

Philippine Wine Regulation

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Outline

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- D. Registration Requirements for Wine
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FDA's Mandate



Regulatory agency mandated to ensure safety, efficacy, purity, and quality of regulated products (e.g. food, drugs, cosmetics, medical devices, diagnostic reagents and household hazardous substances).



FDA Regulatory Requirements

- I. Licensing of establishments
- II. Registration of regulated products

FDA Authorizations

1. License to Operate  Establishments
(e.g. food manufacturer /
food importers)
2. Certificate of Product
Registration  Food products
(e.g. wine)

License to Operate (LTO)

- An approval issued by FDA to an establishment prior to engaging in the manufacture, importation, exportation, sale, distribution, promotion or advertisement of food products.



Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION



Reissuance

LTO NO.: RDI-MM-FI/W-37

LICENSE TO OPERATE
a FOOD DISTRIBUTOR/IMPORTER/WHOLESALE

Pursuant to Section 4 (c) Chapter III of Republic Act No. 3720, as amended, otherwise known as "Foods, Drugs and Devices and Cosmetics Act", License is hereby issued to operate a food distributor specifically as a FOOD DISTRIBUTOR /IMPORTER /WHOLESALE in favor of:

Name of Establishment : SY, INC.
Business Address : 45 Panav Ave., Quezon City
Owner : SY, INC.

Same establishment has been found to comply with the Rules and Regulations and Technical Requirements governing the operation/distribution of food and food products.

This License shall be valid until **29 January 2012** and subject to renewal/revalidation after inspection.

However, should a violation of any of the provisions of the Food, Drugs and Devices and Cosmetics Act and/or the regulations issued thereunder be committed within the period of validity this License will be subject to suspension or revocation.

WITNESS MY HAND, and the Seal of this Office, this 16th day of May 2011.

BY AUTHORITY OF THE SECRETARY OF HEALTH

SUZETTE M. LAZO, MD., FPSECP
Acting Director IV

Date Issued: 16 December 2010 Official Receipt No. 028999 Amount: P 4,000.00

NAL/ajr

REVALIDATION

Year : _____
O.R. : _____
Date : _____
Valid until : _____
Signature : _____

This replaces LTO No. RDI-MM-FI/W-37 issued on 08 July 2004

LIST OF SOURCES SEE ATTACHED

NOTE: This License should be displayed in a conspicuous place within the establishment to facilitate inspection

Certificate of Product Registration (CPR)

- An authorization covering a particular product which serves as the registrant's marketing authority in connection with the activity/ies as permitted in the LTO.

The image shows a sample Certificate of Product Registration (CPR) form from the Food and Drug Administration (FDA) of the Philippines. The form is titled "CERTIFICATE OF PRODUCT REGISTRATION" and is issued by the Department of Health, Food and Drug Administration, Filinvest Corporate City, Alabang, Muntinlupa City. The form includes fields for Product Name, Manufacturer, Repacker, Importer, and Distributor. It also contains a section for the registration status, with checkboxes for "I" and "R". The form is signed by the Secretary of Health and includes the text "BY AUTHORITY OF THE SECRETARY OF HEALTH".

FDA
Food and Drug Administration
PHILIPPINES

Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION
Filinvest Corporate City, Alabang, Muntinlupa City

PSD Form 5
No. FA -

FDA Registration No. :
Registration Status : I R

CERTIFICATE OF PRODUCT REGISTRATION

Pursuant to the provisions of Republic Act 3720 as amended, known as the Foods, Drugs, Devices and Cosmetics Act, the product described hereunder has been found to conform with the requirements and standards for registration of food products per existing regulations in force as of date hereof.

Product Name :
Manufacturer :
Repacker :
Importer :
Distributor :

This registration shall be valid foryear (s) and shall expire on
subject to the conditions listed on the reverse side.

No change in the formulation, labeling and commercial presentation of this product shall be made at any time during the effectivity of this registration without prior written approval of this Office.

This registration is subject to suspension, cancellation or recall should any violation of Republic Act 3720 and/or regulations issued thereunder involving the product be committed.

Witness My Hand and Seal of this Office thisday of 20

BY AUTHORITY OF THE SECRETARY OF HEALTH

RSN :
O.R. No :
Amount :
Date issued :

Product Classification of Wine

- Alcoholic beverages , such as wine, is classified under Category II.
- Locally manufactured / Imported

CATEGORY II

- **Alcoholic Beverages**
- Foods for Special dietary Use (not for general use)
- Foods for Infants and children
- Herbal Tea
- Ethnic Food (with indigenous ingredient)
- Food Additives
- Food Supplements
- Transgenic Food

Registration Requirements for Category II Products

- Completely filled up Assessment Slip
- Notarized Application Letter
- Product Information
 - List of ingredients
 - Finished product specification
- One sample in commercial presentation
- One actual loose label
- Certificate of analysis of the finished product
- Flow diagram of the method of manufacture, packaging and quality control
- Packaging certification of suitability for food use
- Shelf-life analysis
- Justification of label claims

For Imported Products

- Original copy of the Certificate of Free Sale (CFS) issued by the government regulatory agency in the country of origin or equivalent.
 - The CFS should state that the specific product/s applied for registration are *freely sold in the country of origin and fit for human consumption*.

Additional Requirement for Alcoholic Beverages (e.g. wine)

- Methanol Content (Memorandum Circular No.13 s. 1989)
 - Methanol may be present provided it shall be *derived from natural alcohol fermentation and not added.*

Phil. Standards on Wine

1. Standard Administrative Order No. 357 series 1978
(Standardization of Wines)
2. Philippine National Standard/FDA 30:2010
(Phil. National Standard for Tropical Fruit Wines)

Standards Administrative Order No.357 series 1978

- Types:

1. Dry / Semi-Dry / Sweet
2. Fortified & Unfortified
3. Sparkling / Still / Carbonated
4. Red & White
5. Special / Medicinal
6. Basi

General Requirements (SAO No.357 s.1978)

- Ethyl alcohol content: 7 to 16⁰ by volume (except for fortified wine)
- Free from added coloring matter
- Free from any ingredient injurious to health
- Manufactured in premises built & maintained under hygienic conditions

General Requirements (SAO No.357 s.1978)

- Alcohol content
 - a. Dry / Semi-Dry/ Sweet: 7⁰% to 16⁰%
 - b. Fortified : 18⁰% to 22⁰%
- Total Acidity (Tartaric): 0.4 to 1.5 g/100ml
- Volatile Acids (Acetic): 0.08 to 0.12 g/100ml
- Reducing Sugar: 0.1 to 9.6 % (by weight)

General Requirements (SAO No.357 s.1978)

- Marking
 - Name of the product
 - Country of origin
 - Ethyl alcohol content (% alcohol by vol. or proof)
 - Name & address of the manufacturer
 - Contents in mL
 - List of ingredients (for special or medicinal wines)

Philippine National Standard for Tropical Fruit Wines (PNS/FDA 30:2010)

- Alcohol content (ethyl alcohol): 7⁰% to 24⁰% (v/v)
 - Methanol may be present, provided it shall be derived from the alcohol fermentation process & not added.
- pH : 3.0 to 4.0
- Total Acidity : 0.6⁰% to 0.9⁰%
- Soluble Solids: \geq 8.0% (m/m) at 20 °C
- Volatile Acidity (Acetic): \leq 0.14 g/100 mL

Philippine National Standard for Tropical Fruit Wines (PNS/FDA 30:2010)

- Labeling
 - Name of the product
 - Complete list of ingredients & food additives
 - Content by volume (metric system)
 - Name & address of the manufacture, packer &/or distributor
 - Lot or code number identifying product lot
 - Open date marking (“Best/Consume Before” or “Use by” date)

Philippine National Standard for Tropical Fruit Wines (PNS/FDA 30:2010)

- The words “Product of the Philippines” or the country of origin
- Alcoholic strength (percentage by volume)
- Direction for use
- Storage instructions
- Additional requirements:
 - Pictorial presentation of the product and/or the raw material/s used should be indicated on the label.



THANK YOU!