

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...

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

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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

- 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[*].

- 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.

- 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).

- Application for Variation

The following are the applicable variations to an approved LTO as drug RONPD:

1)

Major Variation

(a)

Change of Ownership

(b)

Transfer of Location

2)

Minor Variation – Prior Approval

(a)

Expansion of Establishment

(b)

Change of Business Name

(c)

Zonal Change in Address

3)

Minor Variation –Notification

(a)

Change of Supervising Pharmacist

FDA should be duly informed of any changes to the approved LTO, whether or not these are classified as variations described above. Other changes may also be added to the variations mentioned, which shall be subject of an appropriate regulation.

The list of documentary requirements for the abovementioned variations is attached as Annex B[*].

All variations are subject to the existing variation/amendment fee, except for transfer of location which is subject to initial payment for two (2) years validity of LTO.

RONPDs applying for minor variations may continue business operations provided that an application for such variation has already been filed.

- Accessibility

All electronic fillable forms shall be made accessible at the FDA Website.

III. MULTIPLE RONPD SUPERVISION

Recognizing the need for greater access to drugs of known lesser risks, FDA hereby promulgates the rules for allowing multiple RONPDs under the supervision of a single pharmacist.

A single pharmacist is allowed to supervise multiple RONPDs provided the following rules are met:

1)

The pharmacist is required to dedicate a minimum of two (2) hours a week of physical presence in the RONPD.

2)

The location of each RONPD must be within the same provincial local government unit (LGU) within each region, with the National Capital Region considered as a single area due to its comparatively smaller land mass;

3)

The distance between two farthest RONPDs must not exceed 25 km in distance;

4)

All other RONPDs supervised by a single pharmacist must be within a circumferential area when plotted between the two farthest RONPDs; and

5)

A maximum of fifteen (15) RONPDs is allowed to be supervised by a single pharmacist.

Considerations may be given to geographically disadvantaged areas.

Appropriate disclosure must be made during the application for the LTO. RONPDs and/or pharmacists that shall violate the abovementioned rules shall be subject to appropriate legal actions.

The list of LGUs is attached as Annex C[*], which is based on the latest issuance from the National Statistical Coordination Board (NSCB). Any revision from the NSCB is automatically adopted.

IV. RESPONSIBILITIES OF SUPERVISING PHARMACIST

The pharmacist supervising multiple RONPDs must be responsible in assuring the safety, efficacy and quality of drug product, which shall include:

1)

Observance of Good Storage Distribution, Good Dispensing, as well as Good Pharmacy Practices

2)

Monitoring of inventory of products including expiry dates;

3)

Ensuring any adverse drug reactions/events experienced by patients/consumers are properly handled, documented, and reported to FDA;

4)

Ensuring that the establishment is updated with the latest issuances and advisories from FDA;

5)

Ensuring all drug products offered for sale/made available in the drugstore/pharmacy/botica and similar outlets are registered in FDA; and

6)

Ensuring compliance of the establishment with existing regulations.

The abovementioned responsibilities should be properly translated into a Standard Operating Procedure (SOP) which shall be duly validated during post- licensing inspection.

V. LIST OF NON-PRESCRIPTION DRUGS

Considering currently available evidences of safety and efficacy, not all non- prescription drugs may be made available to the public without the immediate supervision of a pharmacist or pharmacy assistant. It is in this context that the FDA prescribes only selected registered non-prescription drugs (e.g. household remedies, selected traditional medicines, herbal, and other over-the-counter drugs) to be offered for sale in a RONPD.

The official list of drugs that is allowed for sale in RONPDs shall be posted in the FDA website, and shall be regularly reviewed and revised as more recent evidence becomes available.

VI. RESPONSIBILITIES OF OTHER IMPLEMENTING OFFICES

Consistent with the regulatory powers provided under (3), c, Sec. 2, Article III, Book I of the implementing rules and regulations of Republic Act No. 9711, FDA and its Regional Field Offices through the Director General may call on the assistance of any department office and/or government agency for the effective implementation of its rules and regulations.

In addition, Local Government Units (LGUs) are enjoined in monitoring licensed drug RONPDs in their localities for their compliance to the existing laws and their respective rules and regulations. Any violation found by the LGU inconsistent with the FDA rules and regulations shall be reported to FDA for regulatory action.

VII. TRANSITORY PROVISIONS

Existing licensed establishments are required to submit their Risk Management Plan, GPS Coordinates, and credentials of their supervising pharmacist upon renewal of their LTO.

VIII. 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 FDA Circular is declared contrary to law or unconstitutional, other provisions which are not affected remain in force and effect.

IX. EFFECTIVITY

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

(SGD) ATTY. NICOLAS B. LUTERO III, CESO III

Assistant Secretary of Health

OIC, Food and Drug Administration

[*] Text Available at the Office of the National Administrative Register, U.P. Law Complex, Diliman, Quezon City.

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