

FOOD AND DRUG ADMINISTRATION

Alabang, Muntinlupa City Tel. No. 857-1991



CENTER FOR FOOD REGULATION AND RESEARCH CHECKLIST OF REQUIREMENTS FOR INITIAL APPLICATION FOR A LICENSE TO OPERATE FOOD ESTABLISHMENT

A. GENERAL REQUIREMENTS

- 1. Accomplished Integrated Application Form
- 2. Proof of Payment of Fees
- 3. Proof of Business Registration
 - 3.1 If Single Proprietorship: Valid Certificate of Business Name Registration with the Department of Trade and Industry indicating the same name, address and ownership as the establishment applying for a license;
 - 3.2 If a Corporation or Partnership:
 - 3.2.1 Valid Registration with Securities and Exchange Commission (SEC) indicating the same name, address, and ownership as the establishment applying for a license;
 - 3.2.2 Articles of Incorporation; and
 - 3.2.3 Other pertinent documents, as applicable;
 - 3.3 If a Cooperative: Certificate of Cooperative Development Authority (CDA) indicating the same name, address, and ownership as the establishment applying for a license;
- 4. If the business name and/or and address is different from the registered name and/or address in the DTI-, SEC-, or CDA-issued certificate, the following shall be submitted in addition to the documents specified above as applicable:
 - 4.1 If a Corporation or Partnership, SEC Certificate must reflect "Doing business under the name and style of (Name of Establishment)
 - 4.2 Valid Mayor's Business Permit or Barangay Business Permit indicating the same name, address and ownership as the establishment applying for a license;
- 5. Proof of Occupancy (per facility and/or address declared as part of the establishment);
 - 5.1. If the facility and/or address declared as part of application is **not owned** by the applicant:
 - 5.1.1 Notarized valid Contract of Lease of the space or building occupied; and
 - 5.1.2 If the applicant is engaged in distribution (i.e. third-party logistics):
 - Duly notarized warehousing agreement;
 - 5.2 If the facility and/or address declared as part of application is **owned** by the applicant:
 - Copy of Transfer Certificate of Title;
- 6. Product List -
 - 6.1 The list of food products to be manufactured, processed or repacked with proposed brand name per product



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- 6.2 The list of products to be distributed, sold, or offered for sale or use, as appropriate, including the following information per product:
 - 6.2.1 Business name and address of direct source;
 - 6.2.2 Business name and address of facility where the product is last packaged, if different from source;
 - 6.2.3 Business name and address of facility where product is last processed, if different from last packaging site and direct source;
 - 6.2.4 If product is to be imported, a unique global product identification number (if applicable)
- 7. Location Map a graphic illustration indicating the address, landmarks, immediate environment, type of building, and Global Positioning System (GPS) coordinates (if available) for each facility and/ or address declared part of the establishment:
 - 7.1. Food Manufacturer- Manufacturing Plant
 - 7.2. Food Distributor- Office and warehouse/s (if different from the Office)
- 8. Floor plan/layout with dimensions
 - 8.1.Food Manufacturer- Manufacturing Plant
 - 8.2.Food Distributor- Office and warehouse/s (if different from the Office)

B. SPECIFIC REQUIREMENTS

Manufacturer/Processor

- 1. Description of the products to be manufactured (e.g. list of ingredients, physicochemical, and/or microbiological specifications)
- 2. Description of manufacturing process or food processing/preparation, including a flowchart with quality control points, as appropriate to the size of operation
- 3. Quality control procedures, as appropriate to the size of operation
- 4. Results of analysis of Finished Product /s showing compliance with applicable standards
- 5. Facsimile of proposed product label, compliant with FDA standards

Repacker

- 1. Description of the product to be repacked (e.g. name of product, physicochemical, and/or microbiological specifications)
- 2. Description of repacking process, including a flowchart with quality control points
- 3. Quality control procedures
- 4. Results of analysis of Finished Product /s showing compliance with applicable standards



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- 5. Photocopy of duly notarized valid contract or agreement with the manufacturer, and, as appropriate, the License to Operate (LTO) of the manufacturer where the product will be sourced for repacking
- 6. Facsimile of proposed label, compliant with FDA labelling requirements

Toll Manufacturer

- 1. Valid and notarized toll manufacturing agreement with FDA-licensed trader
- 2. Copy of valid LTO including attachments

Importer of Raw Materials for Own Use

- 1. Each item declared in the list of food product(s) to be imported must be identified in <u>any</u> of the following:
 - Pro forma invoice
 - Foreign agency agreement/ Contract Agreement
- 2. Scanned copy of <u>any</u> of the following original documents issued to the source by the regulatory or health authority at the country of origin. Otherwise, attested by recognized business association or chamber of commerce at the country of Origin per source:
 - Valid manufacturer's certificate of registration with GMP compliance, or its equivalent,
 - Valid Sanitary Phyto-sanitary Certificate or Health Certificate,
 - Valid ISO 22000 Certification,
 - Valid HACCP Certificate, or
 - Certificate of Free Sale

*If document is in foreign language other than English, provide an Official English translation by issuing agency or authenticated by Philippine Consulate from country of origin.

3. Appropriate test result or certificate of analysis routinely conducted in the country of origin or source that would indicate or show safety of the product. For test or analysis conducted in the Philippines, the applicant shall be guided by appropriate FDA standards as published in the FDA Website in addition to the recognition or accreditation of laboratories.

Importer-Distributor of Raw Materials/Finished Products/ Ingredients/ Additives for Distribution

- 1. Each item declared in the list of food product(s) to be imported must be identified in <u>any</u> of the following:
 - Pro forma invoice
 - Foreign agency agreement
 - Appointment letter
 - Distributorship agreement



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- 2. Scanned copy of <u>any</u> of the following original documents issued to the source by the regulatory or health authority at the country of origin. Otherwise, attested by recognized business association or chamber of commerce at the country of Origin per source:
 - Valid manufacturer's certificate of registration with GMP compliance, or its equivalent
 - Valid Sanitary Phyto-sanitary Certificate or Health Certificate
 - Valid ISO 22000 Certification
 - Valid HACCP Certificate
 - Certificate of Free Sale
 - * If document is written in foreign language other than English, provide an Official English translation by regulatory/health authority or issued by private entity, authenticated by Philippine Consulate from country of origin
- 3. Appropriate test result or certificate of analysis for salt, flour, cooking oil, rice premixes and other products with current safety issue.

Distributor-Exporter

- 1. Any of the following documents issued to the applicant by the establishment from which it sources the products it exports:
 - Valid notarized distributorship agreement; or
 - Letter of appointment between FDA-licensed manufacturer and exporter
- 2. Valid Certificate(s) of Product Registration

Distributor-Wholesaler

- 1. Any of the following documents issued to the applicant by the establishment from which it sources the products it sells:
 - Valid notarized distributorship agreement; or
 - Letter of appointment between the applicant and FDA-licensed source
- 2. Valid Certificate(s) of Product Registration

Food Trader- any establishment which is a registered owner of food and food product/s and/or procure the raw materials and packing components, quality control standards and procedures, but subcontracts the manufacture of such product to a licensed manufacturer

- Valid and notarized toll manufacturing and/or repacking agreement with FDA-licensed toll manufacturer and/or repacker.