[FDA Circular No. 2014-028, November 21, 2014]

GUIDELINES ON THE IMPLEMENTATION OF NEW RULES AND REGULATIONS ON THE LICENSING OF RETAIL OUTLET FOR NON-PRESCRIPTION DRUGS (RONPDS) 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 retail outlets for non-prescription drugs (RONPDs), 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 establishments.

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 Supervising Pharmacist

The credentials of the identified supervising pharmacist 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 the credentials of the supervising pharmacist, a list of the other RONPDs supervised must be submitted with the respective addresses and LTO numbers, as well as the supervising hours.

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 retailing 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.

A plotted geolocation of all the other RONPDs supervised must also be submitted.

6) Picture of Drugstore with Display of Signage

A picture of the RONPD 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 RONPDs 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. RONPDs 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, senior citizen and persons with disability record books, schedule of visit of supervising pharmacist, location plan of other RONPDs supervised)
- 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)

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).

D. *Application for Variation*