CENTER FOR DRUG REGULATION AND RESEARCH
LIST OF REQUIREMENTS FOR REGISTRATION OF VETERINARY DRUG PRODUCTS

A. Initial Application

1) Integrated Application Form
2) Valid agreements between the manufacturer, trader, importer, distributor, where applicable
3) Unit Dose and Batch Formulation
4) Technical Specifications of all Raw Materials
5) Certificate of Analysis of active Raw Material(s)
   (a) From supplier of API
   (b) From manufacturer of finished product
6) Technical Specifications of Finished Product
7) Certificate of Analysis (CA) of Finished Product (from the same batch of representative sample)
8) Manufacturing Procedure, Production Equipment, Sampling, In-process controls, and Master Packaging Procedure (including specification for container closure system)
9) Assay and Other Test Procedures including Identity, Purity Tests, with Data Analysis, where applicable
10) Stability Studies
11) Labeling Materials (facsimile labels)
12) Representative Sample

Additional Requirements:

1) For products in plastic container:
   (a) Certificate of Analysis for Test of Migratable Substances/ Leachability
2) For imported products:
   (a) Certificate of Pharmaceutical product
   (b) Foreign GMP Clearance
3) For new veterinary drugs:
   (a) Pre-clinical studies
   (b) Protocol for monitored release
4) For fixed-dose combination
   (a) Rationale of the combination

B. Regular Renewal Application

1) Integrated Application Form
2) Unit Dose and Batch Formulation
3) Technical Specifications of Finished Product
4) Certificate of Analysis (CA) of Finished Product (from the same batch of representative sample)

5) Assay and Other Test Procedures including Assay with Data Analysis
6) Stability Studies
7) Labeling Materials (actual/commercial labels)
8) Actual commercial sample

Additional Requirements:

1) Post-marketing commitments (if any)

C. Automatic Renewal Application

1) Integrated Application Form
2) Copy of Certifications issued as a result of post-approval change(s)
3) Labeling materials (actual/commercial labels)
4) Actual commercial sample

Additional Requirements:

1) Post-marketing commitments (if any)

Notes:

- All documentary requirements must be in PDF format to be submitted to PAIR
- Existing image file format shall be followed
- A hard copy of the integrated application form is required
- Samples may be submitted when the application has already been decked, as indicated in the Document Tracking System