FDA CIRCULAR
No. _____

SUBJECT: **Interim Guidelines on the Renewal of Current Good Manufacturing Practice (cGMP) Clearance of Foreign Drug Manufacturers**

I. RATIONALE/BACKGROUND

Pursuant to Administrative Order (AO) No. 2013-0022, entitled, "Guidelines for Current Good Manufacturing Practice (cGMP) Clearance and Inspection of Foreign Drug Manufacturers", and its implementing guidelines, FDA Circular No. 2014-016, the Food and Drug Administration (FDA) conducts inspections of foreign drug manufacturers to ensure compliance with the principles of GMP. Apart from documentary evidence, on-site inspections, when determined by FDA, are required for securing a cGMP clearance prior to registration.

In March 2020, the World Health Organization (WHO) declared COVID-19 a global pandemic. The FDA Philippines recognizes that this ongoing pandemic is not only affecting public health, but it also is posing a crisis in the pharmaceutical sector. Furthermore, this Public Health Emergency of International Concern imposes operational challenges and limitations, rendering foreign inspections not feasible. Conducting on-site inspections poses a clear health risk to the FDA GMP inspectorate.

To ensure the welfare and protection of the Drug GMP Inspectorate Task Force while ensuring availability and access to essential drug products amidst the COVID-19 pandemic, FDA Circular No. 2020-020, entitled, "Interim Guidelines Governing the Issuance of a Permit to Register to Drug Importers for Foreign Drug Manufacturers", was issued.

On 20 August 2020, the FDA issued FDA Circular No. 2020-024, entitled, "Updated Guidelines for Application of Authorizations at the Food and Drug Administration in Light of the Community Quarantine Declarations", declaring that the conduct of all foreign inspections for the year 2020 shall be deferred until further notice pending the lifting of the travel restrictions being imposed in the Philippines and other countries concerned.

In light of the continuing global public health situation, this Circular is hereby issued to provide the interim guidelines on the renewal of cGMP clearance of foreign drug manufacturers to ensure the availability and access to drug products from foreign sources.

II. OBJECTIVES

Considering the COVID-19 pandemic and consistent with the spirit and continuing policy of the government manifested in the pertinent objectives and the declared COVID-19 response and recovery interventions provided under Republic Act No. 11494 or the "Bayanihan to Recover As One Act", this Circular is being issued to provide the interim guidelines on the renewal of cGMP clearance of foreign drug manufacturers.

III. SCOPE

This Circular shall apply to all incoming and previously received foreign cGMP clearance renewal applications.

IV. GUIDELINES

A. *Incoming Renewal Applications*

Renewal applications filed with the FDA shall be submitted in accordance with the following guidelines:

1. Applicants shall follow the process of submission in accordance with the Food and Drug Action Center (FDAC) New Normal Operational Guidelines, as indicated in FDA Circular No. 2020-026 or its latest issuance.
2. The requirements provided in AO No. 2013-0022, FDA Circular No. 2014-016, and related issuances shall be submitted as follows:
    a. Letter of Request
    b. GMP Evidence
       The acceptable GMP evidence issued by a competent authority listed may be in the form of:
        i. GMP Certificate (Certificate of GMP Compliance), or
        ii. WHO Certificate of Pharmaceutical Product; or
        iii. Manufacturer's License or Manufacturing Authorization incorporating the specific medicinal product(s)/ dosage form(s).
    c. Annex B (Request for GMP Evidence Evaluation Form) of AO 2013-0022
    d. Annex C (GMP Evidence Dossier) of AO No. 2013-0022 – for Non-PIC/S
    e. Annex E (Affidavit of Undertaking) of AO No. 2013-0022
    f. Assessment Slip
3. The cGMP Clearances for Foreign Drug Manufacturers issued by the FDA of all incoming renewal applications covered by this Circular shall be extended until 31 December 2021. However, those applications with a longer validity than 31 December 2021 shall be processed.

B. ***Previously Received Renewal Applications***

The validity of cGMP Clearances for Foreign Drug Manufacturers issued by the FDA of all previously received renewal applications shall be extended until 31 December 2021. However, those applications with a longer validity than 31 December 2021 shall be processed.

An application for renewal of a cGMP clearance received after 31 December 2021 shall be subject to a surcharge or penalty equivalent to twice the renewal cGMP clearance fee and an additional 10% per month or a fraction thereof of continuing non-submission of such application to a maximum of one hundred twenty (120) days. Any application for renewal of cGMP clearance filed after the 120-day period shall be considered expired and the application shall be subject to a fee equivalent to the total surcharge or penalty plus the initial filing fee and the application shall undergo the initial filing and evaluation procedure. Further, the Center for Drug Regulation and Research shall take other regulatory actions as warranted.

V. REPEALING AND SEPARABILITY CLAUSE

Provisions in previous circulars and memoranda that are inconsistent with this Circular are hereby withdrawn, repealed and/or revoked accordingly.

If any provision in this Circular, or application of such provision to any circumstances, is held invalid, the remainder of the provisions in this Circular shall not be affected.

VI. EFFECTIVITY

This Circular is an interim guideline during the COVID-19 pandemic and shall take effect immediately and valid until 31 December 2021, unless sooner revoked.

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