Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

CENTER FOR DRUG REGULATION AND RESEARCH

REGULAR RENEWAL REGISTRATION

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

Fees to be Paid : **AO No. 50 s. 2001**
Branded: PHP 10,000.00 + 1% LRF
Unbranded: PHP 7,500.00 + 1% LRF
Additional (if with variation/s)
Payment shall be based on FDA Circular No. 2014-008, Annex D on a per product, per change basis.
Surcharge (based on FDA Circular No. 2011-004) Computation:
2 x (renewal registration fee) + 10%* (renewal registration fee)
*If the renewal application is submitted on the: First month: 10%
First day of the second month: 20% First day of the third month: 30% First day of the fourth month: 40%
Any renewal application filed after the 4th month (120th day) shall be treated as an initial application.

CHECKLIST OF REQUIREMENTS

Documentary Requirements:

a. Copy of previously issued CPR
b. Copy of LTO of manufacturer, importer, trader, and/or distributor (and renewal case number with proof of payment)
c. Copy of Certificate of GMP Clearance for imported product (and/or initial or renewal application, whichever is applicable)

FOR PRESCRIPTION PRODUCTS/ OVER-THE-COUNTER PREPARATIONS/ HOUSEHOLD REMEDIES

1. Integrated Application Form
2. Proof of Payment
3. Unit Dose and Batch Formulation
4. Technical Specifications of Finished Product
5. Certificate of Analysis (CA) of Finished Product (from the same batch of representative sample)
6. Assay and Other Test Procedures including Assay with Data Analysis
7. Stability Studies
8. Labeling Materials (actual/commercial label)
9. Actual commercial samples (w/ Certificate of Analysis) (upon request of the evaluator)
10. If with previously approved/acknowledged variation applications filed prior to CPR renewal: Copy of the approved/acknowledged Certification and/or Notification (Note that request/s for variation shall be filed separately from the renewal application.)

Additional Requirements:

1. Post-marketing commitments (if any)
2. For imported products: Foreign GMP Clearance
3. For oral solid dosage forms, proof of interchangeability (Bioequivalence study or Biowaiver, whichever is applicable)

FOR BIOLOGICALS/SIMILAR BIOTHERAPEUTIC PRODUCTS

1. Integrated Application Form
2. Proof of Payment
3. Periodic Safety Update Report (PSUR) and Risk Management Plan (RMP)
4. Certification that there were no changes during the 5-year period. If there were any, the summary changes made by the manufacturer for the 5-year period shall be incorporated
5. Labeling Materials (actual/commercial labels)
6. Actual commercial sample (w/ Certificate of Analysis) (upon request of the evaluator)
7. If with previously approved/acknowledged variation applications filed prior to CPR renewal: Copy of the approved/acknowledged Certification and/or Notification (Note that request/s for variation shall be filed separately from the renewal application.)

Additional Requirements:

1. Post-marketing commitments (if any)
2. For products qualifying for Generic Labeling Exemption (GLE): Request for GLE
3. For imported products: Foreign GMP Clearance
4. For vaccines: Summary Lot Protocol
5. List of Countries where the vaccine is already licensed and date of approval Adverse event following immunization report (Summary of Annual Reports)
6. MRE to Initial: Risk Management Plan (RMP) & Periodic Safety Update Report (PSUR)
7. If with previously approved/acknowledged variation applications filed prior to CPR renewal: Copy of the approved/acknowledged Certification and/or Notification (Note that request/s for variation shall be filed separately from the renewal application.)

FOR HERBAL MEDICINES/TRADITIONALLY USED HERBAL PRODUCTS

1. Integrated Application Form
2. Proof of Payment
3. Unit Dose and Batch Formulation
4. Technical Specifications of Finished Product
5. Certificate of Analysis (CA) of Finished Product (from the same batch of representative sample)
6. Stability Studies
7. Labeling Materials (actual/commercial label)
8. Actual commercial sample (w/Certificate of Analysis) (upon request of the evaluator)
9. If with previously approved/acknowledged variation applications filed prior to CPR renewal: Copy of the approved/acknowledged Certification and/or Notification (Note that request/s for variation shall be filed separately from the

renewal application.)

Additional Requirements:

1. Post-marketing commitments (if any)
2. For imported products: Foreign GMP Clearance

FOR MEDICAL GAS (OXYGEN)

1. Integrated Application Form
2. Proof of Payment
3. Valid agreements between the manufacturer, trader, importer, distributor, where applicable
4. Certificate of Analysis (CA) of Finished Product (from the same batch of representative sample)
5. Certificate of Analysis issued by CIGI for the product
6. Manufacturing Procedure, Production Equipment, Sampling, In-process controls
7. Labeling Materials (actual/commercial label)
8. If with previously approved/acknowledged variation applications filed prior to CPR renewal: Copy of the approved/acknowledged Certification and/or Notification (Note that request/s for variation shall be filed separately from the renewal application.)

Additional Requirements:

1. Post-marketing commitments (if any)
2. For imported products: Foreign GMP Clearance

FOR VETERINARY DRUG PRODUCTS

1. Integrated Application Form
2. Proof of Payment
3. Unit Dose and Batch Formulation
4. Technical Specifications of Finished Product
5. Certificate of Analysis (CA) of Finished Product (from the same batch of representative sample)
6. Assay and Other Test Procedures including Assay with Data Analysis
7. Stability Studies
8. Labeling Materials (actual/commercial label)
9. Actual commercial sample (w/Certificate of Analysis) (upon request of the evaluator)
10. If with previously approved/acknowledged variation applications filed prior to CPR renewal: Copy of the approved/acknowledged Certification and/or Notification (Note that request/s for variation shall be filed separately from the renewal application.)

Additional Requirements:

1. Post-marketing commitments (if any)
2. For imported products: Foreign GMP Clearance

FOR MONITORED-RELEASE EXTENSION (MRE)

1. Integrated Application Form
2. Proof of payment
3. Copy of Latest Certificate of Product Registration (CPR)

4. Unit Dose and Batch Formulation
5. Actual/Commercial Labeling Materials

Additional Requirements:

1. For MRE/MR to Initial applications, proof of approval/clearance/extension of Post-Marketing Surveillance (PMS) Report
2. MRE to Initial: Periodic Safety Update Report (PSUR), or proof of submission
3. Risk Management Plan (RMP)
4. Periodic Safety Update Report (PSUR)
5. For imported products: Certificate of Pharmaceutical Product (CPP) Foreign GMP Clearance

END