Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

CENTER FOR DRUG REGULATION AND RESEARCH

INITIAL REGISTRATION OF HERBAL MEDICINES

Who May Avail : All Manufacturers, Distributors, Importers, Exporters, Wholesalers, and Traders of Pharmaceutical Products (Herbal Medicines)

Fees to be Paid : **Initial**
Branded: PHP 3,000.00/year + PHP 500.00 (Brand Name Clearance) + 1% LRF
Unbranded: PHP 2,000.00/year + 1% LRF
The applicant may apply for 2/5-year CPR validity
2-year validity:
Branded: PHP 6,000.00 + PHP 500.00 (for Brand Name Clearance) = PHP 6,500.00 + 1% LRF
Unbranded: PHP 4,000.00 + 1% LRF
5-year validity:
Branded: PHP 15,000.00 + PHP 500.00 (for Brand Name Clearance) = PHP 15,500.00 + 1% LRF
Unbranded: PHP 10,000.00 + 1% LRF

CHECKLIST OF REQUIREMENTS

- **Administrative Order No. 172 s. 2004: Guidelines on the Registration of Herbal Medicines**

1. Duly accomplished and notarized Integrated Application Form
2. Proof of Payment
3. Valid agreements between the manufacturer, trader, importer, distributor, where applicable
4. Unit Dose and Batch Formulation
5. Technical Specifications of all Raw Materials
6. 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
7. Technical Specifications of Finished Product
8. Certificate of Analysis (CA) of Finished Product from the same batch of representative sample
9. Manufacturing Procedure, Production Equipment, Sampling, In-process controls, and Master Packaging Procedure (including specification for container closure system)
10. Assay and Other Test Procedures including Identity, Purity Tests, with Data Analysis, where applicable
11. Stability Studies
12. Labeling Materials (facsimile)
13. Evidence of Safety and Efficacy

14. Representative Sample (upon request of the evaluator)

Additional Requirements:

1. For herbal medicines validated by the National Integrated Research Program on Medicinal Plants (NIRPROMP), Copy of the Memorandum of Agreement between NIRPROMP and the applicant; otherwise, a copy of approval of FDA Committee on the registration of the said herbal medicine
2. For products in plastic container: Certificate of Analysis for Test of Migratable Substances/ Leachability
3. For imported products:
   a. Certificate of Pharmaceutical Product (CPP)
   b. Foreign GMP Clearance
4. Valid LTO (Importer/Manufacturer/Distributor/Trader)

END