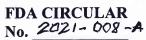


Republic of the Philippines Department of Health FOOD AND DRUG ADMINISTRATION





2 2 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.

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Director General

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