# [ FDA CIRCULAR No. 2014-027, November 21, 2014 ]

## GUIDELINES ON THE IMPLEMENTATION OF NEW RULES AND REGULATIONS ON THE LICENSING OF DRUG MANUFACTURER FOLLOWING ADMINISTRATIVE ORDER NO. 2014-0034, DATED 13 OCTOBER 2014

*Adopted: 21 November 2014*
*Date Filed: 03 February 2015*

### I. RATIONALE

On 13 October 2014, Administrative Order No. 2014-0034 was issued to (a) update and streamline regulatory approaches in licensing of drug establishments, (b) provide faster access of drug products to the public; and(c) promote transparency through the universal use of electronic transaction.

In line with the new rules and regulations on the licensing of establishments classified as drug manufacturers and its subclass (packer/repacker/trader), the Food and Drug Administration (FDA) hereby prescribes the requirements for application for initial and renewal issuance of License to Operate (LTO), variations, as well as other guidelines relevant to these establishments.

### II. LICENSE TO OPERATE (LTO) APPLICATIONS

A. *Documentary Requirements*

1) Application Form

   A completely filled-out and notarized application form signed by the pharmacist and owner/authorized representative must be submitted.

2) Proof of Business Name Registration

   A valid proof of business name registration must be submitted:

   (a) For single proprietorship - Certificate of Business Registration issued by the Department of Trade and Industry (DTI)
   (b) For corporation, partnership and other juridical person - Certificate of Registration issued by the Securities and Exchange Commission (SEC) and Articles of Incorporation
   (c) For cooperative – Certificate of Registration issued by the Cooperative Development Authority and the approved by-laws
   (d) For government-owned or controlled corporation – the law

highlighting the provision creating such establishment.

The proof of business name registration must specify the exact and complete address, e.g., unit number, floor, building, lot, block, phase, street, barangay, city/municipality, province, where applicable.

3) Credentials of the Pharmacist and Other Qualified Personnel

The credentials of the identified pharmacist-in-charge for a specific activity must be submitted, which include:

(a) Valid PRC ID
(b) Certificate of Attendance to appropriate FDA Licensing Seminar
(c) Resignation letter of the pharmacist from previous employer (if previously employed).

The other qualified personnel shall be listed, which include the (1) production manager/head. (2) quality assurance manager/head, (3) quality control manager/head, (4) authorized person for batch release, and (5) pharmacovigilance officer. The credentials will not be submitted during application but may be verified during inspection.

4) Risk Management Plan

A general Risk Management Plan (RMP) for the establishment must be submitted. The RMP shall contain details on how to identify, characterize, prevent or minimize risk relating to the products they engage with. These shall include pharmacovigilance activities and interventions of the establishment to manage the risks.

5) Location Plan

A sketch of the location of the establishment must be submitted which shall be used for inspection purposes. This sketch must indicate clear directions with identified landmarks to locate the establishment.

In addition, the Global Positioning System (GPS) Coordinates in decimal degrees (DD) [Latitude and Longitude] must be indicated in the submission.

6) Site Master File

The Site Master File (SMF) must be submitted, in accordance with the latest edition of the Pharmaceutical Inspection Cooperation Scheme (PIC/s) – Good Manufacturing Practice (GMP).

7) Proof of Payment

Proof of payment (e.g., official receipt or authorized bank payment slip) must be included as proof of filing of application.

8) Self-Assessment Toolkit

To guide and facilitate the submission, a Self-Assessment Toolkit (SATK) must be submitted, which will also serve as the worksheet during evaluation of FDA.
The list of documentary requirements for initial and renewal applications of LTO, reissuance of lost or destroyed LTO, as well as voluntary cancellation is attached as Annex A[*].

B. *Evaluation of Application*

1) Desktop Evaluation

All applications shall be initially reviewed by the respective FDA Regional Field Offices to determine compliance with the administrative and technical requirements.

The FDA, in the course of its evaluation may require additional or supplemental documents as proof of compliance to the existing regulations.

2) Pre-opening Inspection

After evaluation of the LTO application, the establishment shall be subjected to pre-opening inspection to determine compliance with the existing guidelines on Pharmaceutical Inspection Cooperation Scheme (PIC/S)-Good Manufacturing Practices (GMP).

In addition to the documentary requirements submitted during application (Section II, A of this Circular), the following documents shall be verified during inspection:

- Quality Management System
- Quality Manual and Standard Operating Procedures
- Contract Agreement (e.g., Manufacturing/ Packing/ Repacking Agreement for Manufacturer-Trader, Packing for Manufacturer-Packer, Repacking for Manufacturer-Repacker)
- Qualification and Validation Documents
- Master and Batch Production Records
- Specifications
- Credentials of other qualified personnel
- Proof of Ownership/Lease Agreement of the space/bldg. by the establishment occupied
- Relevant reference materials (e.g., Republic Acts, PIC/s-GMP Guide, standard practice guidelines)
- Other procedures, protocols, records, and reports as required by PIC/s- GMP

The abovementioned additional documents will serve as proof of compliance by the establishment with the existing regulations on licensing.

A report shall be issued to the drug establishment after inspection, which shall be the basis for the further decision/action of FDA (e.g.,