REQUIREMENTS FOR INITIAL/RENEWAL REGISTRATION OF VETERINARY DRUGS AND PRODUCTS

_____ *1. Duly accomplished form RF-*AFVDBCD* -05 Application for VDAP Registration (Feed Premixes and Water Soluble Supplement RF FVDB-31;

_____ *2. Memorandum of Agreement between Manufacturer and Distributor (Manufacturing /Foreign Agency or Distributorship Agreement);

_____ 3. Amount 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 products;

_____ 5. Technical specification and physical description of the finished products;

_____ 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;

_____ *10. Photocopy of valid Professional Regulation Commission (PRC) Identification Card of Veterinary Medical Officer;

_____ 11. Maximum Residue Limit (MRL) and Acceptable Daily Intake (ADI) of the product (where applicable);

_____ *12. Original copy of latest Certificate of Product Registration (RF-FVDB-11);

_____ *13. Photocopy of valid LTO (RF-FVDB-08);

_____ *14. Certificate of Analysis of the batch/lot number of samples submitted (CAFAL/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-28).

FOR 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 IMPORTERS

_____ 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

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

Initial Registration:

( ) Unbranded Generic - P 1,200.00 for 2 years

( ) Branded Generic - P 2,400.00 for 2 years

Renewal of Registration:

P 1,800.00 for 5 years

Inspection Fee:

An inspection fee of P0.25 per kilogram and/or 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 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.

* To be submitted upon renewal of registration

** Additional requirements for renewal of registration

:s)and Initial/Renewal VDAP Registration Annex Form,

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