

# Republic of the Philippines Department of Health FOOD AND DRUG ADMINISTRATION



28 November 2014

FDA CIRCULAR No. 2014-029

SUBJECT: PROCEDURE FOR THE USE OF ELECTRONIC REGISTRATION (E-REGISTRATION) SYSTEM FOR RAW MATERIALS OR INGREDIENTS AND LOW RISK PRE-PACKAGED PROCESSED FOOD PRODUCTS

Pursuant to Paragraph (n), Section 2, Article II (A), Book I of the Rules Implementing Republic Act No. 9711, otherwise known as the FDA Act of 2009, Section VI Item F of Administrative Order No. 2014-0029, Rules and Regulations on Licensing of Establishments and Registration of Processed Food Products, and Other Food Products, and for Other Purposes, and consistent with the objective of Republic Act No. 8792 or the Electronic Commerce Act of 2000 in promoting the universal use of electronic transaction in the government and general public, the Food and Drug Administration (FDA) hereby implements an electronic registration (E-registration) system initially applicable for raw materials or ingredients and low risk prepackaged processed food products in order to streamline the application and evaluation process without compromising public health and consumer safety, hence, the promulgation of this Circular.

#### I. Guidelines

- The E-registration will initially cover raw materials or ingredients and low risk food products. Upon proper determination and recommendation by the Office of the Director of the Center for Food Regulation and Research, the coverage of applications shall forthwith be extended to other levels of risk subject to amendment of this Circular.
- 2) The low risk food products covered shall follow the list found in Annex A of Administrative Order No. 2014-0029 (Please see Annex A). The list under each category may be expanded as appropriate for the definition.
- 3) For raw materials or ingredients and low risk food products with existing Certificate of Product Registration (CPR) due for renewal or amendment, and denied applications due for reapplication, the applicant shall submit applications through the e-registration system using the same procedure for initial application in order to translate all the product information into electronic database. The product shall be given a new system-generated FR number. Any existing labels printed with previously assigned FR Number shall be allowed to be exhausted for a period of one year from the date of issuance of the new FR Number.





- 4) Succeeding amendment and renewal applications shall be through the eregistration. For this purpose, the following shall apply:
  - a. Changes that fall as amendment covers only the following:
    - · Change in/Additional Packaging size
    - Change in/Additional Packaging Type or Packaging Material
    - Change in/Additional Packaging Design
    - · Change/Extension in Shelf-Life
    - · Change in Brand Name
    - Change in Product Name
    - Change in Business Name
    - Exportation of previously registered product initially for local distribution
    - Transfer of ownership of a registered product
    - Change in importer/distributor
  - Automatic renewal provided that there are no changes in the previously approved product information.
- 5) The applicant has the option to choose the validity of initial registration from a minimum of 2 years to a maximum of 5 years. Renewal applications shall be valid for 5 years.
- 6) The fees and charges for all applications through the e-registration shall be based on the prevailing rates implemented by the FDA.

#### II. General Procedure

### A. Initial Application

1) The applicant shall be assigned an FDA account in order to apply through eregistration. The applicant shall secure from the company a notarized authorization letter (Annex B) as the company account holder. He/She shall send the scanned authorization to <u>info@fda.gov.ph</u> with "CFRR: E-registration" as the subject, with the following information:

Email Address:

Last Name:

First Name:

Middle Name:

Company Name:

Applicants who have attended and completed the Qualified Person in Industry Regulatory Affairs (QPIRA) Training for CFRR will have the priority. The list of QPIRA who attended for a specific company may be viewed at the FDA website.

The Username and Password is **company-specific**. An officer/representative handling multiple companies shall secure separate Username and Password for each respective company.

- 2) Access the online portal through <a href="https://www.fda.gov.ph">https://www.fda.gov.ph</a>. Provide the company-specific Username and Password, and then click the "Electronic Registration Low Risk Food Product Registration (Initial Application Form)".
- 3) Read carefully the "DECLARATION" before proceeding with the application process. The "DECLARATION" conveys a binding agreement of the applicant with the FDA to provide accurate information, affirm full responsibility for the safety of the product being registered, and comply with all applicable rules and regulations.

Click "Yes, I agree". Declining the declaration shall mean forfeiture of the opportunity to proceed with e-registration.

- 4) After providing the required information, an Order of Payment will be received. Make sure that all information are complete and correct before making any payment.
- 5) Pay the corresponding assessed fee through the FDA Cashier, BancNet online (as soon as available) or any applicable payment system prescribed by the FDA.
- 6) Track the application through the "Process Map" function of the system.
  - a. If the application is denied, an electronic Letter of Denial shall be received in the **Inbox** of the account holder. Reapplication shall be treated as and follow the process for initial applications.
  - b. If the application is approved, the current task that will be indicated is for Releasing. The applicant must then secure the Certificate of Product Registration at the Releasing Section of FDA

### B. Amendment/Renewal Application

- 1) To apply for amendment or renewal, access the online portal through <a href="https://www.fda.gov.ph">https://www.fda.gov.ph</a>. Provide the company-specific Username and Password, and double click on the specific product in the Inbox folder.
- 2) Select the type of application from the drop-down menu after the "Declaration".
- 3) Provide the required information completely and accurately.
- 4) Proceed as in Steps (4) to (6) provided above.

### III. Specific Procedure in Accomplishing e-Registration Applications

- 1) All information filled out by the applicant during the process will be reflected exactly in the final output (either CPR or Letter of Denial). Thus, it is imperative for the client to be strictly cautious and diligent in filling out all required information.
- 2) Fill out all necessary information in ALL CAPS, except for Trademark, Corporate De Facto (e.g. GmbH) and e-mail address.
- 3) A **MINIMUM** of three (3) contact information in the form of E-Mail, Telephone and Mobile Number must be declared.
- 4) Declare ALL ingredients in DESCENDING order of proportion. For multicomponent ingredients (e.g. non-dairy creamer), indicate the phrase "as follows" in parenthesis after the ingredient and declare each specific component also in parenthesis (Figure 1).

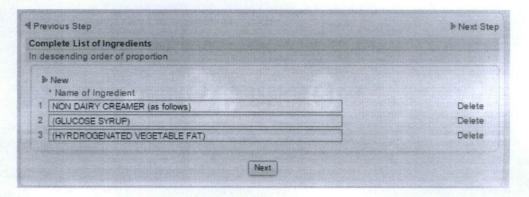


Figure 1. Declaration of Multi-Component Ingredient

- 5) In declaring the product specifications for physical, chemical, and microbiological parameters, ensure the completeness and accuracy of the details for the parameters and specifications since these will be verified later on during Post-Market Surveillance.
- 6) In attaching Product Labels or other supporting documents, make sure that ALL information are reflected **LEGIBLY** and **ACCURATELY**. Limit the attachments to 20 MB using the format ".png" or ".pdf". Refrain from using "jpg", "jpeg" and other similar picture formats since these files are larger and will take a longer time to attach.

Product labels in commercial presentation should be scanned clearly reflecting all sides with complete information. If pictures of the individual sides/panels of the label are attached separately, ensure that the corresponding file names are given.

### IV. Effectivity

All e-registration applications for raw materials/ingredients and low risk food products shall be implemented starting on December 1, 2014.

By Authority of the Secretary of Health

ATTY. NICOLAS B. LUTERO III, CESO III

Assistant Secretary of Health OIC, Food and Drug Administration

### ANNEX A

#### List of Low Risk Food Products

### A. FATS, OILS AND FAT EMULSIONS

- 1. Butter oil, anhydrous milkfat, ghee
- 2. Vegetable oils and fats
- 3. Animal fats (lard, tallow, fish oil and other animal fats)
- 4. Fat emulsions mainly of type oil-in-water, including mixed and/or flavored products based on fat emulsion
- 5. Fat emulsions mainly of type water-in-oil (butter, fat spreads, margarine dairy fat spreads and blended spreads)
- 6. Fat-based desserts excluding dairy-based desserts

# B. PROCESSED FRUITS, VEGETABLE AND EDIBLE FUNGI (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera) SEAWEEDS, AND NUTS AND SEEDS

- 1. Dehydrated fruits or vegetables, including candied fruits (mechanically dried)
- 2. Jams, jellies, marmalades (pastry, topping, filling, coconut spreads)
- 3. Dehydrated Vegetable protein products
- 4. Fruits or vegetables in vinegar, oil or brine
- 5. Fruit-based spreads (e.g. chutney) excluding jams, jellies and marmalades
- 6. Fruit preparations, including pulp, purees, fruit toppings and coconut milk
- 7. Cooked fruits
- 8. Frozen vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera) seaweeds, and nuts and seeds
- Vegetable (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweed, and nut and seedin pulps and preparations (e.g. vegetable desserts and sauces, candied vegetables) other than food in HR Letter B.8 (Vegetable purees, spreads – peanut butter)
- 10. Cooked or fried vegetables(including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), and seaweeds

### C. CONFECTIONERY

- 1. Confectionery including hard and soft candy, nougats, marzipans, etc. other than in MR (cocoa products and chocolate products)
- 2. Chewing gum
- 3. Decorations (e.g. for fine bakery wares, sugar flowers), toppings (non-fruit), and sweet sauces

# D. CEREAL-BASED PRODUCTS, derived from cereal grains, from roots and tubers, pulses, legumes and pith or soft core of palm tree, excluding bakery wares in Letter F below

- 1. Flours, starches (including soybean powder) and flour mixes
- 2. Breakfast cereals including rolled oats
- 3. Pasta and noodles and like products (e.g. rice paper, rice vermicelli, soybean pastas and noodles)
  - a. Fresh pastas and noodles and like products
  - b. Dried pastas and noodles and like products
  - c. Pre-cooked pastas and noodles and like products
- 4. Cereal and starch based desserts (e.g. rice pudding, tapioca pudding, native delicacies)
- 5. Batters (e.g. for breading or batters for fish or poultry)
- 6. Pre-cooked or processed rice products, including rice cakes (Oriental type only)
- Soybean products (excluding soybean-based seasonings and condiments under LR Letter I (seasonings, condiments and sauces)
  - a. Soybean-based beverages
  - b. Soybean-based film
  - c. Soybean curd (tofu)
  - d. Semi-dehydrated soybean curd
    - Thick gravy-stewed semi-dehydrated soybean curd
    - 2) Deep fried semi-dehydrated soybean curd
    - 3) Semi-dehydrated soybean curd, other than in LRD.7.d.1) and 7.d.2)
  - e. Dehydrated soybean curd (kori tofu)
  - f. Other soybean protein products

# E. PROCESSED MEAT AND MEAT PRODUCTS, INCLUDING POULTRY AND GAME

Edible casings (e.g. sausage casings)

## F. BAKERY WARES AND BAKERY RELATED PRODUCTS

- Bread and ordinary bakery wares and mixes
  - a. Breads and rolls yeast-leavened breads and specialty breads, soda breads
  - b. Crackers, excluding sweet crackers
  - c. Other ordinary bakery products (e.g. bagels, pita, English muffins)
  - d. Bread-type products, including bread stuffing and bread crumbs
  - e. Steamed bread and buns
  - f. Mixes for bread and ordinary bakery wares
- 2. Fine bakery wares (sweet, salty or savory) and mixes

Mixes for fine bakery wares (e.g. cakes, pancakes)

### G. SWEETENERS, INCLUDING HONEY

- 1. Refined and raw sugars
  - a. White sugar, dextrose anhydrous, dextrose monohydrate, fructose
  - b. Powdered sugar, powdered dextrose
  - c. Soft white sugar, soft brown sugar, glucose syrup, dried glucose syrup, raw cane sugar
  - 1) Dried glucose syrup used to manufacture sugar confectionery
  - 2) Glucose syrup used to manufacture sugar confectionery
  - d. Lactose
  - e. Plantation or mill white sugar
- 2. Brown sugar excluding products under LRG.1.c (soft white sugar, etc.)
- 3. Sugar solutions and syrups, also (partially) inverted, including treacle and molasses, excluding products under G.1.c(soft white sugar, etc.)
- 4. Other sugars and syrups (e.g. xylose, maple syrup, sugar toppings), including coconut sugar
- 5. Honey
- 6. Table-top sweeteners, including those containing high-intensity sweeteners

### I. SALT, SPICES, SOUPS, SAUCES, SALADS AND PROTEIN PRODUCTS

- 1. Salt and salt substitutes
- 2. Herbs, spices, seasonings and condiments (e.g. seasoning for instant noodles)
- 3. Vinegars
- 4. Mustards
- Soups and broths Mixes for soups and broths
- 6. Sauces and like products
  - a. Mixes for sauces and gravies
  - b. Clear sauces (fish sauce)
- 7. Yeast and like products
- 8. Soybean-based seasonings and condiments
  - a. Fermented soybean paste (e.g. miso)
  - b. Soybean sauce
    - 1) Fermented soybean sauce
    - 2) Non-fermented soybean sauce
    - 3) Other soybean sauces
- 9. Protein products other than from soybeans, marinades

### J. BEVERAGES, excluding dairy products

- Non-alcoholic ("soft") beverages
   Coffee, coffee substitutes, tea, herbal infusions, and other hot cereal and grain beverages
  - 2. Alcoholic beverages, including alcohol-free and low-alcoholic counterparts
    - a. Beer and malt beverages
    - b. Cider and perry
    - c. Grape wines
      - 1) Still grape wine
      - 2) Sparkling and semi-sparkling grape wines
      - 3) Fortified grape wine, grape liquor wine, and sweet grape wine
    - d. Wines (other than grape)
    - e. Mead
    - f. Distilled spirituous beverages containing more than 15% alcohol
    - g. Aromatized alcoholic beverages (e.g. beer, wine and spirituous cooler-type beverages, low-alcoholic refreshers)

### K. READY-TO-EAT SAVOURIES

- 1. Snacks potato-, cereal- or starch-based (from roots and tubers, pulses and legumes), including chips and crunchies
- 2. Chicharon
- 3. Snacks fish-based

### ANNEX B

## TEMPLATE Authorization Letter for E-registration

### [[COMPANY LETTERHEAD]]

(DATE)

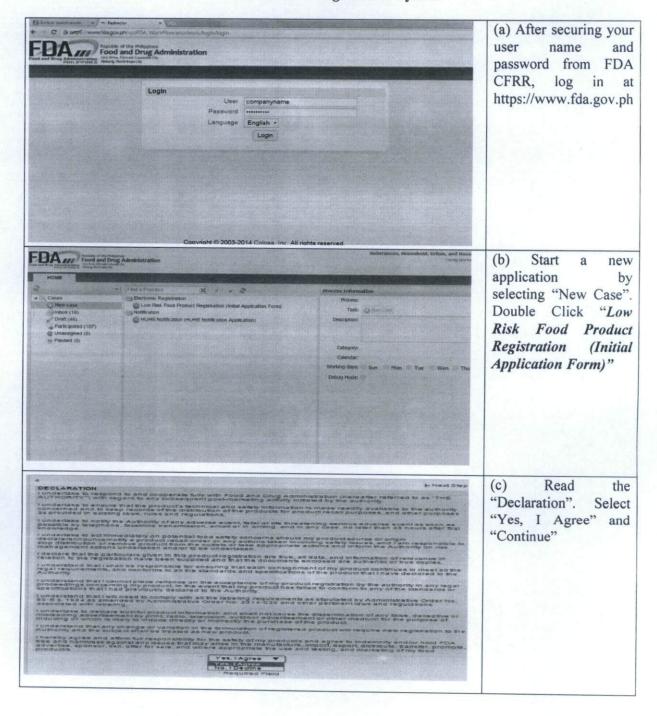
The Director/OIC
Center for Food Regulation and Research
Food and Drug Administration
Civic Drive, Filinvest Corporate City
Alabang, Muntinlupa City

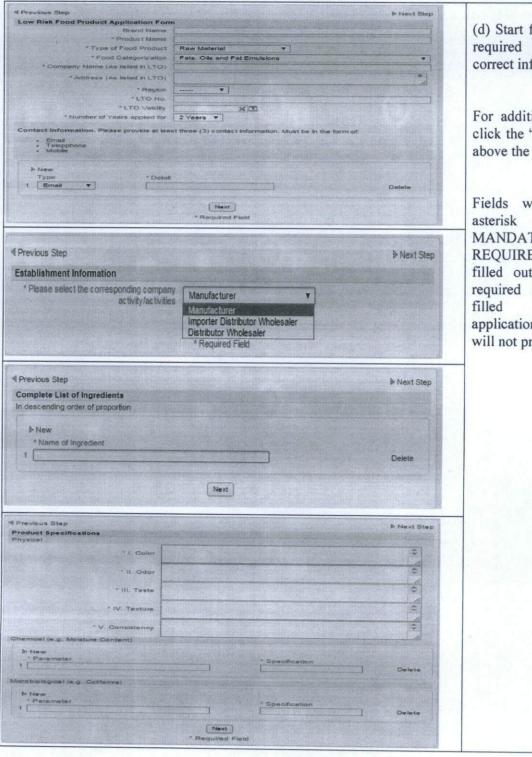
### Sir/Madam:

In accordance with Republic Act No. 97	11 and other related issuances, we
valid until, hereby authorize	(Name of Representative) as
the account holder for e-registration of prepackaged processed food products and sl submitted through e-registration.	raw materials/ingredients/low risk
(Owner/General Manager/President)	
Subscribed and sworn to me this day o	f at
	NOTARY PUBLIC
Doc No	100000
Page No.	
Book No.	
Series of	

### ANNEX C

### FDA CFRR e-Registration System





(d) Start filling out the required fields with correct information.

For additional fields, click the "New" button above the information

Fields with red (\*) asterisk are MANDATORY/
REQUIRED to be filled out. In case a required field is not filled out, the application process will not proceed.

