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

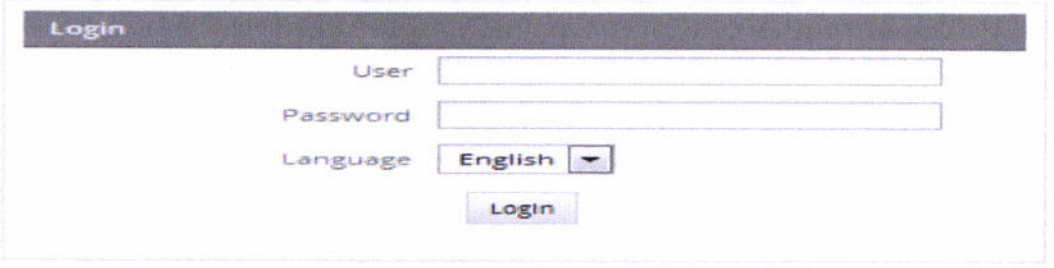
- **FDA Circular 2016-014 (Updated) : Procedure for the E-Registration System for Pre-packaged Processed Food Products (including Raw Material, Low Risk, High Risk Food Products)**
  www.fda.gov.ph/issuances-2/food-laws-and-regulations-pertaining-to-all-regulated-food-products-and-supplements/food-fda-circular/355437-fda-circular-no-2016-014

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

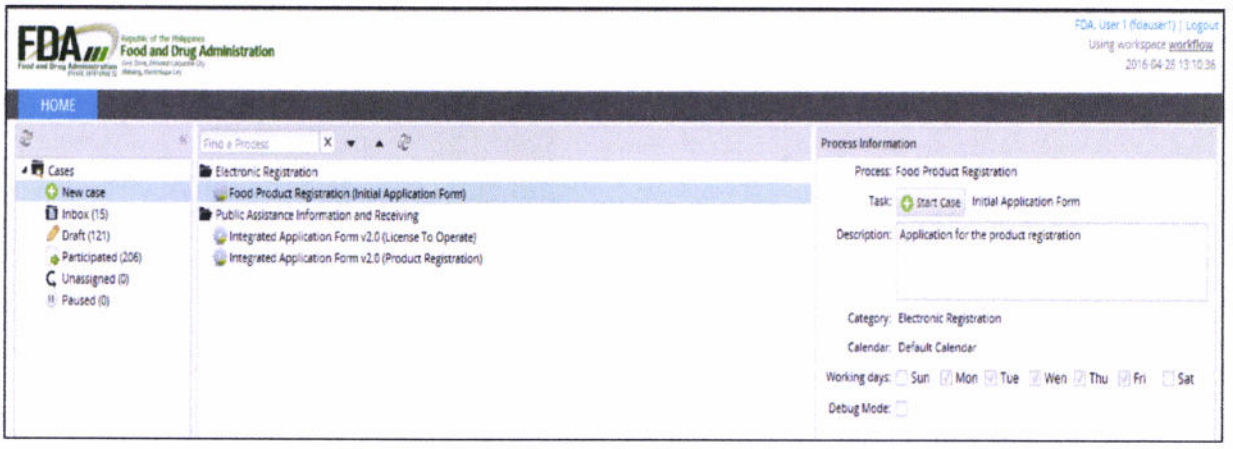
BASIC PROCEDURE ON E –REGISTRATION (as per FDA Circular 2016-014)

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