APPLICATION FOR REGISTRATION OF VETERINARY DRUG AND PRODUCT (VDAP)

(Under RA 3720, RA 9711, RA 6675, RA 1556)

Latest 1" x 1" ID PICTURE (APPLICANT)

_____
Date

Office Address :_____

Telephone No.: _____ Mobile No.:_____Email address: _____

Nature of Business: _____

(VDAP Manufacturer/VDAP Trader/VDAP Distributor/Importer)

Name of Product (Generic):_____

Brand Name (if any): _____

Available scientific and product evidence and experience on the Veterinary use:

_____

_____

(Investigational/New/Tried & Tested/Established/Pharmaceuticals or Therapeutic Innovation of Tried & Tested or Established VDAP)

No. of Active Ingredients : _____

(Single / Fixed dose combination / Multi-component)

Pharmacologic / Therapeutic Category: _____

(As specified in the PNVDF)

Source or Circumstance of VDAP Production :_____

(Imported finished/locally-manufactured from imported/local materials)

Brand Identification & Patent Protection of VDAP:) _____

(Branded & Patented/Branded & Off-Patent/Unbranded & Off-Patent)

Prescribing and dispensing regulations applicable: _____

_____

(OTC/Ethical or Prescription VDAP)

_____
Veterinary Medical Officer

(Signature Over Printed Name)

_____
Signature Over Printed Name of Applicant or Authorized Representative

_____
Designation

SUBSCRIBED AND SWORN to before me this _____day of _____20_____

The Affiant exhibited to me his/her Community Tax Certificate No. _____issued at _____ on _____, 20_____

Doc No. :_____

Page No. : _____

Book No.: _____

Series of _____

Documentary Stamp

_____
Notary Public

RECOMMENDING APPROVAL:

(To be filled-up by BAI-AFVDBCD Staff / Deputized AFVDABCO)

License- To- Operate No. _____

Valid Until: _____

CPR No.: _____

Valid Until: _____

CPR Fee: _____

Official Receipt No.: _____

Date Issued: _____

Remarks: _____

☐ New ☐ Renewal ☐ CIC

APPROVED:

REQUIREMENTS FOR INITIAL/RENEWAL REGISTRATION OF VETERINARY DRUGS AND PRODUCTS

*1. Duly accomplished and notarized form RF FVDB-05 and Initial/Renewal VDAP Registration Annex Form, RF FVDB-*17*;
*2. Certificate of Agreement between Manufacturer and Distributor (Manufacturing /Foreign Agency or Distributorship Agreement);
3. Amounts and technical specifications of all ingredients used as component of the product;
4. Full description of the methods used, the facilities and controls in the manufacture, processing and packaging of the product;
5. Technical specification and physical description of the finished product;
6. Complete assay procedure for active ingredients (finished product and degradation products, if any);
7. Stability studies of the product to justify claimed expiration date. Accelerated/and or actual Stability Data from at least three (3) elevated temperatures;
8. Proposed generic label to be used for the product with actual color and text as per DA AO11 and DOH AO 105, series of 1991;
*9. Brand Name Clearance *Certificate*;
*10. Photocopy of valid Professional Regulation Commission (PRC) ID of the Veterinary Medical Officer;
11. Maximum Residue Limit (MRL) and Acceptable Daily Intake (ADI) of the product (if applicable);
**12. Original copy of latest Certificate of Product Registration(CPR VDAP- RF FVDB-11);
*13. Photocopy of valid LTO VDAP (RF FVDB-08);
*14. Certificate of Analysis of the batch/lot number of samples submitted (CAFAL- *Central Animal Feed Analytical Laboratory* /BAI Recognized Laboratories);
**15. Actual commercial labels (3 copies) and copy of BAI previously approved label; and
*16. Duly accomplished and notarized Declaration Form (RF FVDB-*19*).

CHANGE IN CIRCUMSTANCES (CIC)

1. Duly accomplished and notarized Form (RF FVDB-05);
2. Duly accomplished and notarized Declaration Form (RF FVDB-*19*);
3. Facsimile of label for approval on CIC;
4. BAI previously approved label;
5. Original copy of latest Certificate of Product Registration (RF FVDB-11);
6. Deed of Sale/Transfer of Rights in case of change in ownership; and
7. Official letter re CIC;

Additional Requirements for Importer

1. Government issued Certificate of Clearance and Free Sale or Registration approval of the product from country of origin
2. Government issued Certificate attesting to the status of the manufacturer's competency and reliability of the personnel and facilities

SCHEDULE OF FEES

Initial Registration:

☐ Generic - PHP 1,200.00 for 2 years

☐ Branded - PHP 2,400.00 for 2 years

Renewal of Registration

PHP 1,800.00 for 5 years

Inspection Fee:

An inspection fee of P 0.25 per kilogram and/ or P 1.00 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 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 other approriate fees.

All application together with required documents should be submitted in color-coded folders with ear tags
*To be submitted upon renewal of registration
**Additional requirement for renewal