



**CENTER FOR DRUG REGULATION AND RESEARCH**  
**LIST OF REQUIREMENTS FOR REGISTRATION OF TRADITIONALLY-  
USED HERBAL 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 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 labels)
- 12) Evidence of Safety
- 13) Evidence of Claimed Application
- 14) 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 Traditionally-Used Herbal 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)

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