Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

CENTER FOR FOOD REGULATION AND RESEARCH

FOOD REGISTRATION REQUIREMENTS TO SECURE **CERTIFICATE OF PRODUCT REGISTRATION :**

I. ***REQUIREMENTS :*** The following are the requirements for a product registration (Imported/Locally Manufactured Food Products including Raw Materials ,Bulk Ingredients, Low Risk, Medium Risk, High Risk Conventional Food Pre-packaged Food Products and Food Supplements :

1.)Valid License to Operate (Food Manufacturer/ Exporter/Trader/ Importer/ Distributor /Wholesaler)

2.) Scanned copy of clear and **complete loose labels or artworks** as applicable , of all packaging sizes, or equivalents as defined by FDA regulations and **Picture of the product** in all angles and in different packaging sizes, and from at least two different perspective allowing visual recognition of a product as the same with the one being registered.

For Food Supplement : please include the artworks and /or blister packs Alu-Alu Pack and secondary packaging ie paper box or cardboard box)

3.) For Trader/Wholesaler/ Distributor of Locally Manufactured Food Products (When a product is manufactured or distributed by an establishment other than the FDA Licensed Manufacturer)

- Scanned copy of any of the following :
  - Notarized Distribution
  - Contract agreement with FDA Licensed Food Manufacturer / Repacker

For Importers/Distributors :

- **Scanned copy** of any of the original documents:
  - Foreign Agency Agreement
  - Certificate of Distributorship,
  - Appointment Letter
  - Proforma Invoice
  - Memorandum of Agreement from the manufacturer

- **AND Scanned copy of Any** of the following:
  - Manufacturer's certificate of registration with GMP compliance

Civic Drive, Filinvest City, Alabang 1781 Muntinlupa, Philippines
Trunk Line +63 2 857 1900 Fax +63 2 807 0751
Website: www.fda.gov.ph Email: info@fda.gov.ph

- Valid Phytosanitary Certificate/ Health Certificate
- Valid ISO 22000 Certification
- Valid HACCP Certificate issued in the country of origin;
- Certificate of free sale (CFS) attested by the recognized regulatory body or Chamber of commerce / Phil. Consulate in the country of origin.

4.) **As applicable, documents to substantiate claims**, such as :

- Technical or nutrition health studies or reports
- Market research studies
- Certificate of analysis , quantitative analysis and computations
- Scientific reports or studies published in peer-reviewed scientific journals
- Certificates or certification to support use of logo/seal on Sangkap Pinoy, Halal, Organic, Kosher and in compliance with current labelling requirements.

5.) **Certificate of Analysis** reflecting critical parameters to <u>determine compliance to applicable standards and regulations</u>

- For medium and high risk products with standards of identity (infant formula, milk supplement, food for infants and young children, foods for special medical purposes , foods for special dietary use, food supplements , bottled water, processes meat products etc.) , the corresponding Certificates of Analysis for assessment of compliance to such standard must be uploaded.
- Fortified Food Product covered by R.A. 8176 (iodized salt) and R.A. 8976 (cooking oil, flours and refined sugar)

6.) *Additional requirements for FOOD SUPPLEMENT* :

- **Stabililty study of the finished product**
- **Safety data** (e.g. LD50 or toxicity tests as applicable to products with herbs and botanical ingredients not included in the Official Pharmacopoeias and Generally Recognized as Safe (GRAS) list or other applicable test procedures or reports to assess potential toxicity) must be attached to address uncertainties on safety of the product.

7.) **Actual representative product sample of FOOD SUPPLEMENT (on initial application only)** in commercial presentation with labels. Representative sample must be properly labelled with the respective case numbers, packages accordingly to protect the contents and submitted to FDA Main office within 10 days upon assesses fee through either of the following means:

- Delivery via registered courier that must contain the following information :

To : Food and Drug Administration
Civic Drive , Filinvest City, Alabang
Muntinupa City
From : Company's Complete Name and Address
Subject : Food Product e registration application
Case No :

ISSUANCES ON REQUIREMENTS

- **Administrative Order 2014-0029** : Rules and Regulations on Licensing of Food Establishments and **Registration** of Processed Food Products , and For Other Related Purposes
http://www.fda.gov.ph/attachments/article/194723/AO2014-0029%20-%20Rules%20and%20Regulation%20on%20the%20Licensing%20of%20Food%20Establishement.pdf

- **FDA Circular 2016-007 :** Notification of Sources for Raw Materials, Low Risk, Medium and High Risk Pre-packaged Processed Foods
http://www.fda.gov.ph/issuances-2/food-laws-and-regulations-pertaining-to-all-regulated-food-products-and-supplements/food-fda-circular/343494-fda-circular-no-2016-007
- **FDA Circular 2016-0014 :** Procedure for the use of electronic registration (e-registration) system for pre-packaged processed food products)
www.fda.gov.ph/issuances-2/food-laws-and-regulations-pertaining-to-all-regulated-food-products-and-supplements/food-fda-circular/355437-fda-circular-no-2016-014
- **FDA Circular 2013-010 : Revised Guidelines on the Assessment of Microbiological Quality of Processed** Foods http://www.fda.gov.ph/issuances-2/food-laws-and-regulations-pertaining-to-all-regulated-food-products-and-supplements/food-fda-circular/17218-fda-circular-no-2013-010

II. PROCEDURE :

ISSUANCES ON PROCEDURE

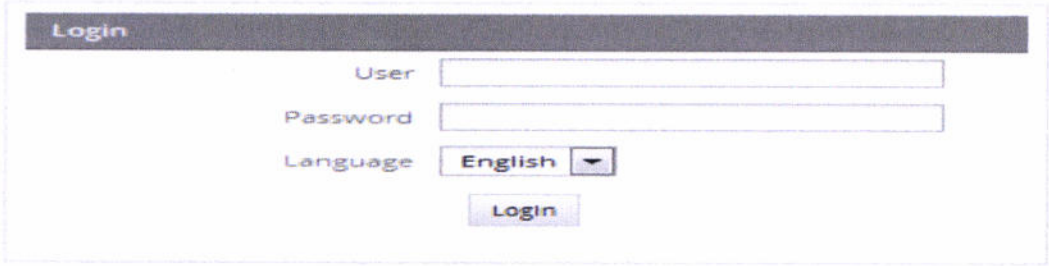
- **FDA Circular 2016-014 (Updated) : Procedure for the E-Registration System for Pre-packaged Processed Food Products (including Raw Material, Low Risk, High Risk Food Products)**
www.fda.gov.ph/issuances-2/food-laws-and-regulations-pertaining-to-all-regulated-food-products-and-supplements/food-fda-circular/355437-fda-circular-no-2016-014

- Risk Classification of Food Products : Low Risk, Medium Risk , High Risk Food Products
- Letter of Authorization
- Affidavit of Undertaking

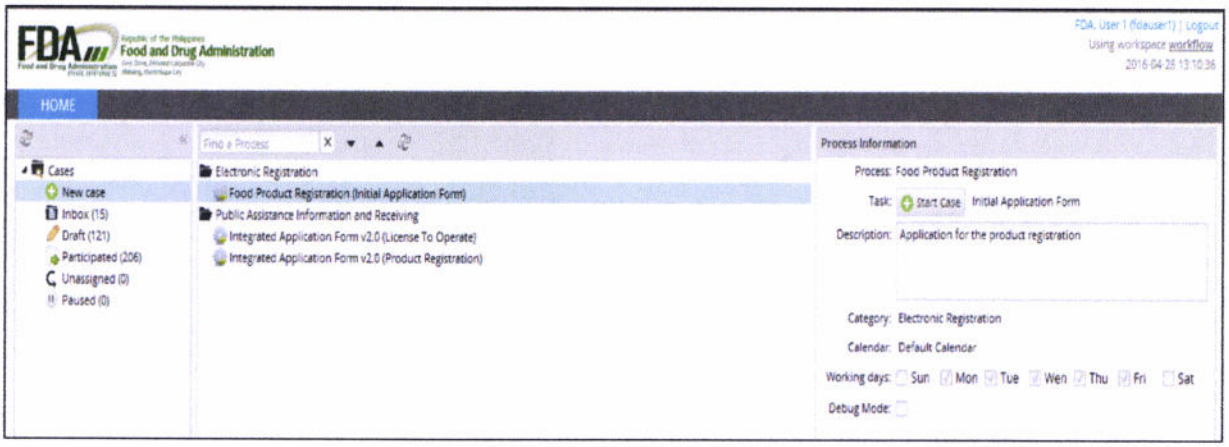
BASIC PROCEDURE ON E –REGISTRATION (as per FDA Circular 2016-014)

Step 1: Secure user name and password and submit/upload the required documents (Letter of Authorization and Affidavit of Undertaking)

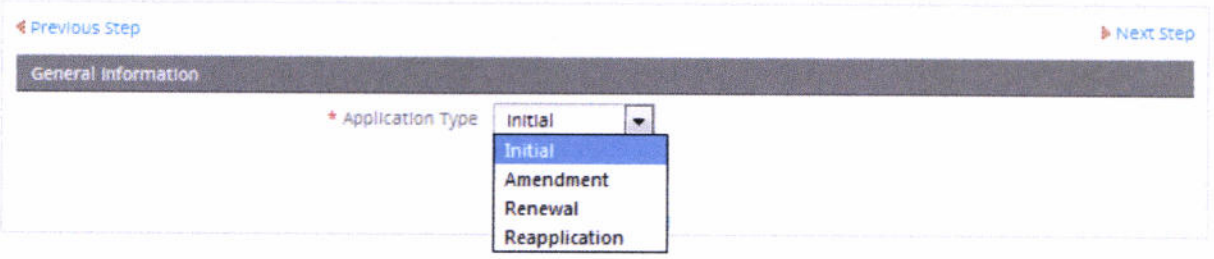
Step 2 : Log In in to FDA website e portal
https://www.fda.gov.ph/sysFDA_WorkFlow/en/neoclassic/login/login



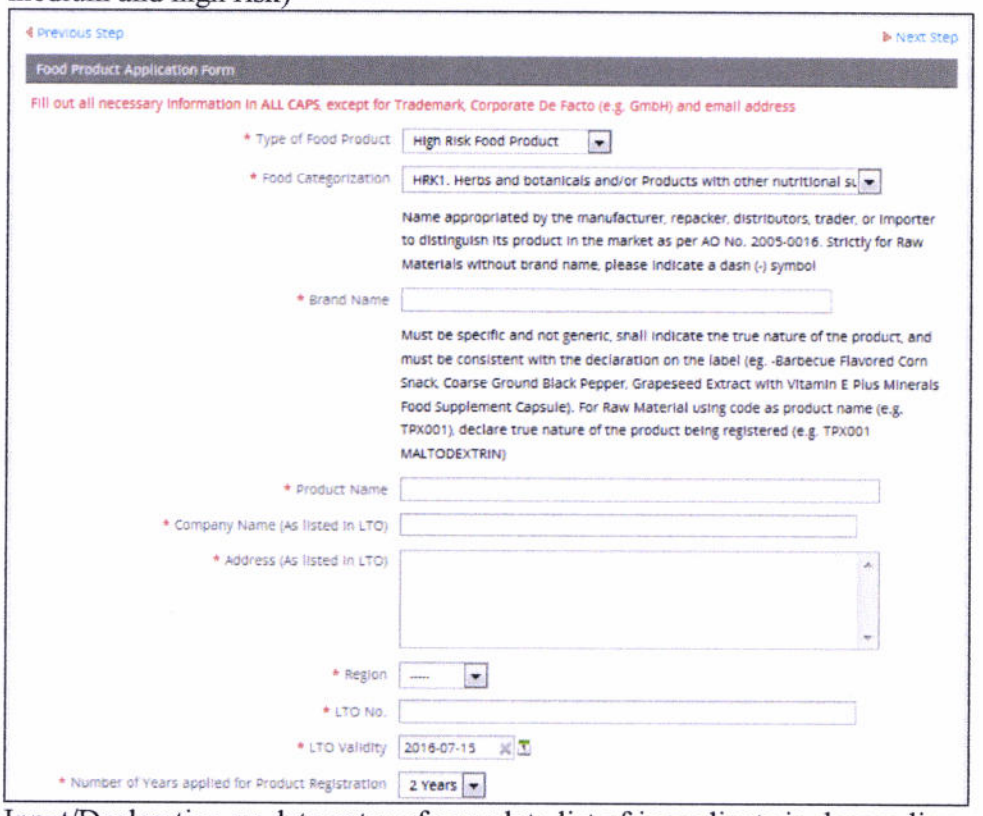
Step 3 : Click New Case (for Initial Application)



Step 3 : Input /Type on the require fields the information pertaining to the product



- Input/Declaration of the brand and product name ; food category (low risk, medium and high risk)



- Input/Declaration on data entry of complete list of ingredients in descending order of proportion.

Previous Step

Next Step

Complete List of Ingredients

In descending order of proportion. Product formulation must be consistent with the ingredient list on the label. Declaration of Food additives should specify its common name not the functional name only and indicate levels eg. LECITHIN (EMULSIFIER) 0.1%.

- For multi-component ingredients declaration:
  NON DAIRY CREAMER (as follows)
  (GLUCOSE SYRUP)
  (HYDROGENATED VEGETABLE FAT)

- For food supplement, ingredients declaration should be in the following format:
  Specific Name of Ingredient Amount per Serving
  Example: Zeaxanthin 1 mg

- For Vitamins and minerals as Food Supplement, ingredients declaration should be in the following format:
  Specific Name (Form/ Chemical nature of Vitamin or Mineral) Amount per Serving
  Example: Vitamin A (Beta-carotene) 300 µgRE

- For Amino acids as Food Supplement, ingredients declaration should be in the following format:
  Specific Name Amount per Serving
  Example: Leucine 50 mg

- For Herbs and Botanicals as Food Supplement, ingredients declaration should be in the following format:
  Specific Name (Scientific name) Plant Part Used Amount per Serving
  Example: Guyabano (Annona muricata) Fruit 100 mg

- For Products with Nutritional Substances (plant or animal origin) as Food Supplement, ingredients declaration should be in the following format:
  Specific name Plant or animal source Amount per Serving
  Examples: Collagen from Fish 500mg
  Allicin from Garlic 100mg

- Input/ Declaration on data entry of the Finished product specification /description (physical, chemical, microbiological) as applicable

Previous Step

Next Step

Product Specifications

Ensure the completeness and accuracy of the details for the parameters and specifications in conerence with FDA Standards (eg. Philippine National Standards, Administrative Orders, and other relevant issuances)

Physical

I. Color

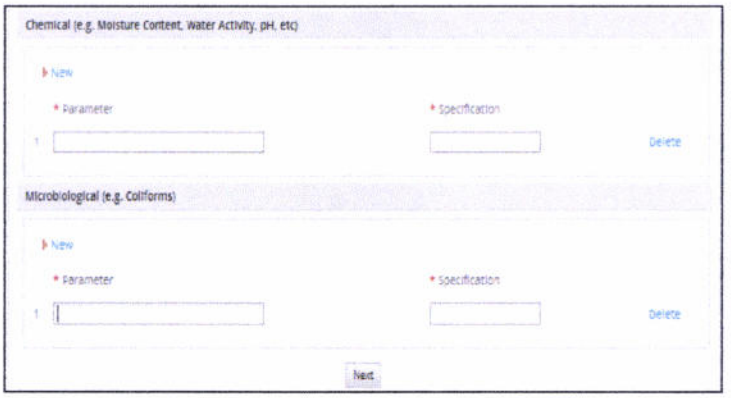
II. Odor

III. Taste

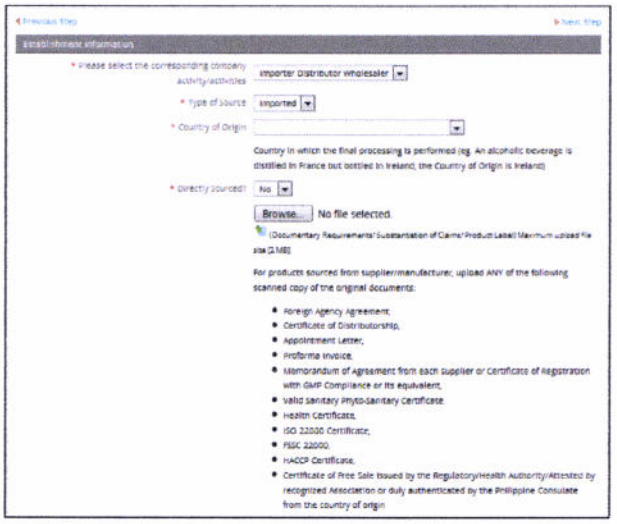
IV. Texture

V. Form

e.g. powder, liquid, gel, etc.



- Input/Declaration on data entry of the Establishment Information .



- Input/ Declaration of the packaging material and presentation ; Shelf-life; storage; allergen information ; Lot Code interpretation

Previous Step | Next Step

Shelf Life and Other Information

* Shelf Life Declaration (in Months)

For Alcoholic Beverages without Shelf Life, indicate 0 (Zero)

* Type: Actual

* Packaging Material Type/Name

eg. Glass Bottle; Polyethylene Terephthalate (PET); Polyethylene; Polypropylene; Cellophane; Paper (such as Glassine, Vegetable Parchment); Can coated with Oleoresinous, Phenolic, Epoxy or Vinyl; Polyamide; Aluminum; Blister Pack; etc

Description of Product in Commercial Presentation

eg. Individually Wrapped in Pillow Packs Inside Laminated Plastic Pack; in Bottle, in Box, in 90g (2sachets x 45g) carton box

Storage Condition Requirements

e.g. Product should be stored in a cool and dry place with air humidity of 70% maximum, cool storage is recommended

Function of the Food material

Function of the Food Material applies to Food Additives and Ingredients only. (e.g. preservative, nutrient, emulsifier, bakery ingredient)

Step 4 : Upload the required documents :

Reminder :

- Maximum of 2MB per attachment in .PNG or .PDF format
- Maximum of 25MB for all attached files per application

Previous Step | Next Step

Documentary Requirements

Please upload the necessary documents

Upload the image of the product label (PNG or PDF File Format) — Browse... No file selected.
(Documentary Requirements/ Substantiation of Claims/ Product Label) Maximum upload file size [2 MB]

Please upload the Picture of the Product in Commercial Presentation in all angles and in different packaging sizes and from at least two different perspectives — Browse... No file selected.
(Documentary Requirements/ Substantiation of Claims/ Product Label) Maximum upload file size [2 MB]

Is your product for Export

No

Upload any of the following, Purchase Order, Request for Quotation, or valid notarized agreement signed by Importing and Exporting parties of the Importing Company — Browse... No file selected.
(Documentary Requirements/ Substantiation of Claims/ Product Label) Maximum upload file size [2 MB]

Do you have Nutrient Content Claim/ Nutrient Function Claim/ Other Function Claims/ Health Claim/ Comparative Claim/ Non-addition claim/ Reduction of disease risk claim/ Other claims?

No

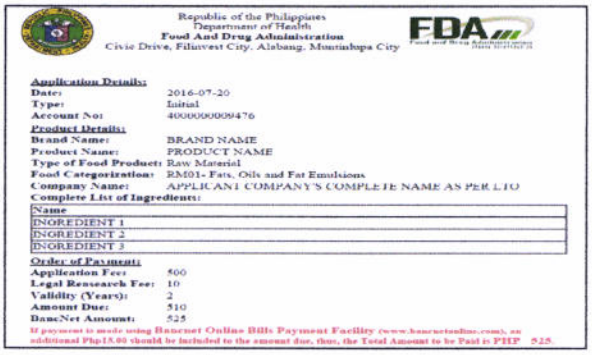
Upload documents to substantiate claims, such as technical, nutritional, or health studies or reports, market research studies, Certificate of Analysis, quantitative analysis and computations, scientific report or studies published in peer-reviewed scientific journals, certificates or certification in compliance with current labelling regulations — Browse... No file selected.
(Documentary Requirements/ Substantiation of Claims/ Product Label) Maximum upload file size [2 MB]

- ✓ **Scanned copy** of clear and complete **loose labels or artworks** and picture of the product in different angles in different packaging sizes and presentation as applicable from at least two different perspectives .
  (For Food Supplement : complete loose label or artworks including the Blister packs, Alu-Alu Pack and secondary packaging)

- ✓ **For Trader/Wholesaler/ Distributor of Locally Manufactured Food Products (When a product is manufactured or distributed by an establishment other than the applicant)**
  - Scanned copy of any of the following :
    - Notarized Distribution
    - Contract agreement with FDA Licensed Food Manufacturer / Repacker

- ✓ **Importers/Wholesaler (Imported Food Products) :**
  - Scanned copy of the original documents: Foreign Agency Agreement, or Certificate of Distributorship, or Appointment Letter, or Proforma Invoice, or Memorandum of Agreement from the manufacturer
  - **AND Any** of the following: Manufacturer's certificate of registration with GMP compliance, or its equivalent, Valid Phytosanitary Certificate/ Health Certificate, Valid ISO 22000 Certification, Valid HACCP Certificate issued in the country of origin; Certificate of free sale (CFS) attested by the recognized regulatory body or Chamber of commerce / Phil. Consulate in the country of origin.
- ✓ As applicable, **documents to substantiate claims**, such as technical or nutrition health studies or reports, market research studies, certificate of analysis , quantitative analysis and computations, scientific reports or studies published in peer-reviewed scientific journals , certificates or certification to support use of logo/seal on Sangkap Pinoy, Halal, Organic, Kosher and in compliance with current labelling requirements.
- ✓ **Certificate of Analysis** reflecting critical parameters to determine compliance to applicable standards and regulations.
- ✓ *FOR FOOD SUPPLEMENT* :
  - **Stabililty study** of the finished product
  - Safety data (e.g. LD50 or toxicity tests as applicable to products with herbs and botanical ingredients not included in the Official Pharmacopoeias and Generally Recognized as Safe (GRAS) list or other applicable test procedures or reports to assess potential toxicity) must be attached to address uncertainties on safety of the product.

Step 5 : Print the Order of Payment . Pay the corresponding assessed fee through FDA Main Office Alabang Cashier or Bancnet on line payment gateway following the procedure per FDA Advisory 2015-021 or any applicable payment system prescribed by FDA.
http://www.fda.gov.ph/advisories/241540-fda-advisory-no-2015-021



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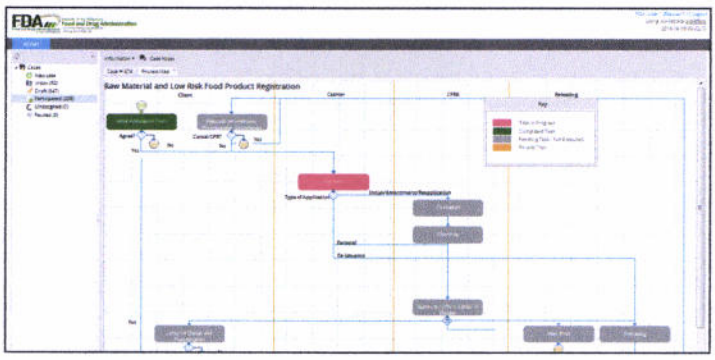
Civic Drive, Filinvest City, Alabang, Muntinlupa City

Application Details:
Date: 2016-07-20
Type: Initial
Account No: 4000000009476
Product Details:
Brand Name: BRAND NAME
Product Name: PRODUCT NAME
Type of Food Product: Raw Material
Food Categorization: RM01- Fats, Oils and Fat Emulsions
Company Name: APPLICANT COMPANY'S COMPLETE NAME AS PER LTO
Complete List of Ingredients:

Name
INGREDIENT 1
INGREDIENT 2
INGREDIENT 3

Order of Payment:
Application Fee: 500
Legal Research Fee: 10
Validity (Years): 2
Amount Due: 510
BancNet Amount: 525
If payment is made using Bancnet Online Bills Payment Facility (www.bancnetonline.com), an additional Php15.00 should be included to the amount due, thus, the Total Amount to be Paid is PHP 525.

Step 6 : Track the application through the Process Map .



III. FEES :

- **Administrative Order 50s, 2001 Revised Schedule of Fees and Charges for the Corresponding Services Rendered by Bureau of Food and Drugs**
  http://www.fda.gov.ph/attachments/article/95568/AO_50_2001.pdf
- **FDA Circular 2011-004(Surcharges) Computation of Surcharges and Penalties**
  http://www.fda.gov.ph/issuances/302-others/others-fda-circular/22-fda-circular-no-2011-004
- FDA Circular 2017-010 : **New Collection Policy and Procedure**
  http://www.fda.gov.ph/issuances-2/others-laws-and-regulations-not-applicable-to-the-above-categories/others-fda-circular/461190-fda-circular-no-2017-010