[FDA CIRCULAR NO. 2014-016, May 30, 2014]

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

Adopted: 30 May 2014
Date Filed: 01 July 2014

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 noncompliant 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, (C2) 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 CDRR 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 CDRR, 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*