



Republic of the Philippines  
Department of Health  
**FOOD AND DRUG ADMINISTRATION**



30 May 2014

**FDA CIRCULAR**  
No. **2014-016**

**SUBJECT: Implementing Guidelines for Administrative Order No. 2013-0022 dated 13 August 2013, Subject: Guidelines for Current Good Manufacturing Practice (cGMP) Clearance and Inspection of Foreign Drug Manufacturers**

**I. RATIONALE**

On 13 August 2013, Administrative Order No. 2013-0022 was issued requiring the creation of systems and procedures that would (1) ensure the compliance of all imported sources of pharmaceutical products with current Good Manufacturing Practices (cGMP), and (2) establish a separate database and coding system for applications of, and those compliant to cGMP.

Thus, the issuance of this Circular to clearly define the rules and regulations, the activities that must be undertaken, as well as the identification of the appropriate office that shall be responsible and accountable for the proper implementation of the said regulation's provisions.

**II. OBJECTIVES**

Given the rationale stated above, the objectives of this Circular are:

- 1) To provide supplementary/implementing guidelines to Administrative Order No. 2013-0022;
- 2) To identify/create the specific units within the FDA, as well as their responsibilities in implementing the said regulation and this issuance; and
- 3) To establish systems that is aimed to ensure compliance of foreign drug manufacturers with cGMP.

**III. SCOPE**

This Circular shall apply to all establishments importing drug, foreign drug manufacturers and concerned Offices of FDA.



#### IV. IMPLEMENTING DETAILS

##### *A. Requirement for GMP Clearance from FDA*

Prior to registration, all importers of drug products must obtain GMP clearance from FDA for each of their foreign drug manufacturer(s) engaged in any and all operations involved in the production. GMP clearance from FDA is now hereby declared a requirement for product registration.

##### *B. Responsibilities of CDRR's and FROO's section, division, office or personnel*

For proper implementation, the appropriate section, division, office or personnel of the Center for Drug Regulation and Research (CDRR) and Field Regulatory Operations Office (FROO) that is in charge of GMP shall be authorized and responsible to re-evaluate and monitor GMP compliance of foreign drug manufacturer who sell or offer their products for sale or distribute in the Philippines.

Consequently, the responsibilities of the section, division, office or personnel at CDRR are:

- 1) Assess the submitted applications for GMP Clearance;
- 2) Recommend to FROO for inspection those that have not provided satisfactory GMP evidence;
- 3) Maintain the database of foreign drug manufacturer compliant and non-compliant with cGMP;
- 4) Maintain the records of reports related to foreign inspections;
- 5) Maintain the database of imported drug products with GMP Clearance;
- 6) Refer to FROO any event that will require inspection; and
- 7) Issue GMP Clearance /Letter of Denial.

On the other hand, the responsibilities of the section, division, office or personnel at FROO are:

- 1) Process applications for Foreign GMP Inspection;
- 2) Coordinate with the local establishment for logistics;
- 3) Handle scheduling of foreign inspections;
- 4) Conduct foreign GMP inspection; and
- 5) Forward to CDRR the result of inspection with recommendation for issuance of GMP Clearance or Letter of Denial.

Finally, the Administration and Finance Office (AFO) and the Policy and Planning Office are expected to provide any necessary and appropriate support needed for the implementation of this Circular.

### *C. Procedure*

#### 1) Submission of Application for GMP Clearance

Application for GMP Clearance via GMP Evidence Evaluation and application for Product Registration of the earliest affected product shall be submitted simultaneously.

The current process of submission as provided in the latest issuance of FDA shall be followed.

#### 2) Evaluation of GMP Evidence Application

The evaluation of the application shall be based on completeness of the requirements, and in accordance with the General Requirements for GMP Evidence Evaluation and other relevant standards, rules and regulations recognized and implemented by FDA.

If, upon evaluation, it was found that the applicant company fraudulently filed or misrepresented, falsified, or withheld any relevant data or information regarding the corresponding application, the CDRR shall disapprove the application outright pursuant to Section 4, Article I, Book II of the IRR of RA No. 9711. The CDRR may also recommend to the LSSC for any appropriate legal actions.

#### 3) Decision on Application for GMP Evidence Evaluation

(a) If upon evaluation it was found that the manufacturing site is compliant to current Good Manufacturing Practices (cGMP), CDRR shall issue a GMP Clearance with validity as provided under Section VII, (C.2) of A.O. No. 2013-0022.

(b) If upon evaluation it was found that there was no satisfactory evidence to prove that the foreign drug manufacturer is compliant to cGMP, a Notice shall be issued to the applicant; copy furnished the FROO, requiring foreign manufacturing site inspection. The applicant shall comply within ninety (90) working days upon receipt of the notice by filing an Application Form for Foreign Drug Manufacturer GMP Inspection and payment of the corresponding fees following the current procedure of FDA. A copy of the Notice shall be included in the application.

#### 4) Coordination by the Applicant with the FROO for Foreign Drug Manufacturer GMP Inspection

- (a) Once the Application Form for Foreign Drug Manufacturer GMP Inspection is received by the FROO, it shall notify the applicant for the logistics arrangements and schedule of the inspection.

Logistic arrangements under the responsibility of the applicant shall include visa application, when needed; plane ticket booking; other transportation requirements and expenses; and hotel accommodations.

- (b) Once the schedule of inspection is decided, the same shall be implemented not later than ninety (90) days from date of decision, unless for justifiable reason it can be extended but not later than thirty (30) days. If the schedule is not implemented for reasons imputable to the applicant, the inspection is deemed abandoned. Accordingly, the FROO shall proceed to recommend for the disapproval of the application for registration covering the importer's drug product.

#### 5) Decision after Foreign Drug Manufacturer GMP Inspection

- (a) If, after inspection, it was found that the manufacturing site is compliant to current Good Manufacturing Practices (cGMP), FROO shall forward to CDOR the results of inspection and recommendation to issue a GMP Clearance.

- (b) Otherwise or when inspection is declared abandoned pursuant to Paragraph (2) of Item F above, a recommendation to issue a Letter of Denial shall be forwarded to CDOR, which in turn notifies the applicant of its decision. Re-application shall be six (6) months after receipt of Letter of Denial by the importer.

#### D. *Renewal of GMP Clearance*

Three (3) months before expiration of the GMP Clearance issued by FDA, drug importers must re-apply and submit the requirements under Initial Application with attached copy of latest GMP Clearance Letter.

Should the GMP clearance issued by FDA be expired without any renewal applications submitted, CDOR shall take regulatory actions as provided below.

#### E. *Regulatory Actions*

FDA may execute any necessary regulatory action should there be any triggers to protect and promote the health of the Filipino people.

Triggers may refer to any situations wherein the quality, safety and efficacy of a product has been compromised, such as, but not limited to, cancellation by the regulatory authority of the originating country of the

authorization, withdrawal from the market due to safety, efficacy or quality issues.

Regulatory action shall include cancellation of an issued GMP Clearance, disapproval of applications for renewal of covered CPRs, product recall and initiation for action for suspension or revocation of CPR. In such situations wherein regulatory action is initiated, the CDRR shall be responsible for informing all affected/involved drug importers of the cancellation of their GMP Clearance, and the subsequent withdrawal from the market of all affected/involved products.

When re-inspection of the manufacturing site is ordered, the applicable procedure provided above and the application fees shall be adhered to. The inspection fees as well as other required expenses shall be shouldered by all concerned drug importers, following the special arrangement and sharing of inspector's fees provided below.

#### F. Fees

The fees shall be as stated under Annex F of A.O. No. 2013-0022:

Application	Fees per application
Initial Application of GMP Clearance	P5,000.00 (per importer per manufacturer per site) + LRF + P5,000.00 (FGC Unit Review) + LRF
Renewal Application of GMP Clearance	P 2,000.00 + LRF
Re-issuance of GMP Clearance	P1,000.00 + LRF
<b>If recommended for Foreign Drug Manufacturer GMP Inspection</b>	
Application Fee for inspection	P3,000.00 + LRF (per application per importer per site)
Inspector's Fees	
• ASEAN	US\$ 3,500.00 + UNDP-DSA*
• Asia Pacific	US\$ 7,000.00 + UNDP-DSA*
• Others	US\$ 10,500.00 + UNDP-DSA*
Accommodations, travel, translator (if necessary), and other incurred fees	Shall be accomplished by importer(s)

\*UNDP-DSA is per inspector; the fixed fee is per inspection

If recommended for Foreign Drug Manufacturer GMP Inspection, the fee for inspection shall be paid upfront upon submission of application. The inspector shall be paid his/her fees after receipt of notification from FDA, but in no case shall be later than three (3) months from scheduled inspection date.

Special arrangements can be made for the following situations wherein inspection is required, subject to the approval of CDRR:

- 1) Same foreign manufacturer for multiple importers;
- 2) Multiple foreign manufacturers in the same vicinity of a single importer;
- 3) Multiple foreign manufacturers in the same vicinity of multiple importers;  
and
- 4) Such other situations that may arise.

Sharing of the inspector's fees and the other incurred fees (accommodations, travel, translator, etc) is allowed, however, the division is outside the scope of FDA jurisdiction and shall be discussed internally by multiple importers. However, the application fee for foreign inspection shall be paid on a per application per importer basis.

#### **V. REITERATION OF EFFECTIVITY DATE**

As per the effectivity requirements, the full implementation of A.O. No. 2013-0022 shall be on 28 September 2014. All initial and renewal applications for product registration, including all existing products, after the said date shall require valid GMP Clearance from FDA - failure to comply shall mean denial of the product application and subsequent revocation of the CPR.

#### **VI. REPEALING CLAUSE/SEPARABILITY CLAUSE**

Provisions of previous FDA circulars and memoranda that are inconsistent with this issuance are hereby withdrawn, repealed, and/or revoked accordingly. In case any part, term or provision of this Circular is declared contrary to law or unconstitutional, other provisions which are not affected remain in force and effect.

#### **VII. EFFECTIVITY**

This Circular shall take effect immediately upon approval and signature by the FDA Director General.

  
**KENNETH Y. HARTIGAN-GO, MD**  
Acting Director General