Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

10 JUL 2020

FDA CIRCULAR
No. 2020-020

SUBJECT: Interim Guidelines Governing the Issuance of a Permit to Register to Drug Importers for Foreign Drug Manufacturers

I. RATIONALE

Consistent with the policy of the State to adopt an integrated and comprehensive approach to health development, which shall endeavor to make essential goods, health and other social services available to all people at affordable cost, Republic Act No. 9502[1] was enacted.

Further, to ensure that essential goods, drug products in particular, that are made available to the people are safe and of quality, Administrative Order (A.O.) No. 2013-0022[2] was promulgated with the aim of creating and implementing systems of evaluation, monitoring, including the conduct of foreign inspections to assure compliance of manufacturers to the Good Manufacturing Practice (GMP) that sells or offers for sale their drug products into the Philippines. Its implementing guidelines, FDA Circular (F.C.) No. 2014-016, further set out when the conduct of foreign inspection is initiated or triggered. Under the said FDA Circular, the Center for Drug Regulation and Research, after assessing the submitted applications for GMP Clearance, recommends to FROO for inspection those that have not provided satisfactory GMP evidence[3]. Once confirmed that the facility manufactures the drug products at an acceptable standard (cGMP) and is issued clearance, the foreign manufacturer, through its local importer(s) can now proceed to register before the FDA its drug product before making them available for commercial distribution locally.

The Coronavirus disease 2019 (COVID-19) pandemic has triggered national and international restrictions that prevent the conduct of certain on-site GMP inspections. This health pandemic has put every country and everyone in an extraordinary situation and with the still increasing number of confirmed COVID-19 cases worldwide and imposed international travel restrictions, the conduct of the foreign inspection in accordance with F.C. No. 2014-016 has been rendered completely not feasible.

Consequently, and with the utmost consideration of the welfare and protection of the Drug GMP Inspectorate Task Force on the one hand, while on the other hand,

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[1] *Universally Accessible Cheaper and Quality Medicines Act of 2008.*
[2] *Guidelines for Current Good Manufacturing Practice (cGMP) Clearance and Inspection of Foreign Drug Manufacturers.*
[3] *Item IV (B) (2) of FDA Circular No. 2014-016.*

the duty to implement the policy of ensuring availability of and access to essential goods, it becomes imperative to issue interim guidelines to facilitate the registration not only of COVID-19 related drug products, but also other essential and life-saving drug products. Hence, this Circular.

II. OBJECTIVE

This Circular shall provide the interim guidelines for the thorough evaluation of submitted applications for GMP Clearance which was recommended for inspection, and the appropriate action thereto to facilitate drug product registration of drug importers due for inspection of foreign manufacturers, which inspection cannot be pursued due to the compelling reasons of protecting the safety and welfare of the Drug GMP Inspectorate Task Force and international travel restrictions brought by the COVID-19 pandemic.

In issuing this Circular, the FDA hereby consistently reiterates its mandate to ensure the safety, efficacy, and good quality of pharmaceutical products applied for registration and made available to the consuming public.

III. SCOPE

This Circular shall apply to all initial applications for GMP Clearance of drug importers and foreign drug manufacturers, with issued Notice for Foreign Inspection (NFI) and have paid the application fee for Foreign Drug Manufacturer Inspection.

Furthermore, this shall also cover the Center for Drug Regulation and Research (CDRR), Field Regulatory Operations Office (FROO), Drug GMP Inspectorate Task Force and other concerned Offices within the FDA.

IV. GUIDELINES

1. The conduct of foreign inspection in accordance with F.C. No. 2014-016 is temporarily suspended for a period of one year from date of effectivity of this Circular unless sooner lifted.

2. The submitted updated GMP evidences of drug importers issued with NFI shall be subjected to thorough evaluation and review by the Drug GMP Inspectorate Task Force of the FROO, provided that a Foreign cGMP clearance shall be issued to manufacturers which have been inspected by Pharmaceutical Inspection Cooperation Scheme (PIC/S), ASEAN Mutual Recognition Agreement (MRA) and part of the WHO Prequalification Program.

3. A Permit to Register shall be issued to the drug importer for applications found satisfactorily complying with the GMP standards based on document review.

   A Permit to Register shall only be an interim approval to allow the applicant to proceed with the drug product registration. Foreign inspection shall still be conducted notwithstanding the issuance of the Permit to Register once foreign inspection resumes pursuant to paragraph 6, Item V of A.O. No. 2013-0022.

If found compliant with the cGMP standards during the foreign inspection, a Foreign cGMP Clearance shall be issued. If found non-compliant, a letter of disapproval shall be issued and all product applications and existing CPRs related to the Permit to Register shall be disapproved, suspended, cancelled or revoked.

4. Those applications which were evaluated to be satisfactory shall be notified to pay 50% of the required inspector's fee, and shall be issued the Permit to Register upon payment. These applications shall be given priority once foreign inspection resumes.

5. Applications which are not satisfactory shall not be issued a Permit to Register, and shall be subject for inspection upon resumption of Foreign GMP Inspection.

6. An incomplete submission of requirements under this Circular shall be denied.

7. Upon the resumption of on-site foreign inspection, drug importers shall be given a schedule of inspection and a directive to pay the remaining fees.

8. In case the drug importer intends to withdraw the application for Foreign cGMP Clearance, a written notification shall be submitted to FDA. The withdrawal shall mean abandonment of any application or intent to apply for drug product registration.

V. APPLICATION PROCESS

1. Filing

Applicants with issued NFI and have paid the application fee for Foreign Drug Manufacturer Inspection before July 2020 shall be notified by FROO to submit the following documents to the Food and Drug Action Center (FDAC) within twenty (20) working days from receipt of the notice, otherwise the application is deemed abandoned, resulting to the issuance of a disapproval:

a. Letter of Intent;
b. Updated GMP Evidence issued by the Drug Regulatory Authority (DRA);
c. Updated GMP Evidence Dossier (Annex C of A.O. No. 2013-0022);
d. Updated duly accomplished Application Form for foreign manufacturer GMP Inspection (Annex D of A.O. No. 2013-0022) should there be any changes in the manufacturer information; and
e. List of Products to be registered.

On the other hand, applicants with issued NFI beginning July 2020 may submit latest requirements stated above.

2. Evaluation

Thorough evaluation and review of the updated GMP evidence shall be conducted by the Drug GMP Task Force 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.

If found satisfactorily complying with the GMP standards based on document review, the FROO shall send an assessment slip for the payment of 50% of the inspector's fee. The required fee shall be paid to the FDA Dollar Account at any DBP branches within twenty (20) working days upon receipt of the assessment slip otherwise, the application is deemed abandoned, resulting to the issuance of a disapproval. Proof of payment shall be submitted to FROO.

Priority shall be given in the following order:

a. COVID-19 related drug products including vaccines as determined by FDA;
b. Innovator drug products;
c. Other Foreign cGMP Inspection applications that were scheduled and have already paid the full inspector's fee prior to the issuance of this Circular;
d. First five (5) products of a molecule;
e. Essential and life-saving drug products with less than five (5) suppliers in the country;
f. Others wherein the order of evaluation shall follow the order of submission.

The FROO shall evaluate the applications according to the priority provided above. The CDRR shall assist FROO in the evaluation, and if necessary, provide a list of products that shall be prioritized in the evaluation.

3. Decision

Upon recommendation of FROO, CDRR shall issue the appropriate decision on the application as provided under these Guidelines with notice to the applicant.

VI. INSPECTOR'S FEES

The Inspector's Fees shall be as follows:

Region	Inspector's Fee	50% of the Inspector's Fee
ASEAN Countries	US$ 3,500	US$ 1,750*
Asia-Pacific Countries	US$ 7,000	US$ 3,500*
All other countries outside Asia-Pacific	US$ 10,500	US$ 5,250*

*The additional current United Nation Development Program – Daily Subsistence Allowance (UNDP-DSA), plane fare and translator's fee shall be paid in full together with the remaining 50% of the inspector's fee.

No refunds shall be considered once the appropriate fees have been paid.

VII. 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 shall be valid for one year unless sooner revoked.

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Director General