Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA CIRCULAR
No. 2021-008

20 APR 2021

SUBJECT: **Updated Guidelines for the Registration of Drug Products under Emergency Use (DEU) for COVID-19**

I. RATIONALE

The global search still continues for an effective treatment for SARS-CoV-2 infection or COVID-19. On 22 September 2020, the Food and Drug Administration (FDA) Circular No. 2020-028 was issued, which provided guidelines for the registration of Drug Products under Emergency Use (DEU) for COVID-19 following the recommendations in the Philippine Society for Microbiology and Infectious Diseases (PSMID) for the Clinical Management of Adult Patients with Suspected or Confirmed COVID-19 Infection.

On 30 March 2021, the Philippine COVID-19 Living Recommendations was first issued, which replaced the previous PSMID guidelines. As a living document, it provides the up-to-date review of scientific evidence and consolidates recommendations from various medical societies and institutions on the treatment, diagnosis, and prevention of COVID-19. In view of the foregoing, there is now a need to update the current regulations on the registration of DEU. This is to ensure access to quality, safe, and effective drug products with positive recommendations which are needed by the COVID-19 patients.

II. OBJECTIVE

This Circular aims to provide streamlined requirements and application process for the registration of drug products for COVID-19.

III. SCOPE AND COVERAGE

This Circular shall be applicable to all licensed drug establishments intending to manufacture and import/distribute the drug products listed in the Philippine COVID-19 Living Recommendations. In order to qualify for DEU, a drug product should have a positive recommendation in the COVID-19 Living Recommendations, and must have a registered counterpart with the FDA at the time of the application.

IV. GUIDELINES

A. Documentary Requirements

Only the following requirements shall be submitted:

1. Integrated Application Form (in excel and in pdf format)
2. Letter of Intent
3. Valid License to Operate as Drug Manufacturer/Repacker/Packer/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 (for imported products)
7. Labeling Materials
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. Application for Generic Labeling Exemption (GLE), if applicable
13. Proof of Payment (Official Receipt or Landbank Oncoll Payment Slip)

GLE may be granted for products exceeding 12,000 units.

B. Application Process

There shall be no need for the scheduling of submission of applications under this Circular. Applications for the registration shall be under Emergency Use Classification and shall be submitted at the Food Drug Action Center (FDAC). Submission of applications may be done either:

Manual submission to FDAC. Submit the requirements in a flash drive at the FDAC – PACD. An Acknowledgement Receipt with a corresponding Document Tracking Number shall be issued to the applicant.

E-mail submission. The applicant shall submit the application through fdac.pacd.cdrr@fda.gov.ph. Guidance for e-mail submission shall be specified in a separate issuance.

C. Fees

The appropriate fees as prescribed under existing regulations shall apply, including the Legal Research Fund (LRF).

Application Type	Fees
Emergency Use Registration	Php 5,000.00 + LRF

Brand Name (if any)	Php 500.00 + LRF per brand name
GLE	Php 500.00 + LRF

D. Validity of the Certificate of Product Registration (CPR)

The CPR shall be valid for one (1) year under DEU Registration Status and is not subject for renewal registration.

New DEU applications for a drug product shall not be accepted under the following circumstances:

a. The Philippine COVID-19 Living Recommendations no longer positively recommends the drug product for COVID-19, or
b. Upon declaration of the lifting of the National State of Calamity.

E. Post-Approval Compliance

Post-Approval Compliance to the CPR shall be strictly required from the MAH.

1. Post-Approval Commitments – 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 fifteen (15) 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 submit to the respective MAH the 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.

F. Supplemental Information

As interim measures for applications and transactions during the community quarantine, electronic signatures in documents shall be temporarily allowed. The requirement for notarized documents shall also be temporarily suspended. Instead, the applicant shall be required to submit a commitment letter for the submission of the notarized documents once available.

V. REPEALING CLAUSE

This issuance repeals FDA Circular No. 2020-028, as amended by FDA Circular No. 2020-028-A, or the *Reissuance of the Guidelines for the Registration of Drug Products Under Emergency Use (DEU) for the Coronavirus Disease 2019 (COVID-19).*

All other FDA issuances which are inconsistent with this Circular are hereby deemed repealed or modified accordingly.

VI. SEPARABILITY CLAUSE

In the event that any provision or part of this Circular is declared unauthorized or rendered invalid by any court of law, those provisions not affected by such declaration shall remain valid and effective.

VII. EFFECTIVITY

This Circular shall take effect immediately upon submission of three (3) certified copies to the Office of the National Administrative Register (ONAR) of the UP Law Center.

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Director General