Licensing Requirements and Procedure for Food Importers

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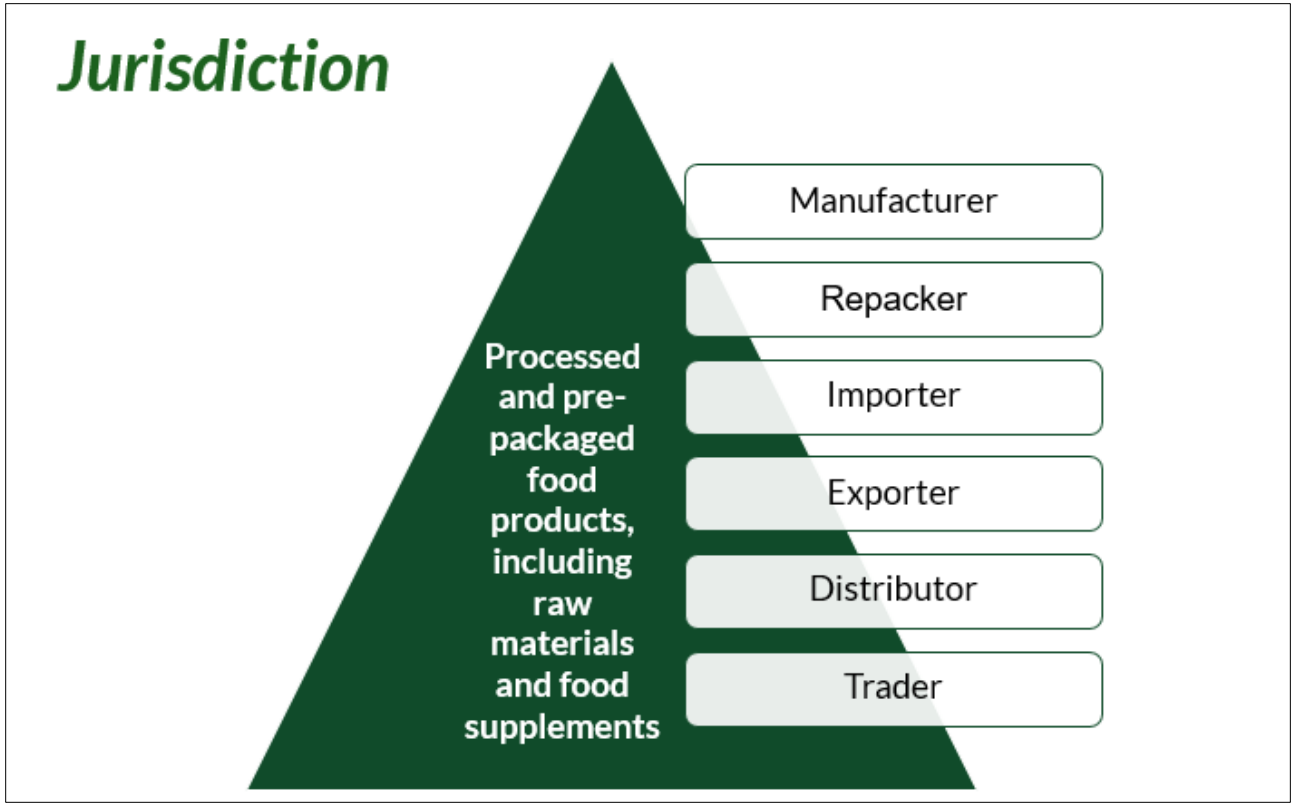
Licensing Section
CENTER FOR FOOD REGULATION AND RESEARCH

Presentation Outline

I. FDA Authorizations
II. Requirements for License to Operate
III. Application Procedure
IV. Processing time for LTO Applications

FDA Authorizations

1. License to Operate (LTO) for Food Establishments
2. Registation of Processed Food Products



Who needs to secure authorizations from FDA?

- ✓ Manufacturer
- ✓ Trader
- ✓ Distributor

  Specific Activities: Importer, Exporter, Wholesaler

FDA Authorization

- **License to Operate (LTO)** is an authorization issued by the Food and Drug Administration (FDA) to an establishment to grant permission to undertake a trade or carry out a business activity.

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

is hereby granted to

ESTABLISHMENT NAME

ESTABLISHMENT ADDRESS

SAMPLE ONLY

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.

DR. SAMUEL A. ZACATE
Director General

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

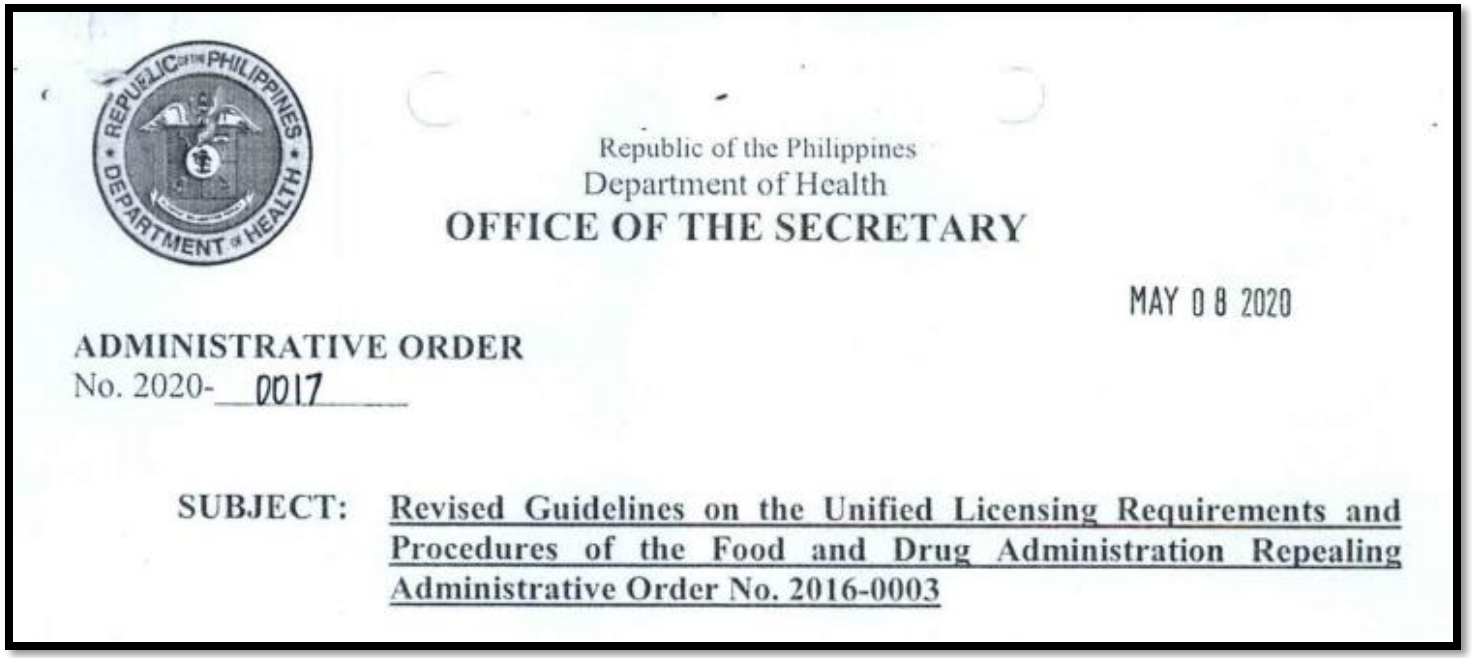
Requirements for License to Operate (LTO)

Food and Drug Administration
PHILIPPINES

Administrative Order No. 2020-017

"Revised Guidelines on the Unified Licensing Requirements and Procedures of the Food and Drug Administration"

(Repealing A.O. No. 2016-0003)



Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

MAY 0 8 2020

ADMINISTRATIVE ORDER
No. 2020-0017

SUBJECT: Revised Guidelines on the Unified Licensing Requirements and Procedures of the Food and Drug Administration Repealing Administrative Order No. 2016-0003

Licensing Requirements (A.O. No. 2020-017)

INITIAL LTO REQUIREMENTS:

- Accomplished e-Application form
- Proof of Business Name Registration
- Business Permit
- Contract of Agreement
- Payment of Fees

How long is the validity of the LTO?

- **Initial** LTO has a validity of

2 years

- **Renewal** LTO has a validity of

5 years

What are the prescribed fees and charges for Food Distributors?

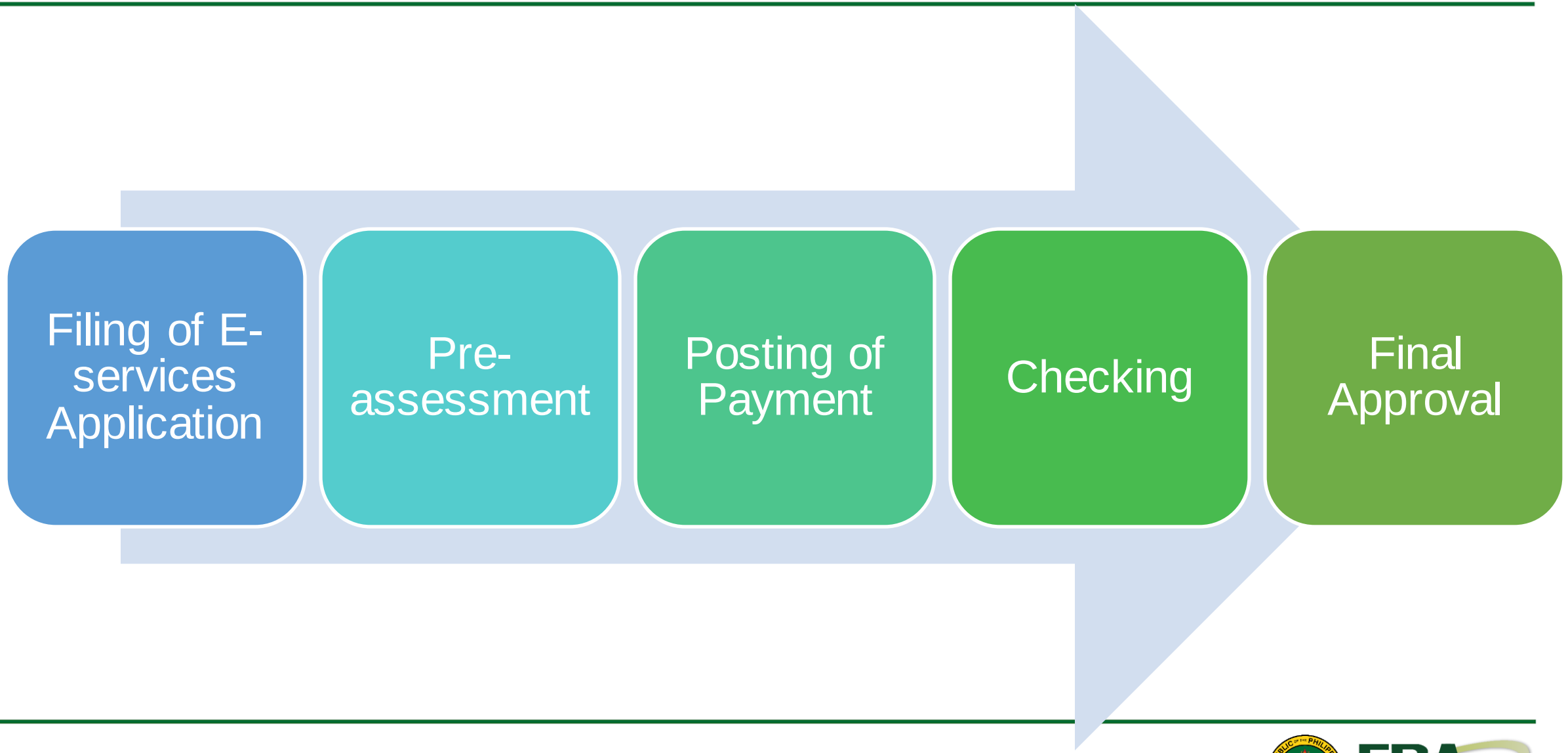
- **The prescribed fee for initial application**

  Php 8,080

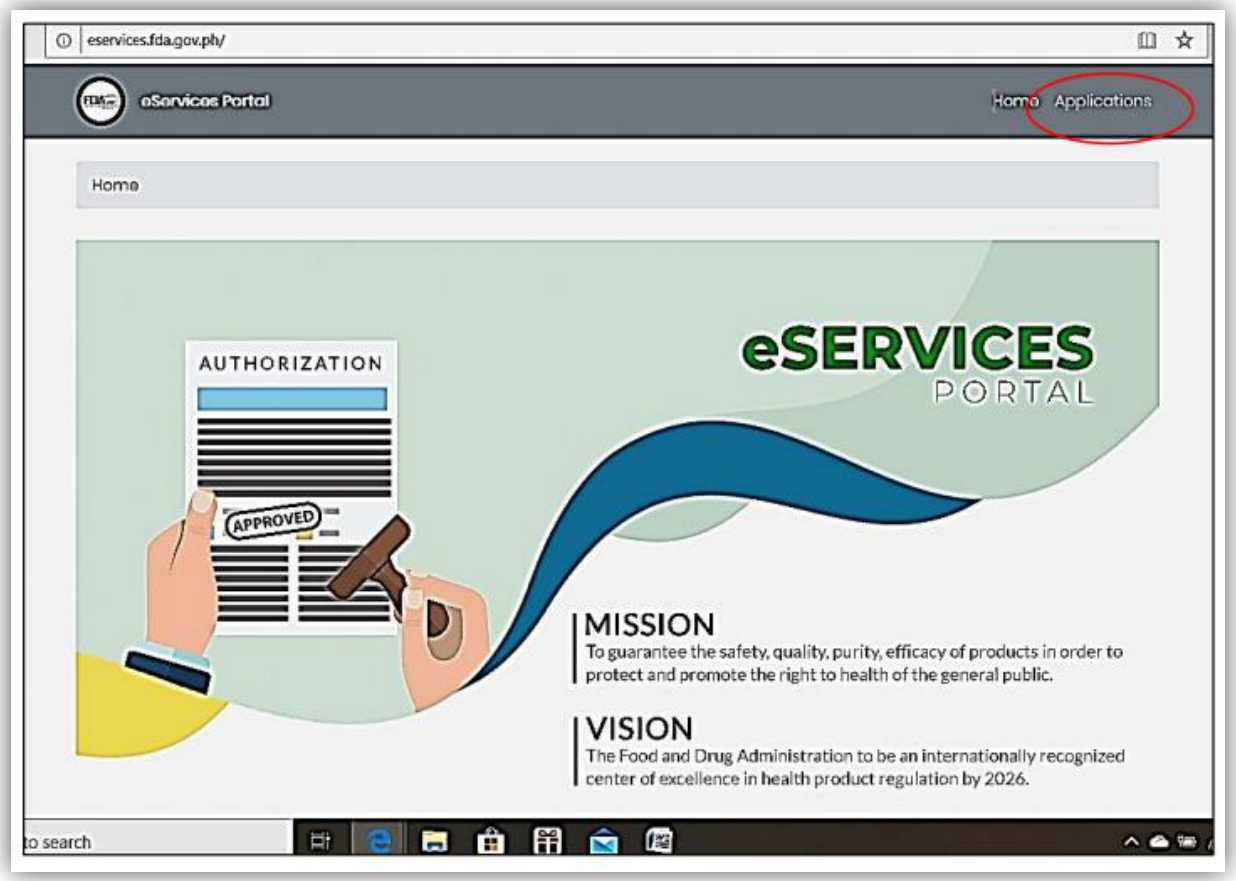
- **The prescribed fee for renewal application**

  Php 20,200

What is the Application Process?



E-SERVICES PORTAL SYSTEM

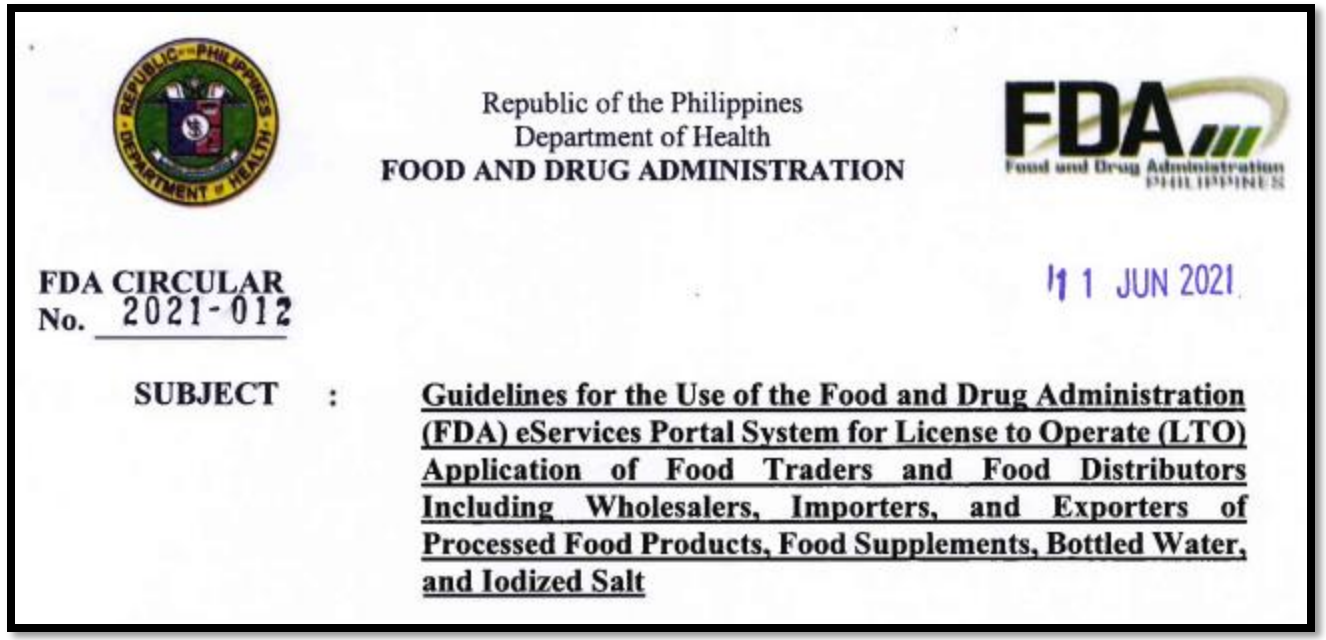


http://eservices.fda.gov.ph/

Food and Drug Administration
PHILIPPINES

FDA Circular No. 2021-012

"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"



Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

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**

Issuance of LTO

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

is hereby granted to

ESTABLISHMENT NAME

ESTABLISHMENT ADDRESS

SAMPLE ONLY

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.

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Director General

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

The Food Importer shall receive the **e-LTO** through its registered **e-mail address**

Food and Drug Administration
PHILIPPINES

Processing Time for Initial LTO for Food Distributors

Processing Time: **14** Working days

Note: The processing time of LTO applied through eServices Portal System, in accordance with the FDA Citizen's Charter ***shall start once the FDA Cashier has posted the Official Receipt of payment***

FDA Verification Portal

https://verification.fda.gov.ph/

Food and Drug Administration PHILIPPINES

For technical inquiries:

Send your e-mail to: **cfrr@fda.gov.ph**

For payment concerns:

Send your e-mail to **cashier@fda.gov.ph**

For issuance of user account or reporting of eportal issues:

Send your e-mail to **fdac@fda.gov.ph**

Contact FDA Action Center at:

Landline: 02 8821 1176, 02 8821 1177, 02 8821 1220

02 8821 1162, 02 8821 1159

Mobile: 0961-6804447, 0961-7709691, 0961-6845994

Food and Drug Administration PHILIPPINES

END

THANK YOU!

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info@fda.gov.ph

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