FDA CIRCULAR
No. _____

SUBJECT: **Interim Guidelines for the Issuance of Current Good Manufacturing Practice (cGMP) Clearance to Foreign Drug Manufacturers**

I. RATIONALE

Republic Act No. 11469 otherwise known as "Bayanihan to Heal as One" was enacted in view of the increasing number of COVID-19 cases in the country. This pandemic posed a serious threat to public health and disruption to the economy of the country which led to the declaration of State of Calamity throughout the Philippines through Proclamation No. 929 s. 2020.

Consistent with the mandate of the Food and Drug Administration (FDA) to ensure the safety, efficacy and quality of health products being made available to the public, Administrative Order No. 2013-0022, or the "Guidelines for Current Good Manufacturing Practice (cGMP) Clearance and Inspection of Foreign Drug Manufacturers" was issued to which cGMP Clearance is a requirement prior to the registration of imported drug products.

However, the conduct of foreign inspection is not feasible as of the moment due to the increasing number of confirmed COVID-19 cases worldwide. Moreover, restrictions were also imposed by various authorities limiting travel which greatly affected the conduct of foreign inspection. With the utmost consideration on the welfare and protection of the GMP Inspectorate Team, it is imperative to issue interim guidelines for securing an appropriate authorization so as not to hamper the process of registration of drug products while ensuring that their respective foreign drug manufacturers are compliant with the existing standards of GMP.

II. OBJECTIVE

This Circular aims to provide interim guidelines to facilitate drug product registration of drug importers with pending inspection of foreign manufacturers due to the COVID-19 pandemic and international travel restrictions.

III. SCOPE

This Circular shall apply to all drug importers and foreign drug manufacturers issued with Notice for Foreign Inspection (NFI). Furthermore, this shall also cover the Center for Drug Regulation and Research (CDRR),

Field Regulatory Operations Office (FROO) and other concerned Offices within the FDA.

IV. GUIDELINES

1. The conduct of foreign inspection is temporarily suspended until further notice.

2. Drug importers issued with NFI prior to this Circular shall be subjected to desktop review upon payment of 50% of the required inspector's fee and shall be given priority once foreign inspection resumes.

3. Upon the resumption of on-site foreign inspection, a notice shall be issued to the drug importer on the schedule of inspection and a directive to pay the remaining 50% of the inspector's fee.

4. In case the drug importer intends to withdraw the application for cGMP Clearance, a written notification must be submitted to FDA. Consequently, this shall mean automatic revocation of the authorization/s issued following this Circular and appropriate regulatory actions shall follow thereafter.

V. DOCUMENTARY REQUIREMENTS

For the purposes of this Circular, the following documentary requirements shall be submitted by the applicant:

1. Updated GMP Evidence issued by the Drug Regulatory Authority (DRA)
2. Updated GMP Evidence Dossier (Annex C)
3. Updated Duly accomplished Application form for foreign manufacturer GMP Inspection (Annex D) should there be any changes in the manufacturer information
4. Proof of payment amounting to 50% of appropriate inspector's fee as per AO No. 2013-0022 and FDA Circular 2014-016

VI. APPLICATION PROCESS

1. Filing

The FROO shall notify the drug importer with NFI and send an assessment slip for the payment of the inspector's fee and list of the required documents for submission. The required fee shall be paid to the FDA Dollar Account at any DBP branches while the required documents shall be filed at the Food and Drug Action Center (FDAC).

2. Evaluation

The desktop review shall be conducted by the GMP Inspectorate Team with verification of the submitted evidence from the issuing DRA, among others. Should there be any clarification to prove compliance, an e-mail shall be sent to the applicant.

VII. DECISION ON AN APPLICATION

An appropriate authorization shall be issued to the drug importer after having been satisfactorily complied with the GMP standards based on desktop review to allow the applicant to proceed with drug product registration. However, this does not preclude the conduct of on-site foreign inspection upon resumption of international travel.

For applications that fail to satisfactorily comply with GMP standards after the desktop review, a notice shall be issued on the matter and will be subjected to on-site foreign inspection upon its resumption.

VIII. EFFECTIVITY

This Circular shall take effect immediately after publication to a newspaper of general circulation and upon submission to the University of the Philippines Office of National Administrative Register (UP-ONAR) and until further notice.

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Director General

Keywords	*GMP, cGMP Clearance, Foreign Drug Manufacturers, Drug Importer, Certificate of Product Registration, Foreign Inspection*
Related Issuances, Laws, Directives	*RA 9711, AO 2013-0022, FDA Circular 2013-023, FDA Circular 2014-016*