Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

CENTER FOR DRUG REGULATION AND RESEARCH

REGISTRATION OF DRUG PRODUCTS UNDER EMERGENCY USE FOR THE CORONAVIRUS DISEASE 2019 (COVID-19) (INITIAL-DEU)

Who May Avail : All Marketing Authorization Holders (MAH) intending to manufacture and import/distribute the drug products listed in the PSMID Interim Guidelines on the Clinical Management of Adult Patients with Suspected or Confirmed COVID-19 Infection and in FDA Circular No. 2020-012, Subject: Guidelines on the Registration of Drug Products under Emergency Use (DEU) for the Coronavirus Disease 2019 (COVID-19).
The list shall be updated following any change/s in the above-stated treatment guidelines and following any amendment/s or changes to the existing guideline (i.e., FDA Circular No. 2020-012).

Fees to be Paid : **Emergency Use Registration:**
PHP 5,000.00 + LRF
Brand Name (if any):
PHP 500.00 + LRF per brand name

CHECKLIST OF REQUIREMENTS

A. Eligibility Criteria as per FDA Circular No. 2020-012: Guidelines for the Registration of Drug Products under Emergency Use (DEU) for the Coronavirus Disease 2019 (COVID-19)

The DEU shall be locally manufactured or imported or distributed for the management of COVID-19 patients during the pandemic, following the PSMID Interim Guidelines.

B. Documentary Requirements [as per FDA Circular No. 2020-012]:

1. Integrated Application Form (in excel and in pdf format)
   - Notarization of required documents shall be waived during the ECQ period. In lieu of this, the applicant shall submit the documents together with a signed letter stating that the notarized copy of the document will be submitted upon lifting of the ECQ. Moreover, the applicant shall be required to submit a self-declaration to read as follows:

     "I declare under the penalties of perjury that the herein submissions are true and correct to the best of my knowledge."
2. Letter of Intent
3. Valid License to Operate (LTO) of Drug Manufacturer/Repacker/Trader (for locally manufactured products) or Drug Importer (for imported products)
4. Certificate of Pharmaceutical Product or Certificate of Free Sale (for imported products)
5. List of countries where the product is marketed (for biologicals)
6. Certificate of Foreign Good Manufacturing Practice (GMP) Clearance duly issued by this Office and/or GMP Certificate issued by the National Regulatory Authority or other competent regulatory authority (for imported products)

7. Labeling Materials
    - Generic Labeling Exemption may be granted for products exceeding 12,000 units
8. Product Composition/Formulation (Unit Dose and Batch Formulation)
9. Finished Product Technical Specifications
10. Finished Product Certificate of Analysis (CoA) and Batch Analysis
11. Stability Studies
    - Drug products with no stability studies shall be given an interim shelf-life of 6 months
12. Proof of Payment (Official Receipt or Landbank Oncoll Payment Slip)

Post-Approval Compliance (As per FDA Circular No. 2020-012):

1. **Post Approval Commitments (PACs)**
   PAC shall be submitted within the CPR validity, or as prescribed below:
   a. Post-Approval Stability Data of Commercial Batch/es for products without stability data submitted upon its registration
   b. Commercial sample from the first batch of manufacture (local) or importation shall be submitted to this Office prior to distribution
   c. Reference standards of the Active Pharmaceutical Ingredient/s (API) – submission shall be within five (5) working days from the CPR issuance

2. **Post-Market Surveillance (PMS)**
   Health institutions (Hospitals, other Health Facilities) and Healthcare Professionals that shall use the products approved under this Circular shall coordinate and submit to the respective suppliers/MAH for Adverse Drug Reaction (ADR) reports. The MAH shall be responsible for the submission of the ADR reports consistent with the latest issuance with this Office. The MAH shall undertake the PMS activities in a separate issuance.

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