Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

CENTER FOR DRUG REGULATION AND RESEARCH

INITIAL REGISTRATION OF OVER-THE-COUNTER DRUGS AND HOUSEHOLD REMEDIES

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

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 or 5-year CPR validity (Based on Bureau Circular No. 5 s. 1997).
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

1. Duly accomplished and notarized Integrated Application Form (with proof of payment)
2. Proof of payment (based on AO No. 50 s. 2001)
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 API
   b. From manufacturer of finished product
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. Representative Samples (w/ COA) may be submitted at a later date, e.g. when the application has already been decked as indicated in the Document Tracking System (upon request of the evaluator).

Additional Requirements:

1. For products in plastic container: Certificate of Analysis for Test of Migratable Substances / Leachability
2. For imported products:
   a. Certificate of Pharmaceutical Product (CPP)
   b. Foreign GMP Clearance
3. For fixed-dose combination: Rationale of the Combination
4. Valid LTO (Importer/Manufacturer/Distributor/Trader)

END