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

Tel. No. 857-1991

CHECKLIST OF REQUIREMENTS FOR AMENDMENT OF LICENSE TO OPERATE FOOD ESTABLISHMENT

1. The following changes are equivalent to an INITIAL licensing application and must satisfy all applicable GENERAL and SPECIFIC requirements:
   a. Change of Ownership
   b. Change of Location of Manufacturing Site or Distribution Office

2. Amendments

2.1 <u>Change of Business Name</u>

a. Accomplished Integrated Application Form
b. Scanned Application Letter stating the intended changes (indicate changes/ amendments to be made)
c. New Business Name registration from DTI/SEC. If registered address with DTI/ SEC is different from the address of the establishment, a photocopy of Business/ Mayor's Permit
d. Proof of Payment of Fees

2.2 <u>Additional Product(s) for manufacturers</u>

a. Accomplished Integrated Application Form
b. Scanned Application Letter stating the intended changes (indicate changes/ amendments to be made);
c. Proof of Payment of Fees
d. Specific requirements for Manufacturer/Processor:
   - Description of the products to be manufactured (e.g. list of ingredients, physico-chemical, and/or microbiological specifications)
   - Description of manufacturing process or food processing/preparation, including a flowchart with quality control points, as appropriate to the size of operation
   - Quality control procedures, as appropriate to the size of operation
   - Results of analysis of Finished Product /s showing compliance with applicable standards
   - Facsimile of proposed product label, compliant with FDA standards

   * *Additional product line will be subject to FDA inspection to verify compliance to GMP*

2.3 Additional Activity(ies):

a. Accomplished Integrated Application Form
b. Scanned Application Letter stating the intended changes (indicate changes/ amendments to be made)
c. Proof of Payment of Fees
d. Specific requirements according to activity:

- ***Manufacturer/Processor***
    1. Description of the products to be manufactured (e.g. list of ingredients, physico-chemical, 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

    ** Additional activity as Manufacturer will be subject to FDA inspection to verify compliance to GMP*
- ***Repacker***
    1. Description of the product to be repacked (e.g. name of product, physico-chemical, and/or microbiological specifications)
    2. Description of repacking process, including a flowchart with quality control points
    3. Quality control procedures
    4. 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
    5. Facsimile of proposed label, compliant with FDA labelling requirements

    ** Additional activity as Manufacturer will be subject to FDA inspection to verify compliance to GMP*
- ***Toll Manufacturer***
    1. Valid and notarized toll manufacturing agreement with FDA-licensed Trader
    2. Copy of valid LTO of Food Trader 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 any 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:
        - 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 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 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, or
        - Distributorship 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 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**
  - Valid and notarized toll manufacturing and/or repacking agreement with FDA-licensed toll manufacturer and/or repacker

2.4 <u>Addition of Sources:</u>

a. Accomplished Integrated Application Form
b. Scanned Application Letter stating the intended changes (indicate changes/ amendments to be made)
c. Proof of Payment of Fees
d. Specific Requirements:
   - ***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 any 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 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 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***
    a) 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, or
        - Distributorship agreement

    b) 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 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*

c) Appropriate test result or certificate of analysis for salt, flour, cooking oil, rice premixes and other products with current safety issue.

- ***For 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

- ***For Food Trader***
  - Valid and notarized toll manufacturing and/or repacking agreement with FDA-licensed toll manufacturer and/or repacker

4. **<u>Deletion of Activity(ies)/Source(s)/Warehouse Address/Manufacturing Plant Address:</u>**
   a. Accomplished Integrated Application Form and Notarized Declaration page in the FDA website as prescribed by current FDA regulations;
   b. Scanned Application Letter stating the intended changes (indicate changes/ amendments to be made); and
   c. Proof of Payment of Fees as prescribed by current FDA regulations

5. **Addition of warehouse address (*subject to FDA inspection to verify compliance)***
   a. Proof of Occupancy
   b. Payment of appropriate fees
   c. Location Map
   d. Lay-out

6. **Change of Warehouse Address/Modification of submitted Proof of Occupancy not involving transfer of location**:
   a. Applicable Proof of Occupancy
   b. Payment of appropriate fees

7. **Change in Distribution Agreement not previously covered/Change of Manufacturing Process/Change of Quality Control Procedure**:
   - Must be reflected in the appropriate document that was required during initial application and shall be submitted during renewal

8. **Re-issuance of a License – for additional original copies**
    a. Accomplished Integrated Application Form as prescribed by current FDA regulations
    b. Proof of Payment of Fees as prescribed by current FDA regulations.