CENTER FOR DRUG REGULATION AND RESEARCH
LIST OF REQUIREMENTS FOR REGISTRATION OF HERBAL MEDICINES

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 Active Raw Material
   (b) From manufacturer of finished product
   (c) Certification of Authenticity of Plant Specimen from the National Museum or any FDA-recognized Taxonomist
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)
12) Evidence of Safety and Efficacy
13) Representative Sample

Additional Requirements:

1) For herbal medicines validated by the NIRPROMP of the PCHRD
   (a) Copy of the Memorandum of Agreement between NIRPROMP and the applicant; or a copy of approval of FDA Committee on the registration of the said herbal medicine
2) For products in plastic container:
   (a) Certificate of Analysis for Test of Migratable Substances/ Leachability
3) For imported products:
   (a) Certificate of Pharmaceutical product
   (b) Foreign GMP Clearance

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) Stability Studies
6) Labeling Materials (actual/commercial labels)
7) 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, triplicate)
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
- Image files should be at least 150 dots per inch (dpi)
- A hard copy of the integrated application form is required
- Samples may be submitted at a later date, e.g. when the application has already been decked as indicated in the Document Tracking System