Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA CIRCULAR
No. 2021-008-A

22 SEP 2021

SUBJECT: **Amendment to FDA Circular No. 2021-008, entitled, "Updated Guidelines for the Registration of Drug Products under Emergency Use (DEU) for COVID-19"**

On 20 April 2021, FDA Circular (FC) No. 2021-008 entitled "Updated Guidelines for the Registration of Drug Products under Emergency Use (DEU) for COVID-19" was issued. The said Circular provided streamlined requirements and application process for the registration of Drug Products for COVID-19.

In line with our efforts in streamlining the application process and requirements for the registration of drug products for COVID-19, Section IV. A. Documentary Requirements and IV. E.1. Post-approval Commitments of FC No. 2021-008 is hereby amended.

A. Documentary Requirements

Only the following requirements shall be submitted by the MAHs:

1. Integrated Application Form (in excel and in pdf format)
2. Valid License to Operate of Drug Manufacturer/Repacker/Packer/Trader (for locally manufactured products) or Drug Importer (for imported products)
3. For imported products:
   - Certificate of Pharmaceutical Product attesting that the manufacturing facilities and operations conform to the good manufacturing practices (GMP), and confirmation of marketing status in the issuing country; or
   - Certificate of Good Manufacturing Practice (GMP) and Certificate of Free Sale;
     - ➢ If the product is not freely sold from the country of origin, an Export Certificate or equivalent document attesting the restricted use/access of the product shall be submitted.
4. Labeling Materials
   - Generic Labeling Exemption, if applicable, may be granted for products that require special handling or with special packaging, and with volume of importation exceeding 12,000 units.
5. Product Composition/Formulation (Unit Dose and Batch Formulation)
6. Finished Product Technical Specifications
7. Stability Studies
   - For drug products with no stability studies at the time of application, an interim shelf-life of 6 months shall be given, and the same storage condition as the registered counterpart.
8. Proof of Payment (Official Receipt or Landbank Oncoll Payment Slip)

E. Post-Approval Compliance

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 with corresponding Certificate of Analysis shall be submitted to this Office prior to distribution.
    c. Reference standard/s of the Active Pharmaceutical Ingredient/s (API/s) shall be submitted together with the commercial sample from the first batch of manufacture or importation.

All the other provisions of FC No. 2021-008 not affected by this change shall remain valid and in effect. This Circular shall take effect immediately.

ROLANDO ENRIQUE D. DOMINGO, MD
Director General

DTN 20210921162942