



**FDA CIRCULAR**  
No. 2021-012

11 JUN 2021

**SUBJECT : Guidelines for the Use of the Food and Drug Administration (FDA) eServices Portal System for License to Operate (LTO) Application of Food Traders and Food Distributors Including Wholesalers, Importers, and Exporters of Processed Food Products, Food Supplements, Bottled Water, and Iodized Salt**

## **I. BACKGROUND**

In order to build efficient regulatory systems, the Food and Drug Administration (FDA) has undertaken process improvement initiatives, including the establishment of information and communication technology infrastructures and digital systems. Such initiatives were further driven by Republic Act (RA) No. 11032 or the “Ease of Doing Business and Efficient Government Service Delivery Act of 2018”. The said law aims to promote streamlined government transactions through digitalization and automation of business-related applications and procedures.

Consistent with the afore-mentioned initiatives, the RA No. 11032, and RA No. 8792 or the “Electronic Commerce Act of 2000”, the FDA issued Administrative Order (AO) No. 2020-0017 or the “Revised Guidelines on the Unified Licensing Requirements and Procedures of the FDA Repealing AO No. 2016-0003”, which established the FDA eServices Portal System as an online licensing platform for License to Operate (LTO) applications of health product establishments.

Through this Circular, the FDA eServices Portal is hereby updated to include LTO applications for Food Traders and Food Distributors, including Wholesalers, Importers, and Exporters of processed food products, food supplements, bottled water, and iodized salt.

## **II. OBJECTIVE**

The objective of this Circular is to provide the guidelines on the FDA eServices Portal System in applying for LTO applications of Food Traders and Food Distributors including Wholesalers, Importers, and Exporters of processed food products, food supplements, bottled water, and iodized salt.

## **III. SCOPE**

This FDA Circular shall cover the following LTO applications:



A. Types of Establishments:

1. Food Traders; and
2. Food Distributors (Wholesalers/Importers/Exporters)

B. Types of Health Products:

1. Processed Food Products;
2. Food Supplements;
3. Bottled Water and;
4. Iodized Salt

C. Types of LTO Application

1. Initial;
2. Renewal; and
3. Variation

#### IV. DEFINITION OF TERMS

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

By applying for an FDA LTO, the applicant understands and abides by the rules and regulations set forth by the Agency. The establishment shall have the ultimate responsibility and accountability with compliance to national and/or international standards of safety, quality, purity, and efficacy of processed food products they provide to the consumers and the general public.

**B. Application Requirements**

Based on AO No. 2020-0017, the following requirements must be submitted.

1. Initial Application

- a. Accomplished eApplication Form with Declaration of Undertaking (provided in the eServices Portal System)
  - i. Location Plan;
  - ii. Global Positioning System (GPS) Coordinates; and
  - iii. Name of Qualified Person, depending on the type of food product establishment (Refer to Annex B of AO No. 2020-0017 for Qualified Person Qualification and Credential Requirements)

b. Proof of Business Name Registration

Any of the following shall be submitted as proof of business name registration:

- i. For single proprietorship, the Certificate of Business Registration issued by the Department of Trade and Industry (DTI);
- ii. For corporation, partnership, and juridical person – 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 the Securities and Exchange Commission (SEC) and Articles of Incorporation, if without original charter.

c. Proof of Capitalization or Proof of Income, as applicable

- i. For Food Traders, proof of income/capitalization, such as a copy of the latest audited Financial Statement with Balance Sheet declaring the capital, shall be submitted. This shall be used to verify the capitalization of the establishment for the proper computation of application fees.
- ii. For newly established companies that have no Financial Statement (FS) yet, Statement/Certification of Initial Capitalization must be submitted signed by the owner and/or accountant. Upon renewal, the audited Financial Statement with Balance Sheet shall be required.

d. Payment of Fees, based on the latest FDA issuance.

e. Business Permit (e.g., LGU/Mayor's Permit, Barangay Business Clearance/Permit – if the business establishment address is different from the business name registration address.

f. Additional requirements, as applicable:

- i. Franchise agreement – For franchises, a copy of the Franchise agreement is recommended to be submitted. The business name of the establishment reflected in the LTO shall be based on the trade name indicated in the franchise agreement. In addition, this must be consistent with the business name registration
- ii. Contract of agreement - For the appropriate determination of activity to be indicated in the LTO, a copy of the Contract of Agreement is recommended to be submitted. The basis for the LTO activity shall depend on the legally binding contract agreement between the applicant and its client/supplier

2. Renewal Application

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

3. Variation Application

- a. Accomplished eApplication Form with Declaration of Undertaking; and
- b. Documentary requirements depending on the type of variation or circumstances of the establishment or product as shown in the table below;

Type of Variation	Document Requirement
Transfer of Location of Offices - Physical transfer of the office of the establishment	Business permit reflecting new location office
Change of Distributor Activity - Addition/change in activity that the distributor engages in	Contract Agreements showing change in activity
Transfer/Addition of Warehouse - Physical transfer and addition of warehouse of the establishment	Business permit reflecting new warehouse
Change of Ownership - Change in ownership of the licensed establishment	a. Business name registration reflecting new ownership b. Any proof on the transfer of ownership such as any of the following: i. Deed of sale or assignment or transfer of rights/ownership ii. Memorandum of Agreement; or iii. Notarized Affidavit of the owner, proprietor, Chairman or CEO of the establishment validating the transfer
Change of Business Name	Proof of Business Name Registration reflecting new name
Zonal Change in Address - Change of the name/number of the street/building without physical transfer of the establishment	Certificate of Zonal change
Change of Qualified Person - Change in the identified qualified person initially registered with the FDA	Name of new qualified person and the corresponding requirements
Change of Authorized Person - Change in the authorized person initially registered with the FDA	Name of new authorized person and updated contact details

- c. Payment of Fees based on the latest FDA issuance.

**C. Qualification and Credential Requirements of the Qualified Person**

Qualification	Training Requirement
Company Regulatory Officer (Authorized Person) and Food Safety	Certificate of Attendance on seminar on food safety, GMP or HACCP given by

Compliance Officer who is preferably a graduate of food-related courses including but not limited to food technology, food and nutrition, chemistry, microbiology, chemical/sanitary engineering, veterinary medicine, fisheries, agriculture (RA 10611)	the academe, WHO, FAO, NGOs, cooperative, food industry organizations, professional organizations, or the FDA Academy
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#### D. Application Process

A step-by-step procedure in the eServices Portal is attached as Annex to this issuance.

1. The application shall be filed online through the eServices Portal website [eservices.fda.gov.ph/](http://eservices.fda.gov.ph/). The creation of an account and password is no longer a requirement to obtain access to the eServices Portal.
2. The authorized officer or qualified personnel of the applicant establishment is expected to read and agree with “**Declaration and Undertaking**” in order to continue with the application. Such action 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 RA 9711, which includes, but not limited to suspension, cancellation, or revocation of the LTO.
3. In filling-up the fields in the eApplication form, the authorized officer or qualified personnel of the applicant establishment will be assisted with written warnings/pop-ups/reminders before proceeding to the next step to ensure accuracy of the information being provided. The establishment applying for LTO shall ensure that the declared information in the eApplication form is consistent with the uploaded supporting documents, e.g., establishment name and owner, establishment’s address, and others.
4. The declared e-mail address under the Contact Information is **unalterable**. Hence, the applicant shall use the company e-mail address. It shall also be within the scope and access of the Authorized Person/s, Qualified Personnel, and/or owner of the establishment. The FDA shall not be held liable in any way for loss of access to the declared e-mail address. In the event that the e-mail address will be changed, a written notification specifying the new e-mail address and the reason for the change shall be submitted to [fdac@fda.gov.ph](mailto:fdac@fda.gov.ph).

The Company Authorized Officer or Qualified Personnel shall have the responsibility to comply with the regulatory and technical requirements of the FDA wherein:

- a. The **Authorized Person** refers to the owner, President, Chief Executive Officers (CEO) or its equivalent, or any organic or full-time employee representing the establishment in an authorized or official capacity; and

- b. The **Qualified Person** refers to an organic or full-time employee of the establishment who possesses technical competence related to the establishment's activities and health products by virtue of his profession, training, or experience. A Qualified Person has the responsibility to comply with the technical requirements of FDA or discuss/clarify matters with the FDA when submitting technical requirements or engage the FDA Officials when conducting inspection or post-market surveillance activities. The Qualified Person may also be the duly Authorized Person of the establishment.
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. Variation and renewal applications must be applied separately. If a Food Product Establishment is due for renewal but is expected to apply for changes in information that need to be reflected in the system or registry, then a renewal application must first be submitted. Upon filing of application, the applicant should declare the LTO number of its most recently issued LTO for the system to generate an updated information of the establishment. *(Please see attached Annex B for the sample LTO format).*
7. The clients should be informed that the LTO to be issued upon renewal will reflect the previous information and the updating should be done through filing of a separate variation, after the issuance of an LTO following a successful renewal application. In addition, the clients cannot apply for a renewal of application if not within ninety (90) days before the expiration date of the LTO.
8. Establishments with a valid LTO issued via ePortal System shall be honored and, consequently, are strongly advised not to file for an initial LTO application in the eServices Portal System.
9. 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.
10. The Application Summary shall be automatically sent to the applicant's registered e-mail address to indicate the successful submission of the application in the eServices Portal.
11. For applications filed through the FDA eServices Portal System, there shall be a change in the format of LTO number as follows:  
Old: 300000XXXXXX  
New: **CFRR-(Region)-(Activity)- (Sequence Number)**
12. All technical specifications of food products for importation, exportation, sale, offering for sale, distribution, transfer, non-consumer use, promotion, advertising, or sponsorship are provided and based in AO No. 2014-0029 *(Rules and Regulations on the Licensing of Food Establishments and Registration of Processed Food, and other Food Products, and for other Purposes).*

13. Applications filed after the prescribed working/office hours or during weekends and holidays shall be considered filed on the next working day.
14. The status of the application can be monitored at the eServices website by validating through the e-mail address used for the application.
15. Establishments with existing/on-going LTO applications via ePortal may opt to apply to the eServices Portal for a new fee provided that the existing eLTO-application is cancelled in writing. However, the previous payment in the ePortal will be considered forfeited, as the filed applications shall be disapproved upon cancellation of the applicant establishment.
16. FDA inspection shall be conducted after the issuance of the LTO as Food Distributor and Food Trader (post-licensing approval) based on the schedule of the concerned FDA Regional Field Office. For guidance during post licensing inspection, the client may refer to FDA Citizen's Charter posted on the FDA website at [fda.gov.ph](http://fda.gov.ph).
17. The FDA shall have the authority to enter any FDA-licensed establishments distributing, trading, and/or selling FDA-regulated food products during operating hours in order to conduct routine or spot check inspections, based on the provisions of RA 9711.

#### **E. Pre-assessment**

1. An FDA evaluator/assessor shall conduct a pre-assessment on the submitted application and documentary requirements with regards to their completeness and correctness. Applications with incomplete documentary requirements and/or inconsistent data entries with submitted documentary requirements based on existing FDA rules and regulations shall not be accepted and the application will not proceed to the next step of the process.
2. The Pre-assessment of applications shall be done within the prescribed working days and office hours of the FDA.
3. The eServices Portal System shall automatically send a notification on the result of pre-assessment through the registered e-mail address of the applicant.
  - a. If the application passed the pre-assessment step, the applicant shall receive the Order of Payment with Reference Number through e-mail indicating the fees to be paid.
  - b. However, if the application did not pass the pre-assessment step, the eServices shall notify the reason(s) or deficiency(ies) found and prompt the applicant to apply again through the eServices Portal using a new case number. The old case number of disapproved applications for pre-assessment is considered closed.

#### **F. Payment of Fees**

1. Payments shall be made only **after** receiving the Order of Payment (OP).

2. The payment of the total application fee as indicated in the 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. Once available, other payment channels will be announced through a separate FDA issuance.
  - a. The clients should always indicate the reference number reflected in the OP when paying through FDA available online payment channels.
  - b. Otherwise, when transacting through over-the-counter payment method, the print-out OP should be endorsed to Cashier Officer for the processing of payment. Clients will be informed of other available channels of payment through an FDA issuance.
3. Once the payment is made, clients are advised that payments are processed and transmitted to the FDA by the payment channel - LBP or Bancnet (except for OTC at FDAC) after at least two (2) banking days. Upon receipt of the bank transaction report, the Cashier Section validates and posts the payment in the eServices Portal, when the payment is confirmed to be made in full. Validation and posting of payment may take a maximum of two (2) days, depending on the volume of paid applications received.
4. The processing time of LTO applied through the eServices Portal System, in accordance with the FDA Citizen's Charter shall start once the FDA Cashier has posted the Official Receipt of payment.
5. Incomplete payment (i.e., amount paid is less than that indicated in the OP) will not be posted until the full amount as indicated in OP is settled. As such, applications with incomplete or unsettled payments will not proceed to the next step of the process.
6. Applicants will receive a system-generated message through the registered email address on the status of the payment made. An Acknowledgment Receipt will be sent if full payment is confirmed to have been made. Otherwise, a notification on payment deficiency will be sent.

#### **G. Approval of the Application**

1. The veracity of the application and compliance with all relevant FDA requirements and standards shall be checked.
2. The applications with complete documentary requirements and payment, shall receive an Acknowledgement Receipt from FDA, containing the Evaluator's number/code who processed the application, reference number, the date and time of application, payment, and the statement of completeness of the documents submitted. An application is considered filed once the applicant receives the Acknowledgement Receipt.
3. The result of the application shall be sent to the applicant's registered e-mail.



- a. If the application is approved, the applicant shall receive the LTO, which will be printed by the applicant in accordance to the provisions in Section I below.
- b. If the application is disapproved, the applicant shall receive a letter of disapproval, which provides the reason(s) for disapproval of such action on the application.

#### **H. Disapproval of Application**

1. The grounds for disapproval of LTO application may be any of the following, as stated in AO No. 2020-0017 and AO No. 2014-029;
  - a. Failure to submit clear, complete, or compliant documentary requirements;
  - b. Absence of physical office upon inspection, without permission or approval from FDA;
  - c. The applicant made misrepresentations, false entries, withhold relevant data contrary to the provisions of the law;
  - d. The owner has violated any of the terms and conditions of its license; and
  - e. Such other analogous grounds or causes as determined by the FDA.

The disapproval of an application is without prejudice to re-application. However, disapproval shall mean outright forfeiture of payment.

#### **I. Release of LTO**

1. The applicant shall receive the LTO through their registered e-mail address. The copy of the LTO may also be accessed through the FDA 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. The printed LTO shall be positioned on the most conspicuous place within the business establishments.
3. A QR Code verifier shall be included in the LTO as means of confirmation of the legitimacy of the document.
4. For Variation requiring changes in details of the previously issued LTO (e.g. Change of business name, additional activity), the applied variation shall automatically be reflected on the LTO. An updated LTO for printing shall be provided to the registered e-mail address of the applicant.

#### **VI. SEPARABILITY CLAUSE**


If any part or term of provision of this Circular shall be declared invalid or unenforceable the validity or enforceability of the remaining portion or provision should not be affected and this Circular shall be construed as it did not contain the particular invalid or enforceable part, term or provision.

**VII. REPEALING CLAUSE**

Issuances, rules, and regulations on the LTO applications for Food Trader and Food Distributor including Wholesaler, Importer, and Exporter of food products found inconsistent with the provisions of this Circular are hereby amended or repealed accordingly.

**VIII. EFFECTIVITY**

This Circular shall be effective immediately.

  
**ROLANDO ENRIQUE D. DOMINGO, MD**  
Director General



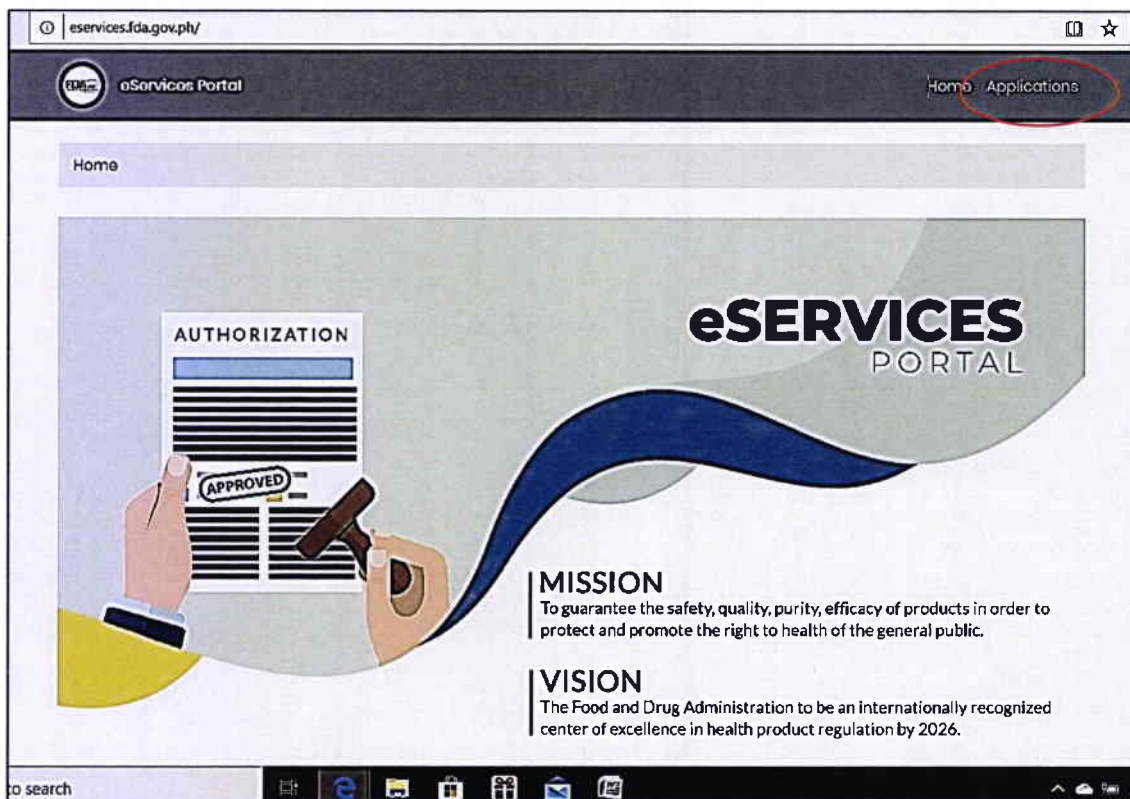
DTN 20210317075717

## ANNEX A

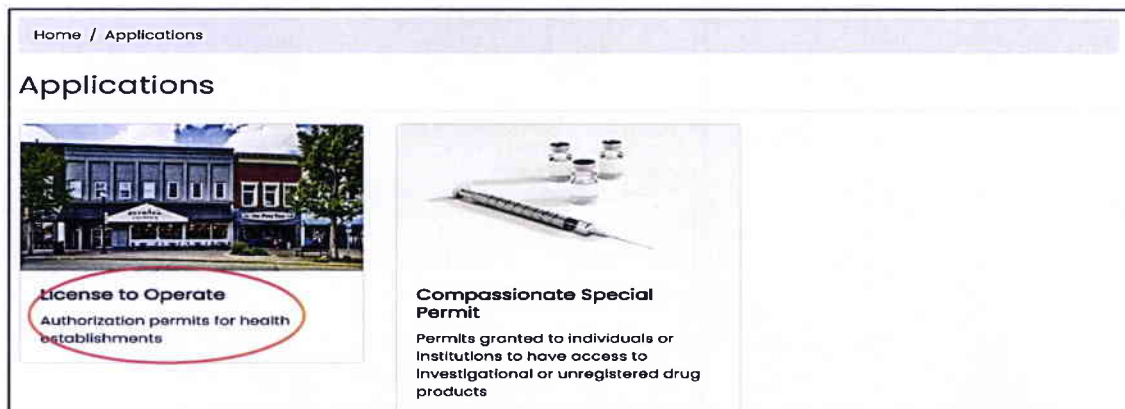
### Procedure for the use of the FDA eServices Portal System for License to Operate Application

#### A. Application for Initial LTO of Food Distributor

1. Access the online portal through [eservices.fda.gov.ph](http://eservices.fda.gov.ph) and click “Applications” found on the upper right corner of the eServices landing page.



2. Click the “License to Operate” for Food and the type of Business Establishment (Distributor). Choose the type of application (Initial) and proceed with the application process. Make sure to declare existing and valid LTO applied through ePortal before proceeding with Initial LTO application.



## License to Operate



### Bottled Water

For establishments that handles bottled water products



### Drug

For establishments that handles drug products



### Food

For establishments that handles food products



### Medical Device

For establishments that handle medical device products

## Food



### Application Status

Check the current status of your application



### Distributor

License authorization for distributor establishments



### Trader

License authorization for trader establishments

## Food Distributor



### Initial

Apply for a new License to Operate



### Renewal

Renew existing License to Operate



### Variations

Apply for changes in the existing License to Operate

3. Read carefully the “**Declaration and Undertaking**” before proceeding with the application process. Make sure to check the box found below and click “**Start Application**”.

Home / Applications / License to Operate / Food / Distributor / Initial

## Food Distributor Initial

- 1 Declaration & Undertaking
- 2 General Information
- 3 Establishment Information
- 4 Office Address
- 5 Warehouse Addresses
- 6 Authorized Officer
- 7 Qualified Personnel
- 8 Documentary Requirements
- 9 Self-Assessment Review

### Declaration & Undertaking

I, duly authorized officer/s or representative/s of the Establishment hereby voluntarily and categorically declare, undertake, and agree that all data and information contained and provided in the attached application, together with all other submissions, including amendments, are true and correct based on my knowledge and are based on existing records, legal documents and available information.

I, likewise declares, undertakes and agrees that:

I. The said establishment shall be open during its business hours under the supervision of a PRC registered pharmacist/s or authorized personnel at all times;

II. The registered pharmacist/s and the other appropriate allied health professionals, upon and during employment in the establishment, is/are not and will not in any way be connected to, employed by or engaged with any other FDA-regulated establishment;

III. The approved and valid License to Operate shall be displayed in a conspicuous place in the establishment visible to my customers;

IV. The establishment will change its business name, and/or brand name in the case of products, in the event that there is a similar, same, or confusingly similar name registered with the Food and Drug Administration, or if the FDA rules later that such name is misleading, offensive, against the law, customs, public morals, public policy or otherwise violative of relevant rules and regulations;

V. The electronic copy of the files, documents, or information submitted in relation to this application are the exact duplicate or scanned copy of the same and any

I agree to the declaration and undertaking  
In order to proceed with your application, you need to agree with the declaration and undertaking.

[Start Application](#)

4. Fill-out the necessary information correctly based on establishment’s activity/ies (Importer, Exporter, and/or Wholesaler). Make sure to properly tick the corresponding activity/ies to proceed on to the next step.

Home / Applications / License to Operate / Food / Distributor / Initial

## Food Distributor Initial

- 1 Declaration & Undertaking
- 2 General Information
- 3 Establishment Information
- 4 Office Address
- 5 Warehouse Addresses
- 6 Authorized Officer
- 7 Qualified Personnel
- 8 Documentary Requirements
- 9 Self-Assessment Review

### General Information

\* Type of Application:

\* Product Type:

\* Primary Activity:

\* Distributor Activities

Importer

Exporter

Wholesaler

[Back](#)
[Next](#)

- Fill-out all the fields under the Establishment Information. Please make sure that the Business Name shall be the same name in the SEC/DTI/CDA permit/Original Charter. Also, please ensure correctness of the declared Business Name as this will be the same name to be reflected in the LTO.

The owner/authorized representative shall ensure that they have access to the declared e-mail address. The FDA shall not be held liable in any way for loss of access to the declared e-mail address.

Please take note that all fields marked with asterisk (\*) are required to be filled-out.

Home / Applications / License to Operate / Food / Distributor / Initial

## Food Distributor Initial

- 1 Declaration & Undertaking
- 2 General Information
- 3 Establishment Information
- 4 Office Address
- 5 Warehouse Addresses
- 6 Authorized Officer
- 7 Qualified Personnel
- 8 Documentary Requirements
- 9 Self-Assessment Review

### Establishment Information

\* Name of Establishment

Business Name shall be the same name in the SEC/DTI/CDA permit/Original Charter. Please ensure correctness of the declared Business Name as this will be the same name to be reflected in the License to Operate

\* Owner of Establishment

For SEC/CDA registered establishments, the name of the corporation/cooperative must be used as the owner

\* Tax Identification Number

### Contact Information

\* Email Address

The owner/authorized representative shall ensure that they have access to the declared email address. The FDA shall not be held responsible or liable in any way for loss of access to the declared email address

\* Mobile Number

Please indicate an 11 digit mobile number

Landline Number

Please indicate the area code followed by the landline number

6. Click the “Get GPS Coordinates” to determine the exact location of the Office Address. Pin accurately the location on the map.

Home / Applications / License to Operate / Food / Distributor / Initial

### Food Distributor Initial

**1** Declaration & Undertaking      **Office Address**

**2** General Information

**3** Establishment Information

**4** Office Address

**5** Warehouse Addresses

**6** Authorized Officer

**7** Qualified Personnel

**8** Documentary Requirements

**9** Self-Assessment Review

\* Region: Please Select

\* Province: Please Select

\* City or Town: Please Select

\* Street Address: Street Address

The declared address shall be the same address indicated in the SEC/DTI/CDA permit. Otherwise, the declared address must be consistent with the one indicated in the business permit.

\* GPS Latitude: GPS Latitude

\* GPS Longitude: GPS Longitude

[Get GPS Coordinates](#)

Back      Next

7. The declared warehouse address shall be the same address indicated in the SEC/DTI/CDA permit. Otherwise, the declared address must be consistent with the one indicated in the business permit.

If there are two or more warehouses provided, the respective GPS coordinates shall be generated as well in the Geo-Coding Map.

Home / Applications / License to Operate / Food / Distributor / Initial

### Food Distributor Initial

**1** Declaration & Undertaking

**2** General Information

**3** Establishment Information

**4** Office Address

**5** Warehouse Addresses

**6** Authorized Officer

**7** Qualified Personnel

**8** Documentary Requirements

**9** Self-Assessment Review

**Warehouse Addresses**

Warehouse #1

\* Region: Please Select

\* Province: Please Select

\* City or Town: Please Select

\* Street Address: Street Address

The declared warehouse address shall be the same address indicated in the SEC/DTI/CDA permit. Otherwise, the declared address must be consistent with the one indicated in the business permit.

\* GPS Latitude: GPS Latitude

\* GPS Longitude: GPS Longitude

[Get GPS Coordinates](#)

[Add Warehouse Address](#)

Back      Next

8. The declared name of the authorized officer is understood to be the one transacting with FDA and shall only have the authority to transact on behalf of the establishment.

Home / Applications / License to Operate / Food / Distributor / Initial

### Food Distributor Initial

- 1 Declaration & Undertaking
- 2 General Information
- 3 Establishment Information
- 4 Office Address
- 5 Warehouse Addresses
- 6 Authorized Officer
- 7 Qualified Personnel
- 8 Documentary Requirements
- 8 Self-Assessment Review

**1** The declared name of the authorized officer is understood to be the one transacting with FDA and shall only have the authority to transact on behalf of the establishment (i.e. follow-ups, receives result).

#### Details of Authorized Officer

\* First Name   
include suffix name on first name

Middle Name

\* Last Name

\* Designation   
select owner for sole proprietorships

#### Government Issued Identification Document

\* Type

\* Identification Number

9. Fill-out the details of the Qualified Personnel.

Home / Applications / License to Operate / Food / Distributor / Initial

### Food Distributor Initial

- 1 Declaration & Undertaking
- 2 General Information
- 3 Establishment Information
- 4 Office Address
- 5 Warehouse Addresses
- 6 Authorized Officer
- 7 Qualified Personnel
- 8 Documentary Requirements
- 8 Self-Assessment Review

#### Details of the Qualified Personnel

##### Personnel Details

\* First Name

Middle Name

\* Last Name

\* Designation or Profession

##### Government Issued Identification Document

\* Type

\* Identification Number



10. Upload the necessary documents.

Home / Applications / License to Operate / Food / Distributor / Initial

### Food Distributor Initial

**1** Declaration & Undertaking      **Documentary Requirements**

**2** General Information

**3** Establishment Information

**4** Office Address

**5** Warehouse Addresses

**6** Authorized Officer

**7** Qualified Personnel

**8** Documentary Requirements

**9** Self-Assessment Review

**\* Proof of Business Name Registration**              
DTI Permit, SEC with Articles of Incorporation/Partnership, CDA Permit, or Government-Owned and Control Corporation (GOCC)

**Business/Mayor's Permit or Barangay Clearance**              
Please upload a business/mayor's permit or barangay clearance if the declared site address is different on the proof of business name registration document.

11. The applicant may review all the details under the “Self-assessment Review”.

Home / Applications / License to Operate / Food / Distributor / Initial

### Food Distributor Initial

**1** Declaration & Undertaking      **Self-Assessment Review**

**2** General Information

**3** Establishment Information

**4** Office Address

**5** Warehouse Addresses

**6** Authorized Officer

**7** Qualified Personnel

**8** Documentary Requirements

**9** Self-Assessment Review

**General Information**

**\* Type of Application**     

**\* Product Type**     

**\* Primary Activity**     

**\* Distributor Activities**       Importer  
 Exporter  
 Wholesaler


**Establishment Information**

**\* Name of Establishment**        
Business Name shall be the same name in the SEC/DTI/CDA permit/Original Charter. Please ensure correctness of the declared Business Name as this will be the same name to be reflected in the License to Operate

**\* Owner of Establishment**        
For SEC/CDA registered establishments, the name of the corporation/cooperative must be used as the owner

**\* Tax Identification Number**

12. After assessing the data entries, the applicant shall confirm the correctness of the data and uploaded documents and click on **“Confirm”** to submit the application.

I'm not a robot  reCAPTCHA  
Privacy - Terms

I hereby confirm that all information I have provided are true and correct to the best of my knowledge.

I understand that any errors that I have committed in this online form may be considered grounds for refusal or cancellation of my application.

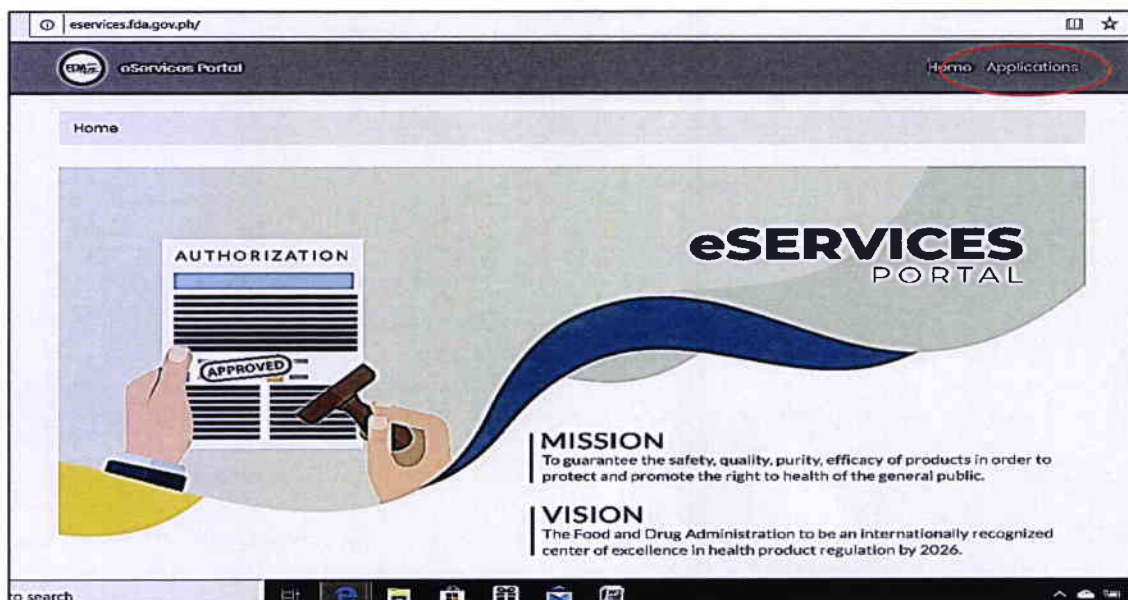
I consent to the use of any personal information provided herein for Government to conduct the necessary records check and verification of facts in connection with my application.

### B. Application for Initial LTO of Food Trader

Proceed as in Step No. 1 to Step No. 12 of Item A (Application for Initial LTO of Food Distributor). Make sure to click the appropriate type of establishment under Step No. 2.

### C. Application for Renewal LTO of Food Distributor

1. Access the online portal through [eservices.fda.gov.ph](http://eservices.fda.gov.ph) and click **“Applications”** found on the upper right corner of the eServices landing page.



- Click the **“License to Operate”** for Food and the type of Business Establishment (Distributor). Choose the type of application (Renewal) and proceed with the application process.

Home / Applications

## Applications




**License to Operate**  
Authorization permits for health establishments




**Compassionate Special Permit**  
Permits granted to individuals or institutions to have access to investigational or unregistered drug products

Home / Applications / License to Operate


## License to Operate




**Bottled Water**  
For establishments that handles bottled water products



**Drug**  
For establishments that handles drug products




**Food**  
For establishments that handles food products




**Medical Device**  
For establishments that handle medical device products

Home / Applications / License to Operate / Food


## Food



**Application Status**  
Check the current status of your application




**Distributor**  
License authorization for distributor establishments




**Trader**  
License authorization for trader establishments

Home / Applications / License to Operate / Food / Distributor


## Food Distributor



**Initial**  
Apply for a new License to Operate



**Renewal**  
Renew existing License to Operate



**Variations**  
Apply for changes in the existing License to Operate

3. Read carefully the “**Declaration and Undertaking**” before proceeding with the application process. Make sure to check the box found below and click “**Start Application**”.

FDA eServices Portal Home Applications

Home / Applications / License to Operate / Food / Distributor / Renewal

## Food Distributor Renewal

1 Declaration & Undertaking

2 License to Operate

3 Contact Information

4 Self-Assessment Review

### Declaration & Undertaking

I, duly authorized officer/s or representative/s of the Establishment hereby voluntarily and categorically declares, undertakes, and agree that all data and information contained and provided in the attached application, together with all other submissions, including amendments, are true and correct based on my knowledge and are based on existing records, legal documents and available information.

I, likewise declares, undertakes and agrees that:

- I. The said establishment shall be open during its business hours under the supervision of a PRC registered professional (e.g. Pharmacists) or authorized personnel at all times;
- II. The pharmacist/s and the other appropriate allied health professionals, upon and during employment in the establishment, is/are not and will not in any way be connected to, employed by or engaged with any other FDA-regulated establishment;
- III. The approved and valid License to Operate shall be displayed in a conspicuous place in the establishment visible to my customers;
- IV. The establishment will change its business name, and/or brand name in the case of products, in the event that there is a similar, same, or confusingly similar name registered with the Food and Drug Administration, or if the FDA rules later that such name is misleading, offensive, against the law, customs, public morals, public policy or otherwise violative of relevant rules and regulations;
- V. The electronic copy of the files, documents, or information submitted in relation to this application are the exact duplicate or scanned copy of the same and, any discrepancy, prejudicial contents, false claims or misrepresentation on any of the data therein shall be a ground for the disapproval of application, or if discovered post-approval shall be a ground for the appropriate sanctions including the revocation of the license or, and/or the filing of the appropriate legal action against me, the owner, its officers or the establishment whenever possible.

I agree to the declaration and undertaking  
In order to proceed with your application, you need to agree with the declaration and undertaking

[Start Application](#)

4. Fill out the required fields. Security code is generated by scanning the QR code in the document. If everything is in order, tick the Captcha box and click Next to proceed to Contact Information.

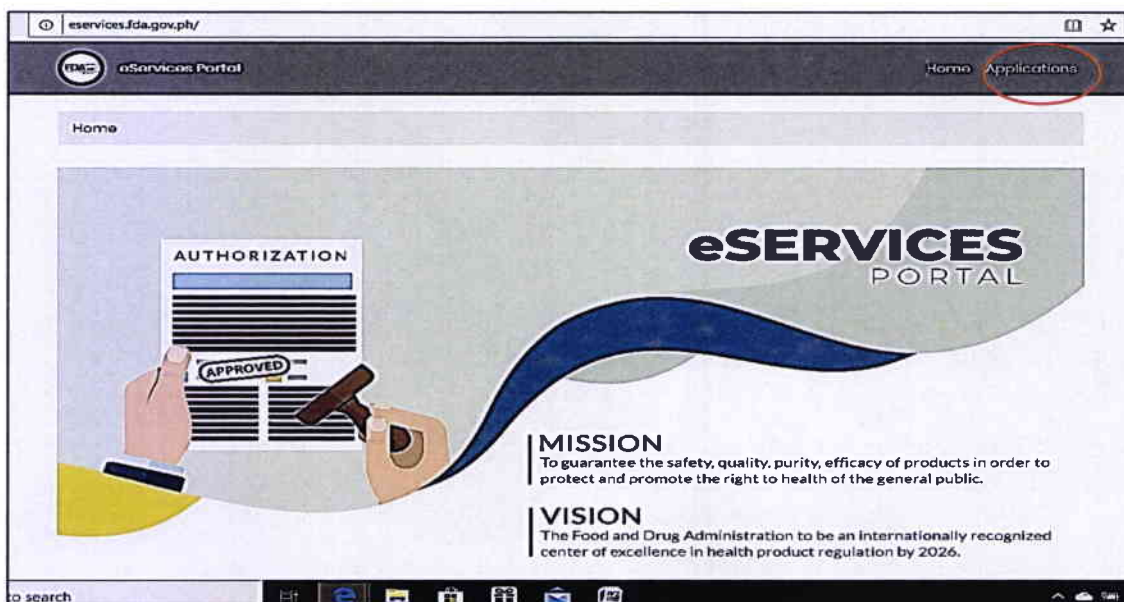
5. Update contact numbers if necessary. Click Next to proceed to Self-Assessment Review.
6. User may review if all details are correct in the “Self-Assessment Review”.

#### D. Application for Renewal LTO of Food Trader

Proceed as in Step No. one (1) to Step No. six (6) of Item C (Application for Renewal LTO of Food Distributor). Make sure to click appropriate establishment under Step # 2.

#### E. Application for Variation in LTO of Food Distributor


1. Access the online portal through [eservices.fda.gov.ph](https://eservices.fda.gov.ph) and click “Applications” found on the upper right corner of the eServices landing page.




- Click the “**License to Operate**” for Food and the type of Business Establishment (Distributor). Choose the type of application (Variation) and proceed with the application process.

Home / Applications

## Applications



**License to Operate**  
Authorization permits for health establishments



**Compassionate Special Permit**  
Permits granted to individuals or institutions to have access to investigational or unregistered drug products

Home / Applications / License to Operate

## License to Operate



**Bottled Water**  
For establishments that handles bottled water products



**Drug**  
For establishments that handles drug products




**Food**  
For establishments that handles food products




**Medical Device**  
For establishments that handle medical device products

Home / Applications / License to Operate / Food


## Food



**Application Status**  
Check the current status of your application




**Distributor**  
License authorization for distributor establishments




**Trader**  
License authorization for trader establishments

Home / Applications / License to Operate / Food / Distributor


## Food Distributor



**Initial**  
Apply for a new License to Operate



**Renewal**  
Renew existing License to Operate



**Variations**  
Apply for changes in the existing License to Operate

3. Read carefully the **“Declaration and Undertaking”** before proceeding with the application process. Make sure to check the box found below and click the **“Start Application”**”.

FDA eServices Portal Home Applications

Home / Applications / License to Operate / Food / Distributor / Variations

## Food Distributor Variations

1 Declaration & Undertaking

2 License to Operate

3 Contact Information

4 Minor Variations

5 Self-Assessment Review

### Declaration & Undertaking

I, duly authorized officer/s or representative/s of the Establishment hereby voluntarily and categorically declare, undertake, and agree that all data and information contained and provided in the attached application, together with all other submissions, including amendments, are true and correct based on my knowledge and are based on existing records, legal documents and available information.

I, likewise declares, undertakes and agrees that:

- I. The said establishment shall be open during its business hours under the supervision of a PRC registered professional (e.g. Pharmacists) or authorized personnel at all times;
- II. The pharmacist/s and the other appropriate allied health professionals, upon and during employment in the establishment, is/are not and will not in any way be connected to, employed by or engaged with any other FDA-regulated establishment;
- III. The approved and valid License to Operate shall be displayed in a conspicuous place in the establishment visible to my customers;
- IV. The establishment will change its business name, and/or brand name in the case of products, in the event that there is a similar, same, or confusingly similar name registered with the Food and Drug Administration, or if the FDA rules later that such name is misleading, offensive, against the law, customs, public morals, public policy or otherwise violative of relevant rules and regulations;
- V. The electronic copy of the files, documents, or information submitted in relation to this application are the exact duplicate or scanned copy of the same and, any discrepancy, prejudicial contents, false claims or misrepresentation on any of the data therein shall be a ground for the disapproval of application, or if discovered post-approval shall be a ground for the appropriate actions including the revocation of the license or, and/or the filing of the appropriate legal action against me.

I agree to the declaration and undertaking  
In order to proceed with your application, you need to agree with the declaration and undertaking

[Start Application](#)

4. Provide the existing LTO Number, Validity Date, and Security Code (by scanning the QR code from the given document). Please ensure the correctness of the data given to proceed with the change in licensing authorization.

The screenshot shows the 'License to Operate' form in the FDA eServices Portal. The breadcrumb trail is 'Home / Applications / License to Operate / Food / Distributor / Variations'. The page title is 'Food Distributor Variations'. On the left, a sidebar lists six steps: 1. Declaration & Undertaking, 2. License to Operate (circled in red), 3. Contact Information, 4. Minor Variations, and 5. Self-Assessment Review. The main form area is titled 'License to Operate' and contains three input fields: 'License Number', 'Date of Validity', and 'Security Code'. Below these fields is a note: 'Please scan the QR Code in the document. For previously issued LTO, enter the sequence number located at the bottom right corner of the document. (e.g. FDA-123456)'. At the bottom right of the form, there is a reCAPTCHA 'I'm not a robot' checkbox and a 'reCAPTCHA Privacy - Terms' link. At the very bottom of the page are 'Back' and 'Next' buttons.

5. Provide an updated contact information if applicable.
6. Key in the required fields. To upload documents, click the File Upload. Fill-out the necessary variations (ex. Transfer of Location of Offices, Change of Distributor Activity, additional warehouse, and expansion of office establishments, change of business name, qualified person, or authorized person).
7. User may review if all details are correct in the “Self-Assessment Review”.
8. Once reviewed, the User shall confirm the correctness of data given and click on “Confirm” to submit the application.

#### F. Application for Variation in LTO of Food Trader

Proceed as in Steps one (1) to eight (8) of Item E (Application for Variation in LTO for Food Distributor). Make sure to click the appropriate establishment on Step # 2.

#### G. Application for LTO of Establishments handling Bottled Water Products

For Establishments that handle bottled water products, the applicant may proceed with the same guidelines for other food products enumerated above. Make sure to declare if the establishment is a “Refilling Station” before proceeding with the application process.

#### H. Procedure for Checking of Application Status in the eServices Portal

1. To check the status of your application, click “Application Status.”
2. Enter the Reference Number and click “submit”.
3. A verification code will be sent to applicant’s registered e-mail address.
4. Enter the verification code to view the progress of your application.



ANNEX B

SAMPLE LTO FORMAT

For Distributor

Page 1



Republic of the Philippines  
Department of Health  
Food and Drug Administration  
Civic Drive, Filinvest Corporate City  
Alabang, Muntinlupa City



**LICENSE TO OPERATE**  
as  
**Food**  
**Distributor-Importer/Wholesaler**  
is hereby granted to

**NAME OF ESTABLISHMENT**

**ADDRESS OF THE ESTABLISHMENT**

Owner: \_\_\_\_\_  
License Number: \_\_\_\_\_  
Application Type: \_\_\_\_\_  
Date of Issuance: \_\_\_\_\_  
Validity of License: \_\_\_\_\_

This LTO shall be renewed within **90 days** before its expiration, upon compliance with relevant laws, rules and regulations and the payment of fees. This LTO may be suspended, cancelled or revoked by this Office for cause if found violating RA 9711 and related issuances.

Furthermore, with this LTO, the FDA allows the establishment to apply for a market authorization [i.e. registration (CPR) or notification] for health products prior to manufacture, importation, sale or offer for sale, distribution, transfer and advertisement as the case may be.

**ROLANDO ENRIQUE D. DOMINGO, MD**  
Director General

*This electronic-LTO (eLTO) is computer generated and does not require signature*

Name of Authorized Officer:

Designation:

**Qualified Personnel:**

Name	Designation	Gov't ID	ID Number	Expiry Date	Birth Date

**Warehouse Addresses:**

Address Details	City/Town	Province	Region	GPS Latitude	GPS Longitude



Republic of the Philippines  
Department of Health  
Food and Drug Administration  
Civic Drive, Filinvest Corporate City  
Alabang, Muntinlupa City



## LICENSE TO OPERATE

as

## Food Trader

is hereby granted to

**NAME OF ESTABLISHMENT**

**ADDRESS OF ESTABLISHMENT**

Owner:

XXXXXXXXXX

License Number:

XXXXXXXXXX

Application Type:

XXXXXXXXXX

Additional Activities

Date of Issuance:

Validity of License:

This LTO shall be renewed within 90 days before its expiration, upon compliance with relevant laws, rules and regulations and the payment of fees. This LTO may be suspended, cancelled or revoked by this Office for cause if found violating RA 9711 and related issuances.

Furthermore, with this LTO, the FDA allows the establishment to apply for a market authorization [i.e. registration (CPR) or notification] for health products prior to manufacture, importation, sale or offer for sale, distribution, transfer and advertisement as the case may be.

**ROLANDO ENRIQUE D. DOMINGO, MD**  
Director General

*This electronic-LTO (eLTO) is computer generated and does not require signature*

Name of Authorized Officer:

Designation:

**Qualified Personnel:**

Name	Designation	Gov't ID	ID Number	Expiry Date	Birth Date

**Warehouse Addresses:**

Address Details	City/Town	Province	Region	GPS Latitude	GPS Longitude