to local and international standards and complies with regulations to assure quality and safety for optimum productivity of animals toward food security without sacrificing consumer safety and well-being."

MISSION

1. To establish a set of rules, regulations and standards that are animal friendly and consumer friendly.
2. To create an auspicious atmosphere for compliance and adherence to quality and safety of the various stakeholders.
3. To advocate responsible nutrition and rational drug use through outreach programs, data banking, international and local collaborations and linkages.
4. To develop well-informed, credible and highly trained human resources who will respond to the needs of the clients.

Organizational Chart



PROGRAM THRUSTS

- ✓ ***National Feeds and Veterinary Drugs and Products Quality Control Program***
- ✓***Regional and International Collaboration***
- ✓***Enhanced Information Campaign***
- ✓***Human Resource Development***
- ✓***Computerization and Streamlining of procedures in the issuances of Permits, Licenses, etc.***
- ✓***Inspection, Monitoring and Compliance***

LEGAL BASIS

- **R.A. 1556** - ***Livestock*** **and Poultry Feeds** ***Act***
- **R.A. 3720** - ***The "Food, Drugs and Devices and Cosmetics Act"***
- **R.A. 9711** - ***The Food and Drug Administration Act of 2009***
- **R.A. 6675** - ***The "Generics Act of 1988"***
- **R.A. 1071** - ***Act to Regulate the Sale of Veterinary Biologics and Medical Preparations***
- **R.A. 8203** - ***Act on Counterfeit Drugs***
- **R.A. 7394** - ***Consumer Act of the Philippines***

Department of Agriculture
BUREAU OF ANIMAL INDUSTRY

ANIMAL FEEDS STANDARD DIVISION

Visayas Avenue, Diliman
Quezon City 1103
PHILIPPINES

Primer on Republic Act (RA) No. 1556 otherwise known as the "Livestock and Poultry Feeds Act"; RA No. 3720 "Food Drugs and Devices and Cosmetics Act"; RA No. 6675 "Generics Act of 1988"; and RA No. 9711 The Food and Drug Administration Act of 2009

SERVICE GUIDE

PRIMER ON REGISTRATION OF VETERINARY DRUG AND PRODUCT AND LICENSING ESTABLISHMENT
Republic Act (RA) No. 1556; RA No. 3720 & RA No. 9711

I. Initial/Renewal Checklist of Requirements for Veterinary Drug and Product Premixes and Water Soluble Establishments/Outlets

a. General Requirements:

1. **Notarized and accomplished Joint Affidavit of Undertaking.
2. **Xerox copy of Mayor's Permit (nature of business specified) for the current year and Official Receipt.
3. Xerox copy of Business Name Registration with BDT/SEC (if corporation) and Articles of Inc.
4. ID (5 x 5 cm) picture of the Owner, Gen. Manager and Veterinarian.
5. **Xerox copy of Pharmacist, Veterinarian Registration/Valid PRC ID.
6. Certificates of Attendance of Veterinarian/Pharmacist to the re-orientation seminar and consultation meeting regarding veterinary drug and product
7. *Notarized valid Contract of Lease of the space/building occupied, if the applicant does not own it.
8. Reference Books:
   a. USP/NF (latest edition)
   b. R.A. 3720, R.A. 6675, R.A. 5921
   c. Remington's Pharmaceutical Sciences (latest edition)
   d. Goodman & Gilman Pharmacological Basis of Therapeutics
   e. British Pharmacologists
   f. Philippine National Veterinary Formulary
9. Location Plan.
10. *List of products to be manufactured/distributed with Generic and Brand Names.
11. *Copy of Inspection and Evaluation Report.
12. Original Copy of previous LTO.

b. Additional Requirements:

1. Manufacturer
   a. *Environmental Clearance Certificate (ECC) from DENR-EMB and Permit to Operate from the local DENR/LLDA.
   b. *Current Floor Plan with complete dimension and proposed floor plan in accordance to approved Good Manufacturing Practice (GMP)
   c. *List of manufacturing/quality control equipment, as described in Annexes A, B, C, D, E, F of Chapter I Section 2.2 of the Joint DA-AO No. 138 and DOH-AO No. 100 series of 1990.
   d. *Photocopy of valid BAI-LSD Laboratory Recognition Certificate of Quality Control Laboratory or contracted laboratory.
   e. * Xerox copy of licensed chemist valid PRC ID.
2. Trader
   a. *Notarized valid contract of Agreement with the manufacturer containing a stipulation that both manufacturer and trader are jointly responsible for the quality of products.
   b. *Environmental Clearance Certificate/Permit to Operate of Contracted Laboratory.
   c. *Photocopy of valid BAI-LSD Laboratory Recognition Certificate of Contracted Laboratory/Licensed chemist valid PRC ID.
3. Distributor
   a. Importer
      - *Foreign Agency Agreement (with authentication from territorial Philippine Consulate in case of Exclusive Distributorship).
      - * Current GMP Certificate issued by a Government Health Agency, duly Authenticated by the Philippine Consulate at the country of origin.
      - *Government Certificate of Clearance and free sale or registration approval of the product from the country of origin duly Authenticated by the Philippine Consulate at the country origin.
   b. Exporter
      - *A valid Contract of Agreement with BAI Licensed VDAP Manufacturer in addition to other requirements set by other competent authorities.
   c. Wholesaler
      - *A valid Contract of Agreement with BAI Licensed VDAP Manufacturer/VDAP Importer.
      - *Complete list of products to be sold with their corresponding product registration numbers and expiry dates.
4. Outlet
   - Complete list of products to be sold with corresponding product registration numbers and expiry dates.
5. Changes of Circumstances
   a. Official Letter re: change of address/owner/business name/Veterinarian/Pharmacist/Chemist/etc.
   b. Surrender original/old LTO.
   c. Deed of Sale/Transfer of Rights in case of change of ownership.
   d. Notarized Affidavit of Veterinarian/Pharmacist/Chemist in case of change.

a. Schedule of Fees**

Establishment	Initial	Renewal
VDAPM	P6,000.00	P12,000.00 (2 yrs.)
VDAPT	3,600.00	7,200.00 (2 yrs.)
VDAPD (Importer/Wholesaler/Exporter)	2,400.00	4,800.00 (2 yrs.)
VDAPDO	240.00	480.00 (2 yrs.)

Surcharge: A fifty percent (50%) of the amount due shall be levied on every expired LTO.

** Upon satisfactory compliance of all general and additional requirements the following fees (non-refundable) shall be charged in full for entire coverage of registration.

II. Checklist of Requirements for Initial/Renewal of Registration of Veterinary Drugs and Product Premixes and Water Solubles

1. **Notarized letter of application from manufacturer / traders / distributor (Annex AFSD Form 3A) for Initial/Renewal.
2. **Duly Accomplished AFSD Form No. 3.
3. ***Contract of Agreement/Authorization between manufacturer & distributor.
4. List of all ingredients used as a component of the product indicating the quantity and technical specification.
5. Full description of the methods used, the facilities and controls in the manufacture, processing and packaging of the product.
6. Technical specification and physical description of the finished products.
7. **Complete assay procedure for active ingredients, finished product and degradation products, if any.
8. **Certificate of Analysis from BAI/LSB/Recognized Laboratory/Manufacturer's Analysis (Imported)/Government Issued.
9. Stability studies on the product to justify claimed expiration date or Accelerated Short Term Stability or actual Stability Data.
10. Unattached generic labels or proposed labels to be used for the product with actual color and text (in accordance with A.O. 55, S. 1988).
11. **Duly accomplished and notarized Declaration Form.
12. Approved Brand Name Clearance.
13. **Xeroxed copy of valid PRC license of Veterinary Medical Officer
14. MRL and ADI of the product (Where Applicable)
15. **Copy of latest Certificate of Product Registration (CPR) and License to Operate (LTO)**
16. **Actual Commercial label and copy of previous BAI approved.
17. Proof of payment of Registration upon approval for CPR.

Refer to Annex C of the Joint DA-AO No. 33 and DOH-AO No. 111-A series of 1991 for specific requirements.

Changes in Circumstances:

1. Official letter re: change of address / owner / business name / Veterinarian / Pharmacist / Chemist/etc.
2. Surrender original CPR and approved label.
3. Duly notarized Declaration Form, Form 3A and Form 3 for any change(s) in the product.
4. Pertinent documents required for the amendment of product claims.
5. Change of Circumstances Fees P100.00

Additional Requirements for Importers or Authorized Distributor from Foreign Sources

1. **Government Certificate of Clearance and Free Sale/ Registration approval of the product from country of origin.
2. **Government Certificate attesting to the status of the manufacturer's competency and reliability of the personnel and facilities.
3. Agreement must be authenticated by the territorial Philippine Consulate in case of Exclusive Distributorship.

Note: Items 1, 2 & 3 should be duly authenticated by territorial Philippine Consulate or in the absence of the Consulate, any equivalent regulatory government agency.

** To be submitted for renewal of registration.
*** Change of Circumstances (COC).

Schedule of Fees

Upon approval of application for registration of a veterinary drug and product, the following fees (non-refundable) shall be charged in full for entire coverage of registration.

1. Initial Registration:
   a. Unbranded Generic –
      P 1,200.00 for 2 years + cost of Laboratory Analysis
   b. Branded Generic –
      P 2,400.00 for 2 years + cost of Laboratory Analysis
2. Renewal of Registration
   a. P 1,800.00 for 5 years + cost of Laboratory Analysis
3. Inspection Fee

   An inspection fee of P0.25 per kilogram and P1.00 per liter for premix additives and supplements that are manufactured locally or imported shall be charged monthly on the basis of total volume of VDAP manufactured locally or imported. Please refer to the Department of Agriculture Administrative Order No. 33 Series of 2000 and Department of Agriculture No. 05 Series of 2004 for the appropriate fees.

Other Services Fee

a. Certification Letter	–	P 25.00/letter
b. Processing Fee	–	P 125.00/product
c. Brand Name Clearance Fee:		
1. Per every brand name applied for		P 10.00
2. Brand Name Approved/Cleared		50.00
3. Brand Name Extension Fee		25.00

SPS Import Clearance

Requirements:

- Pro-forma invoice
- Valid approved Letter of Authority (LOA) if product is not registered with Importer
- Valid approved Certificate of Product Registration (CPR)
- Valid approved License to Operate

Schedule of Fees:

Certification	–	P 25.00/product
Processing Fee	–	P 125.00/product

Export Clearance

Requirements:

- Pro-forma invoice
- Valid approved Certificate of Product Registration (CPR)
- Valid approved License to Operate

Special Import Permit (For trial/sample purposes)

Requirements:

- Pro-forma invoice
- Valid approved Certificate of Product Registration (CPR)
- Valid approved License to Operate
- Processing Fee P 125.00/product

Certification

Processing Fee P 25.00