



CENTER FOR DRUG REGULATION AND RESEARCH

INITIAL REGISTRATION OF TRADITIONALLY-USED HERBAL MEDICINE

Who May Avail : All Manufacturers, Distributors, Importers, Exporters, Wholesalers, and Traders of Pharmaceutical Products (Traditionally-Used 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. 184 s. 2004: Guidelines on the Registration of Traditionally-Used 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 labels)
13. Evidence of Safety



14. Evidence of Claimed Application
15. Representative Sample

Additional Requirements:

1. For products in plastic container: Certificate of Analysis for Test of Migratable Substances/ Leachability
2. For imported products:
 - a. Certificate of Traditionally –Used Herbal Product
 - b. Foreign GMP Clearance
3. Valid LTO (Importer/Manufacturer/Distributor/Trader)

END