Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

21 November 2014

FDA CIRCULAR
No. 2014-025

SUBJECT: **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**

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 temperature-sensitive products.

D. *Application for Variation*

The following are the applicable variations to an approved LTO as drugstore/pharmacy/botica and similar outlets:

1) Major Variation
   (a) Change of Ownership
   (b) Transfer of Location
   (c) Additional Activity
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 the Pharmacist or Pharmacy Assistant
   (b) Deletion of Activity

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.

Drugstore/ pharmacy/ botica and similar outlets applying for minor variations may continue business operations provided that an application for such variation has already been filed.

E. *Accessibility*

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

III. ACTIVITIES REQUIRING PRIOR APPROVAL

The following activities shall require application and prior approval of FDA:

- Online ordering and delivery
- Sterile compounding as well as non-sterile complex compounding, as defined under United States Pharmacopeia, latest edition
- Mobile pharmacy

- Any other activities

The appropriate authorization shall be secured during initial application or may be filed as variation application.

IV. INSTITUTIONAL PHARMACIES REQUIRING LICENSE TO OPERATE

Institutional pharmacies that are required to secure an LTO are those that meet the following criteria:

1) Non-drug establishments that regularly procure drugs to be dispensed to their employees;
2) Drug establishments procuring drugs other than those registered to their names to be dispensed whether at a cost or as part of employee's benefits and/or its dependents.

V. RESPONSIBILITIES OF PHARMACIST AND OWNER

In addition to the agreed responsibilities between the owner and the pharmacist, both must be jointly responsible in assuring the safety, efficacy and quality of drug product, which shall include:

1) Monitoring/supervision of all operations of the establishment;
2) Observance of Good Storage, Good Distribution, Good Dispensing, as well as Good Pharmacy Practices;
3) Promoting the rational use of drugs and ensuring that prescription drugs are dispensed only to patients with a written order or prescription from licensed physician or dentist;
4) Ensuring patient counselling is conducted to the extent possible;
5) Monitoring of inventory of products including expiry dates;
6) Ensuring any adverse drug reactions/events experienced by patients/consumers are properly handled, documented, and reported to FDA;
7) Initiating the removal of the drug products from the shelves and cooperating fully with the market authorization holders (MAHs) should a product recall be ordered by FDA;
8) Ensuring that the establishment is updated with the latest issuances and advisories from FDA;
9) Ensuring all drug products offered for sale/made available in the drugstore/ pharmacy/ botica and similar outlets are registered in FDA and purchased from licensed establishments; and
10) 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.

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 drugstore/ pharmacy/ botica and similar outlets 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 pharmacist and responsible pharmacy assistants 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.

ATTY. NICOLAS B. LUTERO III, CESO III
Assistant Secretary of Health
OIC, Food and Drug Administration

ANNEX A

LIST OF DOCUMENTARY REQUIREMENTS FOR DRUGSTORE/ PHARMACY/ BOTICA AND SIMILAR OUTLETS LTO APPLICATIONS

A. Initial LTO Application
   1) Application Form
   2) Proof of Business Name Registration
   3) Credentials of Pharmacist and Responsible Pharmacy Assistant (where applicable)
   4) Risk Management Plan
   5) Location Plan
   6) Picture of Drugstore with Display of Signage
   7) Proof of Payment (e.g. official receipt or authorized bank payment slip)
   8) Self-Assessment Toolkit

B. Renewal LTO Application
   1) Application Form
   2) Copy of Certifications issued as a result of LTO Variation
   3) Proof of Payment (e.g. official receipt or authorized bank payment slip)
   4) Self-Assessment Toolkit

C. Reissuance of Lost or Destroyed LTO
   1) Letter of Request
   2) Affidavit of Loss or Destruction
   3) Proof of Payment (e.g. official receipt or authorized bank payment slip)

D. Voluntary Cancellation of LTO
   1) Letter of Request
   2) Original LTO

ANNEX B

LIST OF REQUIREMENTS FOR VARIATION APPLICATIONS FOR DRUGSTORE/ PHARMACY/ BOTICA AND SIMILAR OUTLETS

A. Major Variations

Change of Ownership	
C	There is a change of ownership of the drug establishment licensed.
D	1. Application Form 2. Proof of business name registration reflecting the name of new owner 3. Deed of sale or transfer of rights/ownership 4. Proof of payment 5. Self-Assessment Toolkit

Transfer of Location	
C	1. Physical transfer of the drug establishment with changes in the previously approved address. 2. Other variations (e.g. change of pharmacist, and/or business name) may also be included as long as the variation is noted in the application and corresponding requirements for such changes are included. The payment remains as initial fee, regardless of the additional variation.
D	1. Application Form 2. Proof of business name registration reflecting the new address 3. New Location Plan 4. Proof of payment 5. Self-Assessment Toolkit

Additional Activity	
C	1. Additional activity shall include online ordering and delivery, sterile compounding and non-sterile complex compounding, mobile pharmacy and other additional activities that may require appropriate regulation or may be handled on a case to case basis 2. These additional activities may also be applied during initial application.
D	1. Application Form 2. Additional Credentials of Pharmacist (e.g. Certificate of Training, where applicable) 3. Documents related to activity with proof of validation (e.g. SOP, Masterlist of compounding recipes) 4. Proof of payment 5. Self-Assessment Toolkit

B. Minor Variations – Prior Approval

Expansion of Establishment	
C	Shall refer only to the expansion made which is adjacent to the existing location of the establishment.
D	1. Application Form 2. Proof of payment 3. Self-Assessment Toolkit

Change of Business Name	
C	1. Change only in the business name 2. No transfer of location or change of ownership.
D	1. Application Form 2. Proof of business name registration reflecting the new name of the drug establishment 3. Picture of the drugstore with signage bearing the name of the establishment as registered in DTI/SEC (except for franchise drugstore) 4. Proof of payment 5. Self-Assessment Toolkit

Zonal Change in Address	
C	Shall refer to change of the name/number of the street/building without physical transfer of the establishment.
D	1. Application Form 2. Document issued by the local municipality as proof of zonal change 3. Proof of payment 4. Self-Assessment Toolkit

C. Minor Variations – Notification

Change of Pharmacist or Responsible Pharmacy Assistant	
C	1. There is a change of the identified pharmacist or responsible pharmacy assistant. 2. For other pharmacists and pharmacy assistants employed but not registered with FDA, changes on such shall not be required to apply for variation.
D	1. Application Form 2. Credentials of the pharmacist or pharmacy assistant 3. Proof of payment 4. Self-Assessment Toolkit

Deletion of Activity	
C	Shall refer to deletion of any approved/added activity.
D	1. Application Form 2. Proof of payment 3. Self-Assessment Toolkit

*C – Condition
*D – Documents required