



FDA CIRCULAR

No. _____

SUBJECT: Supplement to FDA Circular No. 2014-016, or the “Implementing Guidelines for Administrative Order 2013-0022,” on the Renewal of cGMP Clearance

I. RATIONALE/BACKGROUND

On 30 May 2014, FDA Circular No. 2014-016 was issued to define the rules and regulations, the activities that must be undertaken, as well as the identification of the appropriate office responsible and accountable for the proper implementation of Administrative Order No. 2013-0022.

To further achieve the objectives of Republic Act (RA) No. 9711 of ensuring the FDA’s monitoring and regulatory coverage over health products and providing coherence in FDA’s regulatory system for drug manufacturers and drug products, this Circular is hereby issued.

Furthermore, the issuance of this Circular exemplifies the FDA’s commitment to take appropriate measures to promote integrity, accountability, establish effective practices and the prevention of graft and corruption and transparency in every undertaking in compliance with RA 11032 or the Ease of Doing Business and Efficient Government Service Delivery Act of 2018.

II. OBJECTIVE

This Circular aims to provide the procedural guidelines on the renewal applications of foreign drug manufacturing sites previously inspected by FDA Philippines.

III. SCOPE

This Circular shall apply to all drug importers whose foreign drug manufacturers were previously inspected and issued cGMP Clearance.

IV. IMPLEMENTING DETAILS

Renewal of cGMP Clearance

1. Application Process and Requirements

The current application process as specified in FDA Circular No. 2014-016 shall apply.

Applications for renewal of cGMP Clearance of manufacturers *immediately preceding* the last FDA inspection and granted approval by FDA Philippines shall, as a rule, not be inspected provided it complies with the requirements below.

However, the preceding rule shall not apply in the following cases, and therefore, prior inspection is mandatory:

- a. If during the validity of the initial GMP Certificate, evaluation of the renewal application, or anytime subsequent thereto, there is a finding of quality, safety or efficacy defects in the product registered or sought to be registered with FDA; or
- b. Where evidence exist that the applicant company fraudulently filed, misrepresented, falsified, or withheld any relevant data or information contrary to the provisions of Republic Act No. 3720, as amended by Republic Act No. 9711, its Rules and Regulations or appropriate standards.
- c. Where previous inspection resulted to critical deficiency/ies and/or with major changes relative to the product line/s indicated in the cGMP Clearance

The importer applying for renewal shall submit the following requirements:

- a. Authenticated or Apostilled valid GMP certificate issued by local NRA
- b. Copy of the latest GMP contract between the manufacturer and the importer, including a list of the specific products for supply in the Philippines/ updated list of imported products as reflected in valid distribution agreement
- c. Copy of the latest Site Master File (including any changes from previous inspection of FDA Philippines)
- d. CAPA on previous inspection and proof of CAPA implementation.
- e. History of Quality Defect/s for the past 3 years from date of inspection, if any
- f. Warning letter and/ or regulatory actions (referring to product quality, safety, efficacy) issued by the local and/or other NRA for the past 3 years from date of inspection of FDA Philippines, if any

2. Evaluation

The Center for Drug Regulation Research shall determine whether there is a need for re-inspection based on all of the following:

- a. Assessment of documents submitted as per Section 1 above
- b. Risk Assessment based on the previous inspection of FDA Philippines
- c. History of Quality Defects (for past 3 years) in local distribution, such as but not limited to:
 - i. Product Recalls
 - ii. Failed Market Surveillance Test Results
 - iii. Enforcement Investigation
 - iv. Other indicators of non-compliance

- d. Included in the Department of Health (DOH) programs, priority drugs (e.g., anti-cancer drugs, orphan drugs)

3. Decision

- a. If evaluation of document was found to be satisfactory, the application shall be approved for the issuance of Certificate of GMP Compliance. The product(s) covered by the certificate and locally distributed shall be referred to Product Research Standards and Development Division (PRSDDD) to be included in the Annual Post Marketing Surveillance Plan to monitor compliance to standards.
- b. If evaluation of document shows the application to be unsatisfactory, a Letter of Disapproval from CDRR will be issued with the reason for such.
- c. At any time, where evidence exist that the applicant company fraudulently filed, misrepresented, falsified, or withheld any relevant data or information regarding the corresponding application the CDRR shall disapprove the application outright or cause the suspension, revocation, cancellation of the issued cGMP Clearance pursuant to Section IV, Article I, Book II of IRR RA 9711.

Notwithstanding the issued Certificate of GMP Compliance, the foreign drug manufacturer shall be subject to inspection at any time to validate its continuous compliance with relevant FDA laws, rules, and regulations. Any violation thereof, the FDA reserves the right to suspend, cancel or revoke the said Certificate and impose other regulatory or enforcement tools as may be warranted.

V. SEPARABILITY CLAUSE

All other provisions of FDA Circular No. 2014-016 shall remain valid and in effect.

In case any part, term or provision of this FDA Circular is declared contrary to law or unconstitutional, other provisions which are not affected remain in force and effect.

VI. EFFECTIVITY

This Circular shall be effective immediately.

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Director General