Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA CIRCULAR
No. _____

SUBJECT : **Guidelines for the Use of the FDA eServices Portal System for License to Operate (LTO) Applications Pursuant to Administrative Order (AO) No. 2020-0017**

I. RATIONALE

The Department of Health (DOH) issued Administrative Order (AO) No. 2020-0017 entitled "Revised Guidelines on the Unified Licensing Requirements and Procedures of the Food and Drug Administration Repealing Administrative Order No. 2016-0003" to provide simplified and streamlined regulatory requirements and procedures in applying for License to Operate (LTO) of FDA-regulated establishments. This is in compliance with RA No. 11032, otherwise known as, "Ease of Doing Business and Efficient Government Service Delivery Act of 2018" which aims to promote transparency in the government, re-engineering of systems and processes to expedite business and non-business related transactions, and pursuant to RA No. 8792 or the "Electronic Commerce Act of 2000" that promotes the universal use of electronic transaction in the government services, among others.

The Food and Drug Administration (FDA), through Republic Act (RA) No. 9711 also known as the "FDA Act of 2009", promotes the enhancement of administrative and technical capacity in the regulation of establishments and health products under its jurisdiction. RA No. 11223, otherwise known as the "Universal Health Care Act" is a framework that fosters a whole-of-system, whole-of-government, and whole-of-society approach in the development, implementation, monitoring, and evaluation of health policies, programs and plans.

In this light, the FDA eServices Portal System is developed to provide a streamlined online platform for FDA Authorization applications. The eServices Portal shall be available for LTO applications of Drug Distributors, Drug Traders, Drugstores, Retail Outlet for Non-Prescription Drugs (RONPD), Clinical Research Organization (CRO), and Sponsors.

II. OBJECTIVE

The objective of this Circular is to provide guidelines for the use of the new FDA eServices Portal System for LTO applications of Drug Distributors (Drug Wholesalers, Exporters, and Importers), Drug Traders, Drug Retailers (Drugstores and RONPD), CRO, and Sponsors.

III. SCOPE AND COVERAGE

This FDA Circular shall cover the following LTO applications:

A. Types of Establishment:
1. Drug Distributor (Importer/Exporter/Wholesalers);
2. Drug Trader;
3. Drug Retailer (Drugstore and Retail Outlet for Non-Prescription Drugs);

4. Clinical Research Organization; and
5. Sponsor

B. Types of LTO Application
1. Initial;
2. Renewal;
3. Variation; and
4. Notification

IV. DEFINITION OF TERMS

The terms used in this Circular shall have the same definition as prescribed in RA No. 9711 and its Implementing Rules and Regulations (IRR), AO No. 2020-0017, and other FDA applicable laws and regulations.

V. GUIDELINES

A. The **General** and **Specific Guidelines** on the application for LTO as indicated in AO No. 2020-0017 shall be adopted in this FDA Circular.

By applying for an FDA License to Operate, the establishment understands and abides by the rules and regulations set forth by the FDA. The establishment shall have the ultimate responsibility as to their compliance to national and/or international standards of safety, quality, purity, and efficacy of health products they provide to the consumers and the general public.

B. Application Requirements
The following requirements follow the provisions of AO 2020-0017.

1. Initial Application

a. Accomplished e-Application Form with Declaration of Undertaking (eservices.fda.gov.ph);
b. Proof of Business Name Registration (in pdf, 2MB maximum file size) shall be submitted in any of the following:
   i. For single proprietorship, the Certificate of Business Registration issued by the Department of Trade and Industry (DTI);
   ii. For Corporation, Partnership and other Juridical Person, the Certificate of Registration issued by the Securities and Exchange Commission (SEC) and Articles of Incorporation.
   iii. For Cooperative, the Certificate of Registration issued by the Cooperative Development Authority (CDA) and Articles of Cooperation; or
   iv. For Government-Owned or Controlled Corporation, the law creating the establishment, if with original charter, or its Certificate of Registration issued by SEC and Articles of Incorporation, if without original charter.
c. If the business or establishment address is different from the business name registration address, the applicant shall submit a copy of the Business Permit (e.g. Mayor's Permit, Barangay Business Permit/Clearance).
d. Proof of Income for Drug Trader (in pdf, 2MB maximum file size) such as the latest audited Financial Statement with Balance Sheet (in pdf) shall be

submitted to verify the capitalization of the establishment vis-à-vis their corresponding application fees. For newly established companies that have no Financial Statement yet, a duly notarized Statement/Certification of Initial Capitalization may be furnished instead.

e. Payment of Fees based on the latest FDA issuance.
f. Additional Documents for Drug Establishments shall be presented to FDA during inspection of establishment, such as Risk Management Plan (RMP).

2. Renewal Application

a. Accomplished e-Application Form with Declaration of Undertaking; and
b. Payment of Fees based on the latest FDA issuance.

3. Variation Application

a. Accomplished e-Application Form with Declaration of Undertaking;
b. Documentary requirements depending on the type of variation or circumstances of the establishment or product as shown in the table below; and
c. Payment of Fees based on the latest FDA issuance.

Type of Variation	**Document Requirement**
Transfer of Location of Offices - Physical transfer of the office of the establishment	Proof of business address reflecting the new office location; 1. For Single Proprietorship: Business Permit/ Mayor's Permit or Barangay Business Permit/ Clearance; 2. For SEC-registered establishments: a. Amended Articles of Incorporation (if transferred from one city/ municipality/province); or b. Updated General Information Sheet (GIS) from SEC (if transferred within the same city/municipality/province) 3. LGU/Mayor's Permit or Barangay Business Permit/Clearance reflecting new office location, if the establishment address is different from the address indicated in the SEC registration
Transfer of Location of Drug Retailers - Physical transfer of the drug retailer	Business permit/registration reflecting new location of drug retailers; 1. For Single Proprietorship: Business Permit/Mayor's Permit or Barangay Business Permit/Clearance; 2. For SEC-registered establishments: a. Amended Articles of Incorporation (if transferred from one city/ municipality/province); or b. Updated General Information Sheet (GIS) from SEC (if transferred within the same city/municipality/province)

	3. LGU/Mayor's Permit or Barangay Business Permit/Clearance reflecting new location, if the establishment address is different from the address indicated in the SEC registration
Change of Distributor Activity - additional/deletion or change in activity that the distributor is currently engaged	Contract Agreement showing change in activity
Transfer/Addition of Warehouse - Physical transfer and addition of the warehouse of the establishment	LGU/Mayor's Permit or Barangay Business Permit/Clearance reflecting new warehouse location, if the establishment address is different from the address indicated in the SEC registration
Additional Drugstore Activities	1. Additional Credentials of Pharmacist, as applicable 2. Other documents related or specific to the additional activity, such as but not limited to: a. Adult Vaccination i. Standard Operating Procedure ii. Training Certificate of Pharmacist b. Dispense Vaccines and Biologicals i. Standard Operating Procedure c. Mobile Pharmacy i. Standard Operating Procedure ii. Image/Picture with description of the Mobile Pharmacy Vehicle d. Online Ordering and Delivery i. Standard Operating Procedure ii. Website Link iii. Website Screenshot showing the Ordering System and Placement of LTO details e. Sterile Compounding and Non-Sterile Complex Compounding i. Standard Operating Procedure
Expansion of Office Establishment and Drug Retailers - expansion made which is adjacent to the existing location of the establishment	Expansion floor plan

Change of Ownership - Change in ownership of the licensed establishment	Business name registration reflecting new ownership 1. Any proof on the transfer of ownership such as any of the following: a. Deed of sale or assignment or transfer of rights/ownership; b. Memorandum of Agreement; or c. Notarized Affidavit of the owner, proprietor, Chairman or CEO of the establishment validating the transfer
Change of Business Name - Change only in the business name of the establishment	Business name registration reflecting the new business name
Zonal Change in Address - Change of the name/number of the street/building without physical transfer of the establishment	1. Certificate of Zonal Change 2. Certification from Local Government Unit (City/Municipality) stating no physical transfer of the establishment
Change of Qualified Person - Change in the identified qualified person initially registered with the FDA	1. Name of new qualified person 2. Valid Professional Regulation Commission (PRC) ID 3. Signed Letter of Resignation, if previously connected with another pharmacy/establishment
Change of Authorized Person - Change in the authorized person initially registered with the FDA	1.Name of new qualified person 2.Valid Government ID 3.Updated contact details

4**.** Notification Application

The drug establishment must have a valid License to Operate to be able to apply for the Notification Application. No payment shall be necessary.

a. Accomplished e-Application Form with Declaration of Undertaking; and

b. Documentary requirements depending on the type of notification or circumstances of the establishment or product as shown in the table below.

Type of Notification	**Document Requirement**
Resignation of qualified person	Resignation letter signed of the Qualified Person
Addition and/or Deletion of Reliever Pharmacist or Pharmacy Assistant other than the approved Qualified Person for Drugstores and RONPD	1. Letter signed by the Owner/CEO/Manager or of equivalent position the details of the added and/or Reliever Pharmacist or Pharmacy Assistant 2. Name of Reliever Pharmacist or Pharmacy Assistant 3. Valid Professional Regulation Commission (PRC) ID (for Reliever Pharmacist) or 4. Certificate of Training (for Pharmacy

	Assistant)
Change of Operating Hours	Letter signed by the Pharmacist and Drugstore Manager or of equivalent position the new Operating Hours
Addition or Deletion of Source and/or corresponding Product for Distributors and Traders	1. Agreement between the Distributor/Trader with the Source 2. List of deleted/added products from Source (if applicable)
Closure of Business	Letter of Closure of Business signed by the Owner/CEO/Manager or of equivalent position

C. Application Process

1. The application shall be filed online through the eServices Portal website http://eservices.fda.gov.ph/. Creation of account and password is no longer a requirement to obtain access to the eServices Portal.
2. The **"Declaration and Undertaking"** conveys a binding agreement of the applicant company with the FDA to provide accurate information, affirm primary responsibility over the products, and comply with all the rules and regulations set forth during and after the application process. Any false misrepresentation of the information in this application shall be subjected to administrative and criminal liabilities, provided by the RA No. 9711, which includes, but not limited to suspension, cancellation, or revocation of the License to Operate.
3. All fields on the eApplication form have written warnings/pop-ups/reminders before proceeding to the next step to ensure accuracy of information provided. The establishment applying for LTO shall ensure that the declared information in the eApplication Form are consistent with the uploaded supporting documents, i.e. establishment name and owner, establishment's address and others.
4. Valid Professional Regulation Commission (PRC) Identification Number of the Registered Pharmacist is required as the Qualified Person in the eApplication Form. This shall be in compliance to the provisions under Rule IV, Section 7 of RA 10918.
5. Documents required to be uploaded in the eApplication Form shall be in portable Document file (PDF), with no more than 2 megabytes (MB) file size.
6. Once the eApplication Form is completed, applicants can review the duly filled out form in the Self-Assessment Review. By agreeing to the terms and conditions, the applicant confirms to the correctness of information provided and data privacy terms.
7. The Application Summary shall be automatically sent in the applicant's registered email address to indicate the successful submission of the application in the eServices Portal.
8. Applications filed after the prescribed working/office hours or during weekends and holidays shall be considered filed on the next working day.
9. Status of Application can be monitored at the eServices and validated thru the e-mail used for the application.

10. Establishments with existing LTO applications via ePortal may opt to apply to the eServices Portal for a new fee. Previous payment will be forfeited as the filed applications are already in-process.

The step-by-step procedure in the eServices Portal is attached as Annexes in this issuance.

D. Pre-Assessment

1. FDA evaluator/assessor shall conduct pre-assessment on the submitted application and documentary requirements with regards to their completeness and correctness. Applications with incomplete or incorrect data entry and document submissions shall not be accepted and the application will not proceed to the next step of the process.
2. Pre-assessment of applications shall be done within the prescribed working days and office hours of the FDA.
3. The FDA shall inform the applicant through the registered email address the result of the pre-assessment. If the application passed the pre-assessment step, the applicant shall receive the Order of Payment with Reference Number through email indicating the fees to be paid. If the application did not pass the pre-assessment step, the FDA shall notify the reason/s for disapproval e.g. deficiency/ies found and prompt the applicant to apply again through the eServices Portal.

E. Payment of Fees

1. Payment of the total application fee as indicated in the Order of Payment (OP) maybe done through Over-the-counter (OTC) payment at FDAC, On-coll payment at Land Bank of the Philippines (LBP) branches, or online payment thru Bancnet (including LBP bills payment), based on the existing FDA issuances. Always indicate the Reference Number reflected in the OP. Clients will be informed of other available channels of payment through an FDA issuance.
2. Once the payment is made, the payment channel -LBP or Bancnet (except for OTC at FDAC) will send a transaction report to FDA which usually takes a minimum of two (2) days. Upon receipt of the report, the Cashier Section checks the details and posts the payment in the eServices Portal if payment is made in full. Posting of payment may take a maximum of two (2) days, depending on the volume of paid applications received.
3. Incomplete payment (amount paid is less than that of OP amount) will not be posted until the full amount as indicated in OP is settled. This also means that the application will not proceed to the next step of the process.
4. Applicants will receive a system-generated message through the registered email address on the status of the payment made once posted or need further settlement. If full payment is made, email will contain Acknowledgment Receipt, otherwise, a notification on payment deficiency.

F. Approval of the Application

1. The veracity of the application and compliance with all relevant FDA requirements and standards shall be checked.

2. For emphasis, the grounds for disapproval of LTO application may be any of the following, as stated in AO 2020-0017:

a. the documentary requirements submitted show that the establishment does not meet the required technical requirements and/or appropriate standards;

b. the applicant made misrepresentations, false entries, withhold relevant data contrary to the provisions of the law or appropriate standards;

c. the owner has violated any of the terms and conditions of its license; and

d. such other analogous grounds or causes as determined by the FDA.

3. If the application is approved, the FDA shall send the LTO to the registered email address of the applicant. If the application is disapproved, the FDA shall inform the applicant through its registered e-mail address of the reason for such action on the application.

G. Release of LTO

1. The applicant shall receive the LTO in their registered email address and may also be accessed through the eServices Portal.

2. Upon receipt of the LTO, the establishments shall print the LTO on a standard A4 size (21 cm x 29.7 cm) paper, on full-colored page and in portrait orientation. It shall be positioned on the most conspicuous place within the business establishments.

3. For Variation, the applied variation shall automatically be reflected on the LTO; an updated LTO shall be provided to the e-mail address.

4. For Notifications, all received requests for notification shall automatically be included in the database for verification, as necessary.

VI. REPEALING CLAUSE

Issuance, rule and regulation on the LTO application for Drug Distributor, Drug Trader, Drugstores, RONPD, CROs, and Sponsors found inconsistent with the provisions of this Circular is hereby amended or repealed accordingly.

VII. EFFECTIVITY

This Circular shall be effective immediately.

ROLANDO ENRIQUE D. DOMINGO, MD
Director General