[FDA Circular No. 2014-025, November 21, 2014]

GUIDELINES ON THE IMPLEMENTATION OF NEW RULES AND REGULATIONS ON THE LICENSING OF DRUGSTORE/PHARMACY/BOTICA AND SIMILAR OUTLETS FOLLOWING ADMINISTRATIVE ORDER NO. 2014-0034, DATED 13 OCTOBER 2014

Adopted: 21 November 2014
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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 drugstore/pharmacy/botica, including hospital and institutional pharmacies, the Food and Drug Administration (FDA) hereby prescribes the requirements for the applications 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 Pharmacy Assistant

The credentials of the identified pharmacist-in-charge 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).

In addition to the pharmacist-in-charge, if the establishment employs a pharmacy assistant(s), the responsible pharmacy assistant who will take charge in the absence of the pharmacist-in-charge must be identified and the credential submitted. The credential of the responsible pharmacy assistant shall be the Certificate of Training for Pharmacy Assistants.

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) Picture of Drugstore with Display of Signage

A picture of the drugstore with signage bearing the name of the establishment consistent with the submitted proof of business name registration must be submitted.

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*

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 that will show proof of compliance to the existing regulations.

C. *Post-licensing Inspection*

All drugstore/pharmacy/botica and similar outlets with approved LTO shall be subjected to routine inspection for their compliance to Good Distribution and Storage Practices (GDP and GSP) and other relevant and applicable practices. In addition, major variation applications may require post-licensing inspection prior to the approval of such variation. Drugstore/pharmacy/botica and similar outlets which are subject to regulatory action due to different triggers (e.g., violation of any of the provisions of FDA laws, rules and regulations, and any other laws related thereto, occurrence of adverse drug reactions, as well as other quality, safety, and/or efficacy issues) shall also be inspected.

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

- Agreement between the franchisor and franchisee, where applicable
- Records/E-file (e.g., distribution records, prescription books, senior citizen and persons with disability record books)
- Standard Operating Procedures
- Display of information, education, and communication materials
- Relevant reference materials (e.g., Republic Acts, WHO GDP and GSP Guide, Philippine National Drug Formulary, standard practice guidelines, Pharmacovigilance-related references)

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 further decision/action of FDA (e.g., approval/ disapproval of an application for LTO, and/or for such other purposes)

Compliance with cold-chain management is also required for drugstore/ pharmacy/botica and similar outlets carrying vaccines, biologics, and other