



**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)

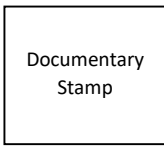
Brand Identification & Patent Protection of VDAP:) _____
(Branded & Patented/Branded & Off-Patent/Unbranded & Off-Patent)

Prescribing and dispensing regulations applicable: _____
(OTC/Ethical or Prescription VDAP)

Veterinary Medical Officer _____ Signature Over Printed Name of Applicant or Authorized Representative _____
(Signature Over Printed Name) _____
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 _____



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

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:

<input type="checkbox"/> Generic	- PHP 1,200.00 for 2 years
<input type="checkbox"/> 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 appropriate 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