Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

21 November 2014

FDA CIRCULAR
No. 2014-026

SUBJECT: **Guidelines on the Implementation of New Rules and Regulations on the Licensing of Drug Distributors 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 drug distributor as importers, exporters, or wholesalers, 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 shall 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 pharmacovigilance officer, among others. The credentials will not be submitted during application for these other qualified personnel 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) Proof of Payment

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

7) 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 that will show 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 Good Distribution and Storage Practices (GDP and GSP) including cold-chain management (where applicable).

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
- Distributorship Agreement with foreign source/ supplier/ manufacturer authenticated by the Territorial Philippine Consulate (e.g., between local importer and foreign manufacturer, local supplier and local wholesaler)
- GMP Certificates or equivalent document of contracted foreign manufacturers issued by the drug regulatory authority in the country of origin
- 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, World Health Organization [WHO] GDP and GSP Guide, 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).

Compliance with cold-chain management is also required for drug distributors carrying vaccines, biologics, and other temperature-sensitive drug products.

C. *Post-licensing Inspection*

All drug distributors with approved LTO shall be subjected to routine inspection following the applicable provisions mentioned for pre-opening inspection under Section II, B of this Circular. In addition, major variation applications may require post-licensing inspection prior to the approval of such variation. Drug distributors 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.

D. *Application for Variation*

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

1) Major Variation
   (a) Change of Ownership
   (b) Transfer of Location
2) Minor Variation – Prior Approval
   (a) Change of Activity
   (b) Expansion of Establishment
   (c) Change of Business Name
   (d) Zonal Change in Address
3) Minor Variation – Notification
   (a) Change of Pharmacist or other Qualified Personnel
   (b) Deletion of Activity
   (c) Transfer/Addition of Warehouse

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.

Drug distributors 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. EXEMPTION IN PROVIDING ANOTHER PHARMACIST FOR ADDITIONAL LICENSED ACTIVITY

Exemption may be granted to drug distributor pharmacist to handle retailing activity provided that the following conditions are satisfied:

1) The activities sought to be licensed belong to one establishment only; establishment herein shall refer to a single business entity with the same business name registration and ownership who may engage in more than one licensed business activity;
2) The activities to be handled by the pharmacist are confined only in one office and warehouse within the same premises.

This exemption shall be duly noted in the application indicating the pharmacist's duties and responsibilities as well as the schedule and hours of supervision to each establishment signed both by the pharmacist-in-charge and the owner/ authorized representative.

IV. 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 distributors 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.

V. TRANSITORY PROVISIONS

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

VI. 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.

VII. 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 DRUG DISTRIBUTOR LTO APPLICATIONS

A. Initial LTO Application
   1) Application Form
   2) Proof of Business Name Registration
   3) Credentials of Pharmacist
   4) Risk Management Plan
   5) Location Plan
   6) Proof of Payment (e.g. official receipt or authorized bank payment slip)
   7) 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 DRUG DISTRIBUTORS

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 personnel, 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

B. Minor Variations – Prior Approval

Change of Activity	
C	1. Shall refer to an additional activity engaged by the distributor (e.g. LTO as Distributor-Importer with additional activity as Exporter) 2. Shall also refer to a change from the initially licensed activity (e.g. LTO as Distributor-Importer to Distributor-Exporter).
D	1. Application Form 2. Contract Agreements to prove activity 3. Proof of payment 4. Self-Assessment Toolkit

Expansion of Establishment	
C	1. Shall refer to the expansion made which is adjacent to the existing location of the establishment. 2. Expansion shall also include additional floors where the building is occupied.
D	1. Application Form 2. Proof of payment 3. Self-Assessment

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. Proof of payment 4. 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 other Qualified Personnel	
C	1. There is a change of the identified pharmacist or other qualified personnel registered with FDA. 2. For other pharmacists and key personnel employed but not registered with FDA, changes on such shall not be required to apply for variation.
D	1. Application Form 2. Credentials (for change of pharmacist only) 3. Proof of payment 4. Self-Assessment Toolkit

Deletion of Activity	
C	Shall refer to deletion of any approved/added distributor activity.
D	1. Application Form 2. Termination of contract or conformance letter 3. Proof of payment 4. Self-Assessment Toolkit

Transfer/Addition of Warehouse	
C	1. Shall refer to the physical transfer of warehouse. 2. Shall also refer to an addition of warehouse aside from the existing and previously inspected warehouse by FDA.
D	1. Application Form 2. New Location Plan 3. Proof of payment 4. Self-Assessment Toolkit

*C – Condition
*D – Documents required