Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

26 FEB 2021

FDA CIRCULAR No. 2020-033

SUBJECT : Procedure for the Use of the Modified Electronic Registration System for Raw Materials and Prepackaged Processed Food Products Repealing FDA Circular No. 2016-014 "Procedure for the Use of Electronic Registration System for Prepackaged Processed Food Products"

I. BACKGROUND

FDA Circular (FC) No. 2016-014 was issued on 12 August 2016 to be 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 provision of services to the general public, the Food and Drug Administration (FDA) implemented an electronic registration (E-registration) applicable for all prepackaged processed food products in order to streamline the application and evaluation process.

The initial implementation of E-registration showed an improvement in the process of application and issuance of Certificate of Product Registration (CPR). At the same time, the experience in the initial implementation uncovered the need to further enhance specific features of the E-Registration System. The review of the system paved the way to the development of new and improved E-Registration System.

Moreover, the passing of Republic Act (RA) No. 11032, otherwise known as the Ease of Doing Business and Efficient Government Service Delivery Act of 2018 has led to the review of registration requirements and evaluation process. Thus, this Circular provided for a more user-friendly E-Registration System attuned with the requirements of the RA No. 11032.

II. OBJECTIVE/S

The Circular aims to provide detailed guidance on how to apply for and obtain CPR using the new E-Registration System.

III. SCOPE

The E-Registration System shall cover initial, renewal, reapplication, and amendment registration of prepackaged processed food products (raw materials or ingredients, low risk, medium risk, and high risk).

IV. GUIDELINES

A. General Guidelines

1. The risk classification of food products shall follow the list found in Annex A of the Administrative Order No. 2014-0029 (Annex A). The list is not limited to Annex A but may be expanded to cover other food products as may be required by FDA.

2. The validity period of Certificate of Product Registration (CPR) applications filed through the E-registration shall be based on existing FDA rules and regulations.

3. The fees and charges for all applications through the e-registration shall be based on the current prescribed fees as implemented by the FDA.

4. Food establishments with multiple manufacturing plants producing the same product shall file one (1) CPR per product per plant for the purpose of traceability and consistency in the E-Registration database.

5. Food establishments with License to Operate (LTO) activity as Importer, Trader, Wholesaler and Manufacturer shall be regarded as the Market Authorization Holder (MAH). The MAH shall be primarily responsible for the filing of CPR applications using its own account, ensuring safety and continued compliance of the product with applicable rules and regulations of FDA.

6. All certificates of analysis submitted must be issued within twelve (12) months from the date of filing of the application or the date of payment.

7. Only one case number shall be used per product produced by the same manufacturer. Duplicate applications for products having the same brand name, product name, formulation and manufacturer/plant address with multiple case numbers shall be cancelled prior to processing.

8. Food products with CPR issued prior to implementation of the new E-Registration System that are due for renewal or with amendment/s shall be applied through the new E-Registration System by choosing "Renewal" or

"Amendment", respectively, on the General information step of the E-Registration application.

9. The new e-registration system will automatically capture all uploaded documents from the old e-registration system provided that the account used is the same and the provided old Case Number is correct. This is not applicable for amendment application to change the Market Authorization Holder (MAH) since this should be applied using a new user account. Note that the new system will not capture all uploaded documents from the old system if companies will not use their existing user accounts and if they will not provide the correct Case Number of their previously approved applications in the old E-Registration system.

10. Label Exhaustion (E.g. Label of products covered by Milk Code reflecting old FR Number) can be requested provided that there is a letter of justification and the inventory with the target date for consumption is clearly stated.

11. For products that are not included in the list of food categories, companies can classify these products under High Risk, "L. NOVEL / NEW INNOVATIONS in FOOD New in the international or local market".

B. Specific Guidelines

1. Using the E-Registration System, the initial registration shall require the encoding of all the product information for every product application and submission of all labels and supporting documents.

2. For approved product applications filed through the E-Registration System, the Company E-Registration Account Holder may apply for Renewal, Amendment, or Cancellation of their respective products through the E-Registration portal. The account holder shall be the authorized representative of the applicant company.

3. Succeeding amendments of food products approved through the E-Registration System shall cover the following changes:

    a. Change in/Additional Commercial Presentation (i.e. Packaging Size)
    b. Change in/Additional Packaging Type or Packaging Material
    c. Change in/Additional Packaging Design
    d. Change/Extension in Shelf-Life
    e. Change in Brand Name
    f. Change in Product Name/ Additional Product Description
    g. Change in Business/Company Name

h. Change in Business/Company Address (Not Applicable to Manufacturer and Repacker)
i. Exportation of previously registered product initially for local distribution
j. Transfer of ownership of a registered product
k. Change in/Additional Supplier
l. Change in Importer/Distributor/ Trader
m. Other cases as declared in succeeding FDA issuances

4. Applications for Renewal/Automatic Renewal will undergo pre-assessment to verify if the remarks are already complied. CPR remarks shall be complied through amendment prior to filing of renewal application.

5. Should a product fail to meet the requirements for product registration, applicable product standards and labelling regulations, a Letter of Denial shall be electronically issued to the inbox of the respective user account of the applicant. The applicant shall be given a maximum of six (6) months to comply and file for re-application. Any application submitted thereafter shall be considered as initial application.

6. For medium and high risk food products including for "institutional use only" with standard of identity (e.g. Infant Formula, Milk Supplement, Foods for Infants and Young Children, Foods for Special Medical Purposes, Foods for Special Dietary Uses, food supplements (FS), bottled water, etc.), the corresponding Certificates of Analysis for assessment of compliance to such standards must be uploaded. In addition, these products should conform to the chemical and microbiological parameters and nutritional requirements based on existing FDA regulations.

7. For food products covered by Republic Act No. 8172 otherwise known as "*An Act for Salt Iodization Nationwide (ASIN)*" and Republic Act No. 8976 or the "*Philippine Food Fortification Act of 2000*", the Certificate of Analysis attesting its conformity to prescribed fortification levels must be uploaded. Levels of iodine must conform to the latest acceptable level of fortification (30 to 70 ppm based on FDA Circular 2013-007).

8. For Food Supplement, the physical, chemical, and microbiological analysis, Stability Data of the finished product and Safety Data (e.g. LD50 or toxicity tests as applicable to products with herbs and botanical ingredients not included in Official Pharmacopeias 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.

9. Nutrition and Health Claims declared on the product labels must be supported by relevant documents (e.g. scientific research, etc.) following Bureau Circular 2007-002 *(Guidelines in the Use of Nutrition and Health Claims in Food).*

10. All CPR remarks shall be complied within the validity of the CPR prior to renewal of the application.

C. Procedural Guidelines

1. Issuance of a CFRR E-Registration User Account

   The User Account issued and revalidated by CFRR through the old system does not need to request for new User Account. These accounts will be automatically included in the interface of the new electronic registration system once implemented.

   Applicants without existing CFRR User Account shall secure a new User Account.

   a. The CFRR E-Registration User Account and Password is company-specific. An officer/representative handling multiple companies shall secure a separate user account and password for each respective company.

   b. The applicant shall be assigned an FDA account to apply through the E-Registration System. The applicant shall secure a notarized Authorization Letter from the company being represented indicating its valid LTO Number (**Annex B**) or the company account holder. The applicant shall send a request for a User Account to **cfrr@fda.gov.ph** following the format specified below with the scanned notarized authorization letter:

      SUBJECT: CFRR: E-Registration

      BODY: Email Address:

      Last Name:

      First Name:

      Middle Name:

      Company Name:

      LTO No.:

      LTO validity:

   c. The CFRR E-Registration User Account shall be sent to the e-mail provided in the request. The validity of the User Account issued by CFRR is the same as LTO validity.

d. When the representative of the applicant company is changed, the applicant shall request for a change in credentials of the CFRR E-Registration User Account by sending an e-mail to cfrr@fda.gov.ph following the format specified on Letter C.1.b. and attaching a scanned copy of the notarized Affidavit of Undertaking (**Annex C**).

e. The applicant shall renew the user account at least 90 days prior to expiration of user account by sending an e-mail to cfrr@fda.gov.ph and following the format specified on Letter C.1.b.

f. The issued user account by the FDA Action Center (FDAC) for Electronic License to Operate (E-LTO) can be revalidated in order to access E-Registration by sending an e-mail to cfrr@fda.gov.ph and following the format specified on Letter C.1.b.

g. In case of problems with username and/or password, the owner of the applicant company should send an email to cfrr@fda.gov.ph following the format specified on Letter C.1.b. and attaching scanned copy of the Affidavit of Undertaking (**Annex C**) to request retrieval of username and/or password of E-Registration account.

2. Accomplishing E-Registration Applications

a. Access the online portal through https://eportal.fda.gov.ph/. Provide the company-specific Username and Password, and then click the **"CFRR Electronic Registration – Food Product Registration EODB (Application Form)"**.

b. Read carefully the **"DECLARATION"** before proceeding with the application process. The "**DECLARATION**" conveys a binding agreement between the applicant and the FDA to provide complete and accurate information, assuming full responsibility for the safety of the product being registered, with an undertaking to comply with all applicable rules and regulations. Click the "**Yes, I agree**" button to continue the registration process. If the user fails to do so, access to proceed to E-Registration shall be denied.

c. All information filled out by the applicant during the process shall be reflected in the final output (either CPR or Letter of Denial) based on consistency with uploaded documents. Thus, it is imperative for the client to be diligent in filling out all required information. To ensure proper classification of the products being applied, please refer to **Annex A** (Risk Classification of Food Products).

d. Fill out all necessary information in **ALL CAPS**, except for Trademark, Corporate De Facto (e.g. GmbH) and e-mail address.

e. A **MINIMUM** of two (2) contact information in the form of Telephone and Mobile Number must be declared.

f. Declare ALL ingredients in DESCENDING order of proportion. For multi-component ingredients (e.g. non-dairy creamer), indicate the phrase "as follows" in parenthesis after the ingredient and declare each specific component also in parenthesis (e.g. "NON-DAIRY CREAMER (AS FOLLOWS): (COMPONENT 1), (COMPONENT 2)").

g. Declare the appropriate product description of the food including type of packing medium, form or style, and the condition or type of treatment it has undergone (e.g. Canned Spanish Style Tuna Chunks, Pickled Cucumber in Brine, Dried Fish, Frozen Corn Kernel, Milk powder, etc.). In declaring the product specifications for physical, chemical, and microbiological parameters, ensure the completeness and accuracy of the details since these shall be verified later during Post-Market Surveillance.

h. Declare the packaging material/s including primary and secondary packaging (e.g. Blister pack by 10's; Box of 60's) and corresponding shelf life of the product for each packaging materials (e.g. 6 months for PET bottle; 12 months for aluminum can).

i. For FS, declare the recommended usage of the product per day (e.g. one tablet once a day).

j. In attaching Product Labels and other documentary requirements, make sure that ALL information is reflected **CLEARLY** and **ACCURATELY**. Limit the total size of attachments to 25 MB with a limit of 2 MB per file using the format ".png" or ".pdf". Refer to **Annex D** for the Reference Guide to stakeholders to assess compliance of submitted documents as complete requirements for food product registration.

k. Product labels in commercial presentation should be scanned clearly reflecting all sides with complete information and shall be named accordingly indicating the appropriate net weight for multiple packaging sizes

l. For FS, one (1) representative sample in commercial presentation consistent with the E-Registration application shall be submitted to Food and Drug Action Center (FDAC) at 3rd Floor Starmall, Alabang,

Muntinlupa City before continuing the application to Pre-Assessment through either the following means:

i. Personal Delivery to FDAC, Starmall, Alabang, Muntinlupa City; or

ii. Delivery via registered courier that must contain the following information:

TO:	FOOD AND DRUG ACTION CENTER (FDAC) 3rd Floor Starmall, Alabang, Muntinlupa City
FROM:	Company's complete name & address
SUBJECT:	Food Product E- Registration Application (Case No.)

The proof of submission of sample (Acknowledgement Receipt from FDAC or Receipt from Registered Courier) shall be uploaded together with the other documentary requirements.

3. Pre-Assessment

a. Make sure that all information is complete and correct before continuing the application to Pre-Assessment. After providing the required information and forwarding application to pre-assessment, a system-generated notification shall be sent to applicant's email.

b. Upon checking of completeness of submission of documentary requirements during pre-assessment, a system-generated email notification stating complete or incomplete requirement submission shall be sent to the E-Registration account holder.

i. Upon receipt of system-generated result of pre-assessment indicating complete requirements for registration, pay the corresponding assessed fee through the FDA Cashier at FDAC, Starmall, Alabang or BancNet online payment gateway following the procedure per FDA Circular No. 2017-010 or any applicable payment system prescribed by the FDA.

ii. Upon receipt of system-generated result of pre-assessment indicating incomplete requirements for registration, the applicant can download the result of pre-assessment attached in the email notification stating the deficiencies. No application will be subject to "payment" and "evaluation" with incomplete requirements. The case number of pre-assessed application with incomplete requirements is considered closed. Start a new case by filing another application for this product.

Upload initially submitted documentary requirements together with documents for compliance to deficiencies mentioned. For FS, the proof of submission of sample can be re-uploaded to the new application.

4. Action on the Registration Application

   a. Day 1 of prescribed Citizen's Charter timeline of 20 working days for filing of application for registration starts with the date of posting of payment by FDA Cashier.

   b. On the 20th working day after posting of payment, a system-generated email notification shall be sent to the applicant company's email indicating the result of the registration application. However, in the event that an application cannot be processed within 20 working days due to situations beyond FDA's control (e.g. *force majeure*, system failure, etc.), the applicant shall be notified and the application shall be processed in the soonest possible time.

      i. If the application for registration is denied, a system-generated email notification with attached Letter of Denial (LOD) indicating clearly the grounds for denial shall be sent. The electronic LOD may also be downloaded in the **Inbox** of the account holder. All applications which are not approved may file for re-application.

      ii. If the application is approved, a system-generated email notification with attached CPR shall be sent. The applicant can download and print the system-generated CPR in the **Inbox** of the account holder.

5. Re-application

   a. To apply for re-application, access the online portal through https://eportal.fda.gov.ph/. Provide the company-specific Username and Password, and double click on the specific product in the **Inbox** folder.

   b. Click the Case Number to forward the application to "Letter of Denial and Reapplication".

   c. Double click on the specific product in the Inbox folder again to file for reapplication.

   d. Select "Yes, I would like to reapply".

e. Attach documents (e.g. letter of justification or clarification, scanned compliant labels, etc.) conforming to the grounds for denial per electronically issued Letter of Denial.

f. Forward the application to "pre-assessment" step.

g. Upon receipt of system-generated result of pre-assessment indicating complete reapplication requirements, pay the corresponding assessed fee through the FDA Cashier at FDAC, Starmall, Alabang or BancNet online payment gateway following the procedure per FDA Circular No. 2017-010 or any applicable payment system prescribed by the FDA.

h. Upon receipt of system generated result of pre-assessment indicating incomplete reapplication requirements, proceed as in letter (c) above.

6. Amendment/Renewal Application

a. Amendment/Renewal applications shall be filed within 6 months prior to expiration of the CPR.

b. To apply for amendment or renewal, access the online portal through https://eportal.fda.gov.ph/. Provide the company-specific Username and Password, and double click on the specific product in the **Inbox** folder.

c. Select the type of application from the drop-down menu after the "Declaration".

d. Provide the required information completely and accurately. For amendment applications, select all amendment types for the desired changes except for any changes that is equivalent to an INITIAL application. For renewal of applications with remarks indicated in the CPR, upload documents (i.e. revised label and documents to substantiate claims) to verify compliance to indicated CPR remarks. For amendment and renewal of applications initially approved in the old E-Registration or manual system, upload all initial requirements.

e. Proceed as in No. 5 (Re-application) (f) and (g) provided above.

f. Upon receipt of system-generated result of pre-assessment indicating incomplete amendment or renewal requirements, proceed as in letter (a) above.

V. Transitory Provisions

V. Transitory Provisions

Starting 08 March 2021, the new E-Registration System shall be accessible for applications for registration of all pre-packaged processed food products and the old registration system can no longer be accessed.

All pending applications filed through the old E-Registration System shall be processed with priority in the old portal.

Continued use of existing labels printed with previously assigned Food Registration (FR) Number shall be allowed for a period of one (1) year from the date of issuance of the new FR Number provided by the E-Registration System.

VI. Repealing Clause

The FDA Circular No. 2016-014 and other issuances inconsistent with this Circular are hereby repealed and/or modified accordingly.

VII. Separability Clause

If any provision of this Circular be declared as invalid or unenforceable, the validity and enforceability of the remaining portions or provisions shall remain in full force and in effect.

VIII. Effectivity

The electronic registration of all prepackaged processed food products using the new and improved E-Registration System shall be fully implemented starting 08 March 2021.

ROLANDO ENRIQUE D. DOMINGO, MD.
Director General

DTN 20200309141501

ANNEX A

RISK CLASSIFICATION OF FOOD PRODUCTS

Table 1. Low Risk (LR) Foods – foods that are unlikely to contain pathogenic microorganisms and will not normally support their growth because of food characteristics and foods that are unlikely to contain harmful chemicals.

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 9. 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) 7. Soybean products (excluding soybean-based seasonings and condiments under LR Letter I (seasonings, condiments and sauces) a. Soybean-based beverages b. Soybean-based film

LOW RISK FOOD PRODUCTS
c. Soybean curd (tofu) d. Semi-dehydrated soybean curd 1) 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 1. 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 i. Dried glucose syrup used to manufacture sugar confectionery ii. 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 5. 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 sauce 9. Protein products other than from soybeans, marinades

LOW RISK FOOD PRODUCTS
J. BEVERAGES, excluding dairy products 1. 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

Table 2. Medium Risk (MR) Foods – foods that may contain pathogenic micro-organisms but will not normally support their growth because of food characteristics; or food that is unlikely to contain pathogenic micro-organisms because of food type or processing, but may support the formation of toxins or the growth of pathogenic micro-organisms.

MEDIUM RISK FOOD PRODUCTS
A. DAIRY PRODUCTS and ANALOGUES, excluding products under Fats, Oils and Fat Emulsions 1. Condensed milk and analogues (plain) (evaporated/reconstituted milk) a. Condensed milk (plain) b. Beverage whiteners 2. Milk powder and cream powder and powder analogues (plain)
B. FROZEN DESSERTS 1. Non-Dairy based (e.g. sherbet, sorbet) 2. Edible ices – popsicles
C. 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. Tomato products 2. Frozen fruits 3. Canned or bottled (pasteurized) or retort pouch fruit and vegetable preserve in juice, syrup, brine 4. Fruit-based desserts, gelatin (including water-based fruit flavored desserts, i.e. gels) 5. Fermented fruit products 6. Fruit fillings for pastry 7. Fermented vegetable products (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera) and seaweed products, excluding fermented soybean products MR Letter E.1 and E.2 (fermented soybeans and fermented soybean curd) and LR Letters I.8.b. 1) to 3) (soybean sauces) 8. Vegetable protein products (canned and frozen)
D. CONFECTIONERY Cocoa products and Chocolate products including imitations and chocolate substitutes a. Cocoa mixes (powders) and cocoa mass/ cake b. Cocoa mixes (syrups) c. Cocoa-based spreads, including fillings d. Cocoa and chocolate products, including *"tablea"*; and imitation chocolate, chocolate substitute products
E. CEREAL-BASED PRODUCTS, derived from cereal grains, from roots and tubers, pulses, legumes and pith or soft core of palm tree – Soybean products 1. Fermented soybeans (e.g. natto, tempe) 2. Fermented Soybean curd
F. PROCESSED MEAT AND MEAT PRODUCTS, INCLUDING POULTRY AND GAME *** 1. Processed meat, poultry and game products in whole or cuts a. Non-heat treated processed meat, poultry and game products (cured, fermented, chilled)

1) Cured (including salted) non-heat treated processed meat, poultry and game products 2) Cured (including salted) and dried non-heat treated processed meat, poultry and game products 3) Fermented non-heat treated processed meat, poultry and game products 2. Processed comminuted meat, poultry and game products a. Non-heat treated processed meat, poultry and game products (cured, fermented, chilled) 1) Cured (including salted) non-heat treated processed meat, poultry and game products 2) Cured (including salted) and dried non-heat treated processed meat, poultry and game products (jerky, shredded beef/ pork) 3) Fermented non-heat treated processed meat, poultry and game products
H. PROCESSED FISH AND FISH PRODUCTS, INCLUDING MOLLUSCS, CRUSTACEANS AND ECHINODERMS 1. Processed fish and fish products, including molluscs, crustaceans and echinoderms a. Smoked, dried, fermented, and/or salted fish and fish products, including molluscs, crustaceans and echinoderms 2. Semi-preserved fish and fish products, including molluscs, crustaceans and echinoderms a. Fish and fish products, including molluscs, crustaceans and echinoderms – marinated and/or in jelly b. Fish and fish products, including molluscs, crustaceans and echinoderms – pickled and/or in brine c. Salmon substitutes, caviar and other fish roe products d. Semi-preserved fish and fish products, including molluscs, crustaceans and echinoderms (e.g. fish paste), excluding products under MR Letter H.2.a to c above
I. EGG AND EGG PRODUCTS 1. Preserved eggs, including alkaline, salted and canned eggs (salted eggs, century eggs) 2. Egg-based desserts (e.g. custard)
J. BAKERY WARES AND BAKERY RELATED PRODUCTS Fine bakery wares (sweet, salty or savory) and mixes a. Cakes, cookies, pies, pastries, doughnuts, sweet rolls, scones, muffins, waffles – plain / without filling b. Frozen dough
K. SALT, SPICES, SOUPS, SAUCES, SALADS AND PROTEIN PRODUCTS 1. Soups and broths Ready-to-eat soups and broths, including canned, bottled and frozen 2. Sauces and like products a. Emulsified sauces and dips (e.g. mayonnaise, salad dressing, onion dips) b. Non-emulsified sauces (ketchup, cheese sauce, cream sauce, brown gravy) 3. Salads (e.g. macaroni salad, potato salad) and sandwich spreads excluding cocoa- and nut-based, spreads under HR Letter B.8 (peanut butter)and MR D.1.c (cocoa-based spreads)
L. BEVERAGES, excluding dairy products 1. Non-alcoholic ("soft") beverages a. Fruit and vegetable juices - (fruit juice, vegetable juice, concentrates for fruit juice, concentrates for vegetable juice) b. Fruit and vegetable nectars (fruit nectar, vegetable nectar, concentrates for fruit nectar, concentrates for vegetable nectar) c. Water-based flavored drinks, including "sport," "energy," or "electrolyte" drinks and particulated drinks 1) Carbonated water-based flavored drinks 2) Non-carbonated water-based flavored drinks, including punches and ades 3) Concentrates (liquid or solid) for water-based flavored drinks d. Powdered cocoa drink mixes (cocoa)
M. FOOD SUPPLEMENT/ HERBAL FOOD/ HERBAL DIETARY SUPPLEMENTS 1. Vitamins and minerals 2. Amino acids
N. READY-TO-EAT SAVOURIES Processed nuts, including coated nuts and nut mixtures (with e.g. dried fruits)

***Regulated by the Department of Agriculture – National Meat Inspection Service (DA-NMIS) subject for transfer to Food and Drug Administration per succeeding issuance

Table 3. High Risk (HR) Food – foods that may contain pathogenic microorganisms and will support the formation of toxins or the growth of pathogenic microorganisms and foods that may contain harmful chemicals.

HIGH RISK FOOD PRODUCTS
A. DAIRY PRODUCTS and ANALOGUES, excluding products under Fats, Oils and Fat Emulsions 1. Milk and dairy-based drinks a. Milk (plain) and buttermilk (plain) b. Dairy-based drinks, flavored and/or fermented (e.g. chocolate milk, cocoa, eggnog, drinking yoghurt, whey-based drinks)

2. Fermented and renneted milk products (plain), excluding dairy-based drinks in HR A.1.b
   a. Fermented milks (plain)
      1) Fermented milk (plain), not heat-treated after fermentation
      2) Fermented milks (plain), heat-treated after fermentation
   b. Renneted milk (plain)
3. Cream (plain) and the likes (cream analogs)
   a. Pasteurized cream (plain)
   b. Sterilized and UHT creams, whipping and whipped creams, and reduced fat creams (plain)
   c. Clotted cream (plain)
   d. Cream analogues
4. Cheese and analogs
   a. Unripened cheese
   b. Ripened cheese
      1) Ripened cheese, includes rind
      2) Rind of ripened cheese
      3) Cheese powder (for reconstitution; e.g. for cheese sauces)
   c. Whey cheese
   d. Processed cheese
      1) Plain processed cheese
      2) Flavored processed cheese, including those containing fruits, vegetables, meat, etc
   e. Cheese analogues
   f. Whey protein cheese
5. Dairy-based desserts (e.g. pudding, fruit or flavored yoghurt)
6. Whey and whey products, excluding whey cheeses
   a. Liquid whey and why products
   b. Dried whey and whey products
7. Milk for manufacture
8. Dairy-based frozen desserts (e.g. ice cream)

B. PROCESSED FRUITS, VEGETABLES and EDIBLE FUNGI (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera) seaweeds, and nuts and seeds

1. Dried Fruits and vegetable – plain/ sun-dried (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera) seaweeds, and nuts and seeds
2. Vegetable (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweed, and nut and seed – purees, spreads (e.g. peanut butter)

D. CONFECTIONERY

Chocolate with nuts

F. BAKERY WARES AND BAKERY RELATED PRODUCTS

1. Fine bakery products with fillings: meat, milk, poultry, cream, other perishable foods; icings; and coatings
2. Cookies with nuts

G. PROCESSED MEAT AND MEAT PRODUCTS, INCLUDING POULTRY AND GAME

Processed meat, poultry and game products in whole or cuts

a. Heat-treated processed meat, poultry and game products (canned)
b. Frozen processed meat, poultry and game products (marinated pork/ beef/ chicken cuts)

1. Processed comminuted meat, poultry and game products
   a. Heat-treated processed meat, poultry and game products (canned)
   b. Frozen processed meat, poultry and game products (nuggets, patties, dumplings, salami, meat loaf, hotdog)

H. PROCESSED FISH AND FISH PRODUCTS, INCLUDING MOLLUSCS, CRUSTACEANS AND ECHINODERMS

1. Processed fish and fish products, including molluscs, crustaceans and echinoderms
   a. Frozen fish, fish fillets and fish products, including molluscs, crustaceans and echinoderms
   b. Frozen battered fish, fish fillets and fish products, including molluscs, crustaceans and echinoderms; including value added products (battered, marinated, smoked, spiced, fish and squid balls preparations)
   c. Frozen minced and creamed fish products, including molluscs, crustaceans and echinoderms
   d. Cooked and/or fried fish and fish products, including molluscs, crustaceans and echinoderms
      1) Cooked fish and fish products
      2) Cooked molluscs, crustaceans and echinoderms
      3) Fried fish and fish products, including molluscs, crustaceans and echinoderms
2. Fully preserved, including canned or fermented fish and fish products, including molluscs, crustaceans and echinoderms

I. EGG AND EGG PRODUCTS

Egg products

a. Liquid egg products

b. Frozen egg products (e.g. frozen eggs, frozen egg whites, frozen egg yolks) c. Dried and/or heat coagulated egg products (e.g. dried eggs, dried egg whites, dried egg yolks)
J. FOODSTUFFS INTENDED FOR PARTICULAR NUTRITIONAL USES 1. Infant formula, follow-on formula and formula for special medical purposes for infants 2. Complementary foods for infants and young children 3. Dietetic foods intended for special medical purposes (excluding products under HR Letter J.1) 4. Dietetic formula for slimming purposes and weight reduction 5. Dietetic foods (e.g. supplementary foods for dietary use) excluding products under HR Letter J.1 to 4 and Letter K, Food supplements) 6. Weaning foods for infants and growing children 7. Dietetic foods for special medical purpose 8. Dietetic formulas for weight control
J. BOTTLED WATER
K. FOOD SUPPLEMENT/ HERBAL FOOD/ HERBAL DIETARY SUPPLEMENTS 1. Herbs and botanicals 2. Products with other nutritional substances
L. NOVEL / NEW INNOVATIONS in FOOD New in the international or local market

ANNEX B

AUTHORIZATION LETTER

[COMPANY LETTERHEAD]

(DATE)

(NAME)
Director General
FOOD AND DRUG ADMINISTRATION
Civic Drive, Filinvest Corporate City
Alabang, Muntinlupa City

Attn: **(NAME)**
Director IV
Center for Food Regulation and Research

Sir/Madam:

In accordance with Republic Act No. 9711 and other related issuances, we, _____ (Company Name), with LTO number _____ issued on _____ valid until _____, hereby authorize _____ (Name of Representative) as the account holder for e-registration of processed food products and shall be responsible for all applications submitted through e-registration.

_____
(Owner/General Manager/President)

Subscribed and sworn to me this _____ day of _____ at _____.

_____
NOTARY PUBLIC

Doc No. _____
Page No. _____
Book No. _____
Series of _____

ANNEX C

AFFIDAVIT OF UNDERTAKING

[COMPANY LETTERHEAD]

I, _____ Filipino Citizen, of legal age, with residence address at _____, having been duly sworn to in accordance with the Law, do hereby certify that:

1. I am the President/General Manager of _____, with business address located at _____, a duly registered company with the Food and Drug Administration under LTO Number _____ issued on _____ valid until _____.

2. I hereby appoint and authorize _____, of legal age, residing at _____as the company's Regulatory Officer in replace of _____ whose name appears as representative in the E-Registration System of the Philippine Food and Drug Administration

3. _____ is also hereby authorized to transact in behalf of the company for E-Registration concerns and matter.

Subscribed and sworn to me this _____ day of _____ at _____.

NOTARY PUBLIC

Doc No. _____
Page No. _____
Book No. _____
Series of _____

ANNEX D. REFERENCE GUIDE TO STAKEHOLDERS TO ASSESS COMPLIANCE OF SUBMITTED DOCUMENTS AS COMPLETE REQUIREMENTS FOR PRODUCT REGISTRATION

REQUIRED TECHNICAL INFORMATION ABOUT THE APPLICANT COMPANY AND THE PRODUCT BEING APPLIED WHICH ARE NEEDED TO FILL UP DATA ENTRY (ELECTRONIC APPLICATION FORM)

Application Steps	Data entries to be filled up	Reference Technical Document to Fill Up Data Entry
General Information	Note: Indicate whether the application is initial or renewal. For Renewal/ Amendment Data Capture applications, indicate the following information: Food Registration Number Case Number CPR Issued Date CPR Validity For Reapplication Data Capture applications, indicate the following information: Application Number (Ex. 400000123456)	Previously issued Certificate of Product Registration (CPR)
Food Product Application Form	Food classification and food categorization, Brand name, Product name Note: Category of food products can be found in Annex A of Administrative Order 2014-0029. This is also listed in Food Registration Manual posted in the FDA website.	Product label
	Applicant company details: a. LTO number b. Validity c. Company Name d. Complete Address e. Region f. Company Activity Note: These details should be consistent with the issued LTO	License to Operate (LTO) of applicant company Product label
	Applicant company's contact details:	

General Requirements for all food categorization
All documents submitted must be clear and readable. Non-compliance is ground for Letter of Denial (LOD)

ANNEX D. REFERENCE GUIDE TO STAKEHOLDERS TO ASSESS COMPLIANCE OF SUBMITTED DOCUMENTS AS COMPLETE REQUIREMENTS FOR PRODUCT REGISTRATION

	a. Landline # b. Fax # c. Mobile #	
Complete List of Ingredients	Product's complete list of ingredients in decreasing order of proportion. Note: The list of ingredients should be consistent with declaration on the label.	Product label Product formulation
Establishment information	Applicant company's activity Note: The activity (e.g. wholesaler, trader, distributor) of the applicant should be consistent with the issued LTO.	LTO of applicant company Product label
	Source/s of the product (if imported) a. Country of origin b. Supplier's name and address c. Manufacturer's name and address Note: Details on the name and address of manufacturer and/or supplier in the data entry should be consistent with uploaded documents.	Foreign Agency Agreement or Certificate of Distributorship or Appointment Letter or Proforma Invoice or Memorandum of Agreement Certificate of Registration with GMP Compliance or its equivalent or Valid Sanitary Phyto-Sanitary Certificate or Health Certificate or ISO 22000 Certificate or FSSC Certificate or HACCP Certificate or Certificate of Free Sale.
	Source/s of the product (if sourced locally) a. Supplier's name and address b. Manufacturer's name and address Note: Details on the name and address of manufacturer and/or wholesaler/trader in the data entry should be consistent with issued LTOs of these establishments. The product being applied should be included in FDA's approved list of products in the LTO of the manufacturer.	Notarized Distributorship agreement, Memorandum of Agreement, LTO of manufacturer/ wholesaler/ trader
Product Specifications	Product description Physical parameters Chemical parameters Microbiological parameters Note: Details of the product description should be consistent with the picture of the finished product. A	Product label Finished Product Specifications set by the manufacturer/marketing authorization holder. Certificate of Analysis on physico-chemical and Microbiological parameters of the finished product FDA Circular 2013-010

General Requirements for all food categorization

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ANNEX D. REFERENCE GUIDE TO STAKEHOLDERS TO ASSESS COMPLIANCE OF SUBMITTED DOCUMENTS AS COMPLETE REQUIREMENTS FOR PRODUCT REGISTRATION

	complete product description describing full details of the product should be provided such as form (cube, powder, paste), texture (hard, soft, chewy), shape (round, oblong, square), color (white, brown, black, etc.) and packing medium (in brine, in syrup, in oil, etc.). Test results in the uploaded Certificate of Analysis should conform with physico-chemical and microbiological parameters in the data entry. The microbiological parameters of the product being applied should conform with FDA Circular 2013-010, as applicable.	
Shelf Life and Other Information	Shelf life in months Type of shelf life study conducted Packaging material type/name Note: Shelf life of the product declared in the data entry should be consistent with the conducted shelf life study of the product being applied. The packaging material type/name declared in the data entry should be consistent with the actual packaging as shown in the uploaded pictures of the product.	Shelf life study of the finished product conducted by in-house laboratory or other institutions Picture of the product in commercial presentation
	Description of product as packed in commercial presentation Storage condition Sources of Allergen Lot identification code and interpretation Open date marking	Product label Picture of the product in commercial presentation Food Product Specifications Sheet
	Function of the food material (if Raw material) Note: This should be filled up as it is an important information. Only food grade ingredients and listed food additives which are included in the Updated List of Food Additives should be applied as food raw material. Raw material which is intended as ingredient for drugs or cosmetics or for industrial use shall not be approved as raw material for food.	Food Product Specifications Sheet; Product Information as provided by the manufacturer/supplier
	Usage (if Food Supplement)	Food Product Specifications Sheet Safety data Rationale of the product

General Requirements for all food categorization
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ANNEX D. REFERENCE GUIDE TO STAKEHOLDERS TO ASSESS COMPLIANCE OF SUBMITTED DOCUMENTS AS COMPLETE REQUIREMENTS FOR PRODUCT REGISTRATION

RAW MATERIALS (Locally Manufactured)			
REQUIREMENTS	**FOR APPROVAL**	**GROUNDS FOR DENIAL**	**BASIS**
1.*Clear and complete loose labels or artworks, as applicable, of all packaging sizes, or equivalents as defined by FDA regulations except for bulk raw materials	-Readable -Reflects all sides of packaging -With submitted secondary and/or primary packaging -Reflects product name/code, lot number -Consistent product information in data entry and label/artwork/picture -Complete labels with the proposed packaging sizes	-No submitted complete picture/artwork/label -Unclear/unreadable information on the picture/artwork/label submitted -Inconsistent product information in data entry and label/artwork/picture -Not all labels for proposed packaging sizes are submitted	Administrative Order 2014-0030 Administrative Order 2014-0029 FDA Circular 2016-014
2.Picture of the product in all angles and in different packaging sizes, and from at least two different perspectives allowing visual recognition of a product as the same with the one being registered, as applicable;	-Readable -Consistent to the declared packaging material type in the data entry -Consistent product information in data entry -With submitted secondary and/or primary packaging -Reflects product name/code, lot number	-No submitted picture --Inconsistent product information in data entry and label/artwork/picture -Not all labels for proposed packaging sizes are submitted -Unclear/unreadable information on the picture	Administrative Order 2014-0029 FDA Circular 2016-014
3. Certification to support use of logo/seal on Sangkap Pinoy, Halal, Organic, or Kosher food and in compliance with current labelling regulations.	-Valid Certificates or certification to support use of logo/seal on Sangkap Pinoy, Halal, Organic, or Kosher food, etc. issued by reputable issuing body	-No submitted Certificate -Submitted Certificate is not valid -Submitted Certificate is self-issued	Administrative Order 2014-0029
4. Certificate of Analysis for Locally manufactured SALT/Wheat flour/Cooking Oil/Refined Sugar/Rice product:	-Certificate of Analysis must be signed/verified by QA Analyst/Manager reflecting the specific content of the fortificant used, specific fortificant used, appropriate unit of measurement (ppm, mg/Kg or mcg/g), date of analysis, product description/name, specifications, method of analysis and batch code/ expiry date/ manufacturing date	-No submitted Certificate of Analysis (COA) -Submitted COA does not meet the tolerable level of fortificant used -Submitted COA contains incomplete information	Administrative Order 2014-0029 FDA Circular 2016-014 Republic Act 8976 Republic Act 8172

General Requirements for all food categorization
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ANNEX D. REFERENCE GUIDE TO STAKEHOLDERS TO ASSESS COMPLIANCE OF SUBMITTED DOCUMENTS AS COMPLETE REQUIREMENTS FOR PRODUCT REGISTRATION

RAW MATERIALS
(Locally Manufactured)

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<tr><td>4. cont.</td><td>
<table>
<tr><th>Product</th><th>Approved Fortificant</th><th>Tolerable level of Fortificant</th></tr>
<tr><td>Salt</td><td>Potassium iodide/ iodate</td><td>30 - 70 mg/kg</td></tr>
<tr><td rowspan="3">Wheat Flour</td><td>Retinol palmitate/acetate</td><td>3.0 - 6.5 mg/kg</td></tr>
<tr><td>Elemental iron or</td><td>70 - 105 mg Fe/kg</td></tr>
<tr><td>Ferrous sulfate/ fumarate</td><td>50 - 75 mg Fe/kg</td></tr>
<tr><td>Cooking Oil (palm oil, corn oil, coconut oil and soy oil)</td><td>Retinol palmitate</td><td>12 - 23 mg Re/L</td></tr>
<tr><td>Refined Sugar</td><td>Retinol palmitate</td><td>5 - 30 mg/kg</td></tr>
<tr><td>All Rice except brown rice and locally produced glutinous rice</td><td>Ferrous sulfate</td><td>60 - 90 mg Fe/kg raw rice</td></tr>
</table>
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<tr><td>4. cont.</td><td>For Locally manufactured Soy Sauce product:
-Certificate of Analysis must be signed/verified by QA Analyst/Manager reflecting the specific 3-MCPD content (</= to 0.4 ppm), appropriate unit of measurement (ppm, mg/Kg or mcg/g), date of analysis, product description/name, specifications, method of analysis and batch code/ expiry date/ manufacturing date</td><td>-No submitted COA
-Submitted COA does not meet the tolerable level of 3-MCPD
-Submitted COA contains incomplete information</td><td>FDA Memorandum 2011-028</td></tr>
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ANNEX D. REFERENCE GUIDE TO STAKEHOLDERS TO ASSESS COMPLIANCE OF SUBMITTED DOCUMENTS AS COMPLETE REQUIREMENTS FOR PRODUCT REGISTRATION

5. *Source documents			
a. For Locally produced products, Certificate of Distributorship or Appointment letter or Memorandum of Agreement from each supplier	For Wholesaler: -Valid, notarized and duly signed Distributorship agreement or Memorandum of Agreement -Applicant company's and Supplier's Name and Address are reflected on the Distributorship Agreement or Memorandum of Agreement -In case products are listed on the agreement, then the product being applied should be included in the list	For Wholesaler: -No submitted Distributorship agreement or Memorandum of Agreement -Not duly signed, invalid, and/or not notarized Distributorship agreement or Memorandum of Agreement -Applicant company's and/or Supplier's Name and Address is/are NOT reflected on the Distributorship agreement or Memorandum of Agreement - The product being applied is NOT included in the list of products as indicated in the agreement of products	FDA Circular 2016-007
5.a. cont.	For Trader: -Valid, notarized and duly signed Toll Manufacturing agreement -Trader's and Toll Manufacturer's Name and Address are reflected on the Toll Manufacturing agreement -In case products are listed on the agreement, then the product being applied should be included in the list	For Trader: -No submitted Toll Manufacturing agreement -Not duly signed, invalid, and/or not notarized Toll Manufacturing agreement -Applicant company's and/or Supplier's Name and Address is/are NOT reflected on the Toll Manufacturing agreement - The product being applied is NOT included in the list of products as indicated in the agreement of products	FDA Circular 2016-007
6.*Valid LTO	For Manufacturer: -Valid LTO as Food Manufacturer -Product being applied is listed in FDA approved Product Line/ category -Consistent Company information in the data entry and on the LTO	For Manufacturer: -Expired and Non-renewal of LTO as Food Manufacturer -Product being applied is NOT listed in FDA approved Product Line/ category -Inconsistent Company information in the data entry and on the issued LTO	FDA Circular 2016-007 Administrative Order 2014-0029
	For Wholesaler/Trader: -Valid LTO as Food Importer/Distributor/Wholesaler and/or Food Wholesaler and/or Food Trader -Consistent Company information in the data entry and on the LTO	For Wholesaler/Trader: -Expired and Non-renewal LTO as Food Distributor/Wholesaler and/or Food Wholesaler and/or Food Trader -Inconsistent Company information in the data entry and on the issued LTO	

General Requirements for all food categorization
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ANNEX D. REFERENCE GUIDE TO STAKEHOLDERS TO ASSESS COMPLIANCE OF SUBMITTED DOCUMENTS AS COMPLETE REQUIREMENTS FOR PRODUCT REGISTRATION

Note: Please make sure that all compliant and complete labels and supporting documents are uploaded for every product application before continuing the application to Pre-Assessment. The Case Number will close upon assessment of initial (or data capture) applications having INCOMPLETE submission of documentary requirements. If the pre-assessment is disapproved, you will need to upload again ALL previous and current documents using a new case number.

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RAW MATERIALS (Imported)			
REQUIREMENTS	**FOR APPROVAL**	**GROUNDS FOR DENIAL**	**BASIS**
1. *Clear and complete loose labels or artworks, as applicable, of all packaging sizes, or equivalents as defined by FDA regulations except for bulk raw materials	-Readable -Reflects all sides of packaging -With submitted secondary and/or primary packaging -Reflects product name/code, lot number -Consistent product information in data entry and label/artwork/picture -Complete labels with the proposed packaging sizes	-No submitted complete picture/artwork/label -Unclear/unreadable information on the picture/artwork/label submitted -Inconsistent product information in data entry and label/artwork/picture -Not all labels for proposed packaging sizes are submitted	Administrative Order 2014-0030 Administrative Order 2014-0029 FDA Circular 2016-014
2. Picture of the product in all angles and in different packaging sizes, and from at least two different perspectives allowing visual recognition of a product as the same with the one being registered, as applicable;	-Readable -Consistent to the declared packaging material type in the data entry -Consistent product information in data entry -With submitted secondary and/or primary packaging -Reflects product name/code, lot number	-No submitted picture --Inconsistent product information in data entry and label/artwork/picture -Not all labels for proposed packaging sizes are submitted -Unclear/unreadable information on the picture	Administrative Order 2014-0029 FDA Circular 2016-014
3. Certification to support use of logo/seal on Sangkap Pinoy, Halal, Organic, or Kosher food and in compliance with current labelling regulations.	-Valid Certificates or certification to support use of logo/seal on Sangkap Pinoy, Halal, Organic, or Kosher food, etc. issued by reputable issuing body	-No submitted Certificate -Submitted Certificate is not valid -Submitted Certificate is self-issued	Administrative Order 2014-0029
4. Certificate of Analysis for Imported SALT/Wheat flour/Cooking Oil/Refined Sugar/Rice product:	-Certificate of Analysis must be signed/verified by QA Analyst/Manager reflecting the specific content of the fortificant used, specific fortificant used, appropriate unit of measurement (ppm, mg/Kg or mcg/g), date of analysis, product description/name, specifications, method of analysis and batch code/ expiry date/ manufacturing date	-No submitted Certificate of Analysis (COA) -Submitted COA does not meet the tolerable level of fortificant used -Submitted COA contains incomplete information	Administrative Order 2014-0029 FDA Circular 2016-014 Republic Act 8976 Republic Act 8172

General Requirements for all food categorization
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ANNEX D. REFERENCE GUIDE TO STAKEHOLDERS TO ASSESS COMPLIANCE OF SUBMITTED DOCUMENTS AS COMPLETE REQUIREMENTS FOR PRODUCT REGISTRATION

RAW MATERIALS
(Imported)

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-Certificate of Analysis must be signed/verified by QA Analyst/Manager reflecting the specific 3-MCPD content (</= to 0.4 ppm), appropriate unit of measurement (ppm, mg/Kg or mcg/g), date of analysis, product description/name, specifications, method of analysis and batch code/ expiry date/ manufacturing date</td><td>-No submitted COA
-Submitted COA does not meet the tolerable level of 3-MCPD
-Submitted COA contains incomplete information</td><td>FDA Memorandum 2011-028</td></tr>
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General Requirements for all food categorization
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ANNEX D. REFERENCE GUIDE TO STAKEHOLDERS TO ASSESS COMPLIANCE OF SUBMITTED DOCUMENTS AS COMPLETE REQUIREMENTS FOR PRODUCT REGISTRATION

5. *Source documents			
a. For Imported products, Foreign Agency Agreement or Certificate of Distributorship or Appointment letter or Proforma Invoice or Memorandum of Agreement from each supplier	For Importer: -Valid, notarized and duly signed Distributorship agreement or Foreign Agency Agreement -Duly signed Certificate of Distributorship or Appointment letter or Memorandum of Agreement -Product being applied for registration is listed on the Proforma invoice -Applicant company's and Supplier's Name and Address are reflected on the Foreign Agency Agreement or Certificate of Distributorship or Appointment letter or Proforma Invoice or Memorandum of Agreement -In case products are listed on the agreement, then the product being applied should be included in the list	For Importer: -No submitted Foreign Agency Agreement or Certificate of Distributorship or Appointment letter or Proforma Invoice or Memorandum of Agreement from each supplier -Not duly signed, invalid and/or not notarized Distributorship agreement or Foreign Agency Agreement -Not duly signed Certificate of Distributorship or Appointment letter or Memorandum of Agreement -Product being applied for registration is NOT listed on the Proforma invoice -Applicant company's and/or Supplier's Name and Address is/are NOT reflected on the Foreign Agency Agreement or Certificate of Distributorship or Appointment letter or Proforma Invoice or Memorandum of Agreement -The product being applied is NOT included in the list of products as indicated in the agreement of products	FDA Circular 2016-007

General Requirements for all food categorization
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ANNEX D. REFERENCE GUIDE TO STAKEHOLDERS TO ASSESS COMPLIANCE OF SUBMITTED DOCUMENTS AS COMPLETE REQUIREMENTS FOR PRODUCT REGISTRATION

b. For Imported products, Certificate of Registration with GMP Compliance or its equivalent or Valid Sanitary Phyto-Sanitary Certificate or Health Certificate or ISO 22000 Certificate or FSSC Certificate or HACCP Certificate or Certificate of Free Sale issued by the Regulatory/ Health Authority/ Attested by recognized Association or duly authenticated by the Philippine Consulate from the country of origin	-Scanned Copy of the Original and Valid Certificate of Registration with GMP Compliance or its equivalent or Valid Sanitary Phyto-Sanitary Certificate or Health Certificate or ISO 22000 Certificate or FSSC Certificate or HACCP Certificate or Certificate of Free Sale; or -Scanned Copy of the Original and Valid Sanitary Phyto-Sanitary Certificate or Health Certificate or Certificate of Free Sale issued by Competent Regulatory/ Health Authority or if issued by Chamber of Commerce or Attested by recognized Association, authentication from the Philippine Consulate or with affixed Apostille from the country of origin must be submitted (from Manufacturer or Supplier); or -Scanned Copy of the Original and Valid GMP Compliance or its equivalent or ISO 22000 Certificate or FSSC Certificate or HACCP Certificate issued by competent Regulatory Authority or Recognized Issuing body (issued to Manufacturer) Note: The Certificate of Free Sale must declare that the product is fit for human consumption and/or is freely sold from the country of origin (see AO and BC on CFS)	-No submitted Certificate of Registration with GMP Compliance or its equivalent or Valid Sanitary Phyto-Sanitary Certificate or Health Certificate or ISO 22000 Certificate or FSSC Certificate or HACCP Certificate or Certificate of Free Sale issued by the Regulatory/ Health Authority/ Attested by recognized Association or duly authenticated by the Philippine Consulate from the country of origin -Expired Certificate of Registration with GMP Compliance or its equivalent or Sanitary Phyto-Sanitary Certificate or Health Certificate or ISO 22000 Certificate or FSSC Certificate or HACCP Certificate or Certificate of Free Sale -Certificate of Free Sale is self-issued or NOT issued by the Regulatory/ Health Authority/ Attested by recognized Association or duly authenticated by the Philippine Consulate or without affixed Apostille from the country of origin (from Manufacturer or Supplier) -Scanned copy of photocopy of Documents stated on the list of requirements stated in FDA Circular 2016-007 -Submission of documents not stated in FDA Circular 2016-007 (ISO 9001 Certificate and/or ISO 14001 Certificate) -The submitted Certificate of Free Sale does not declare that the product is fit for human consumption or freely sold in the country importing.	FDA Circular 2016-007

General Requirements for all food categorization
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ANNEX D. REFERENCE GUIDE TO STAKEHOLDERS TO ASSESS COMPLIANCE OF SUBMITTED DOCUMENTS AS COMPLETE REQUIREMENTS FOR PRODUCT REGISTRATION

6. *Valid LTO	For Importer/Distributor: -Valid LTO as Food Importer and/or Food Importer/Distributor -Consistent Company information in the data entry and on the LTO	For Importer/Distributor: -Expired and Non-renewal LTO as Food Importer and/or Food Importer/Distributor -Inconsistent Company information in the data entry and on the issued LTO	FDA Circular 2016-007 Administrative Order 2014-0029
Note: Please make sure that all compliant and complete labels and supporting documents are uploaded for every product application before continuing the application to Pre-Assessment. The Case Number will close upon assessment of initial (or data capture) applications having INCOMPLETE submission of documentary requirements. If the pre-assessment is disapproved, you will need to upload again ALL previous and current documents using a new case number.			

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ANNEX D. REFERENCE GUIDE TO STAKEHOLDERS TO ASSESS COMPLIANCE OF SUBMITTED DOCUMENTS AS COMPLETE REQUIREMENTS FOR PRODUCT REGISTRATION

LOW RISK FOOD PRODUCTS
(Locally Manufactured)

<table>
<tr><th>REQUIREMENTS</th><th>FOR APPROVAL</th><th>GROUNDS FOR DENIAL</th><th>BASIS</th></tr>
<tr><td>1. *Clear and complete loose labels or artworks, as applicable, of all packaging sizes, or equivalents as defined by FDA regulations except for bulk raw materials</td><td>-Readable
-Reflects all sides of packaging
-With submitted secondary and/or primary packaging
-Reflects product name/code, lot number
-Consistent product information in data entry and label/artwork/picture
-Complete labels with the proposed packaging sizes</td><td>-No submitted complete picture/artwork/label
-Unclear/unreadable information on the picture/artwork/label submitted
-Inconsistent product information in data entry and label/artwork/picture
-Not all labels for proposed packaging sizes are submitted</td><td>Administrative Order 2014-0030
Administrative Order 2014-0029
FDA Circular 2016-014</td></tr>
<tr><td>2.*Picture of the product in all angles and in different packaging sizes, and from at least two different perspectives allowing visual recognition of a product as the same with the one being registered, as applicable;</td><td>-Readable
-Consistent to the declared packaging material type in the data entry
-Consistent product information in data entry
-With submitted secondary and/or primary packaging</td><td>-No submitted picture
-Inconsistent product information in data entry and label/artwork/picture
-Not all labels for proposed packaging sizes are submitted
-Unclear/unreadable information on the picture</td><td>Administrative Order 2014-0029
FDA Circular 2016-014</td></tr>
<tr><td>3. As applicable, documents to substantiate claims, but not limited to, such as technical, nutritional or health studies or reports, market-research studies, Certificate of Analysis to confirm compliance to R.A. 8976, R.A. 8172, F.M. 2011-028, quantitative analysis and computations, scientific report or studies published in peer-reviewed scientific journals, certificates or certification to support use of logo/seal on Sangkap Pinoy, Halal, Organic, or Kosher food and in compliance with current labelling regulations.</td><td>For Imported and Locally manufactured SALT/Wheat flour/Cooking Oil/Refined Sugar/Rice product:
-Certificate of Analysis must be signed/verified by QA Analyst/Manager reflecting the specific content of the fortificant used, specific fortificant used, appropriate unit of measurement (ppm, mg/Kg or mcg/g), date of analysis, product description/name, specifications, method of analysis and batch code/ expiry date/ manufacturing date
<table>
<tr><th>Product</th><th>Approved Fortificant</th><th>Tolerable level of Fortificant</th></tr>
<tr><td>Salt</td><td>Potassium iodide/ iodate</td><td>30 - 70 mg/kg</td></tr>
<tr><td rowspan="3">Wheat Flour</td><td>Retinol palmitate/acetate</td><td>3.0 - 6.5 mg/kg</td></tr>
<tr><td>Elemental iron or</td><td>70 - 105 mg Fe/kg</td></tr>
<tr><td>Ferrous sulfate/ fumarate</td><td>50 - 75 mg Fe/kg</td></tr>
<tr><td>Cooking Oil (palm oil, corn oil, coconut oil and soy oil)</td><td>Retinol palmitate</td><td>12 - 23 mg Re/L</td></tr>
<tr><td>Refined Sugar</td><td>Retinol palmitate</td><td>5 - 30 mg/kg</td></tr>
<tr><td>All Rice except brown rice and locally produced glutinous rice</td><td>Ferrous sulfate</td><td>60 - 90 mg Fe/kg raw rice</td></tr>
</table></td><td>-No submitted COA
-Submitted COA does not meet the tolerable level of fortificant used
-Submitted COA contains incomplete information</td><td>Administrative Order 2014-0029
FDA Circular 2016-014
Republic Act 8976
Republic Act 8172</td></tr>
</table>

General Requirements for all food categorization

All documents submitted must be clear and readable. Non-compliance is ground for Letter of Denial (LOD)

ANNEX D. REFERENCE GUIDE TO STAKEHOLDERS TO ASSESS COMPLIANCE OF SUBMITTED DOCUMENTS AS COMPLETE REQUIREMENTS FOR PRODUCT REGISTRATION

LOW RISK FOOD PRODUCTS (Locally Manufactured)			
REQUIREMENTS	**FOR APPROVAL**	**GROUNDS FOR DENIAL**	**BASIS**
3. *cont.*	For Locally manufactured Soy Sauce product: -Certificate of Analysis must be signed/verified by QA Analyst/Manager reflecting the specific 3-MCPD content (</= to 0.4 ppm), appropriate unit of measurement (ppm, mg/Kg or mcg/g), date of analysis, product description/name, specifications, method of analysis and batch code/ expiry date/ manufacturing date	-No submitted COA -Submitted COA does not meet the tolerable level of 3-MCPD -Submitted COA contains incomplete information	FDA Memorandum 2011-028
	-Valid Certificates or certification to support use of logo/seal on Sangkap Pinoy, Halal, Organic, or Kosher food, etc. issued by reputable issuing body	-No submitted Certificate -Submitted Certificate is not valid -Submitted Certificate is self-issued	Administrative Order 2014-0030
	-Nutrition and Health claims that conform to BC 2007-002	-Non-conformance of Nutrition and Health claims to BC 2007-002	BC 2007-002
	-Conformance of Micronutrient Fortification of Processed Foods to AO 4-A s. 1995	-Non-conformance of Micronutrient Fortification of Processed Foods to AO 4-A s. 1995	Administrative Order 4-A s, 1995

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ANNEX D. REFERENCE GUIDE TO STAKEHOLDERS TO ASSESS COMPLIANCE OF SUBMITTED DOCUMENTS AS COMPLETE REQUIREMENTS FOR PRODUCT REGISTRATION

LOW RISK FOOD PRODUCTS (Locally Manufactured)			
REQUIREMENTS	**FOR APPROVAL**	**GROUNDS FOR DENIAL**	**BASIS**
4. Source Documents a. For locally produced products, Certificate of Distributorship or Appointment letter or Memorandum of Agreement from each supplier	For Wholesaler: -Valid, notarized and duly signed Distributorship agreement or Memorandum of Agreement -Applicant company's and Supplier's Name and Address are reflected on the Distributorship Agreement or Memorandum of Agreement -In case products are listed on the agreement, then the product being applied should be included in the list -Name and address of distributor should be consistent in data entry and submitted Distributorship Agreement or Memorandum of Agreement.	For Wholesaler: -No submitted Distributorship agreement or Memorandum of Agreement -Not duly signed, invalid, and/or not notarized Distributorship agreement or Memorandum of Agreement -Applicant company's and/or Supplier's Name and Address is/are NOT reflected on the Distributorship agreement or Memorandum of Agreement -In case products are listed on the agreement, the product being applied is NOT included in the list	FDA Circular 2016-007
	For Trader: -Valid, notarized and duly signed Toll Manufacturing agreement -Trader's and Toll Manufacturer's Name and Address are reflected on the Toll Manufacturing agreement -In case products are listed on the agreement, then the product being applied should be included in the list -Name and address of Toll Manufacturer should be consistent in data entry and submitted Toll Manufacturing agreement	For Trader: -No submitted Toll Manufacturing agreement -Not duly signed, invalid, and/or not notarized Toll Manufacturing agreement -Applicant company's and/or Supplier's Name and Address is/are NOT reflected on theToll Manufacturing agreement -In case products are listed on the agreement, the product being applied is NOT included in the list	FDA Circular 2016-007

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LOW RISK FOOD PRODUCTS (Locally Manufactured)			
REQUIREMENTS	**FOR APPROVAL**	**GROUNDS FOR DENIAL**	**BASIS**
5. *Valid LTO	For Manufacturer: -Valid LTO as Food Manufacturer -Product being applied is listed in FDA approved Product Line/ category -Consistent Company information in the data entry and on the LTO	For Manufacturer: -Expired and Non-renewal of LTO as Food Manufacturer -Product being applied is NOT listed in FDA approved Product Line/ category -Inconsistent Company information in the data entry and on the LTO	FDA Circular 2016-007 Administrative Order 2014-0029
	For Wholesaler/Trader: -Valid LTO as Food Importer/Distributor/Wholesaler and/or Food Wholesaler and/or Food Trader -Consistent Company information in the data entry and on the LTO	For Wholesaler/Trader: -Expired and Non-renewal LTO as Food Importer/Distributor/Wholesaler and/or Food Wholesaler and/or Food Trader -Inconsistent Company information in the data entry and on the LTO	

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LOW RISK FOOD PRODUCTS
(Locally Manufactured)

REQUIREMENTS	FOR APPROVAL	GROUNDS FOR DENIAL	BASIS
6. *Label requirements	Compliant with Administrative Order 2014-0030, Bureau Circular 2007-002, Bureau Circular 2 s. 1999, Department Circular 2008-0006 and RIRR of Executive Order 51 (as applicable): -Brand Name -Product Name -Net Weight and/or Drained Weight -Complete name and address of Manufacturer, Wholesaler or Trader as per LTO -Complete List of Ingredients (including common name and function of all food additives used which are listed in Updated List of Food Additives) -Nutrition Information (Energy, Protein, Carbohydrates, Sugar, Total fat, Saturated fat, Trans fat, Cholesterol, Dietary fiber and Sodium) and For Locally manufactured products: RENI values of nutrients based on RENI 2002 -Expiration date/use by date/consume before date (in prescribed format, eg. dd/mmm/yyyy) -Lot Identification Code -Food Allergen Information (As applicable) -Direction for use (As applicable) -Storage Instructions (As applicable) -"Serving Suggestion" (As applicable) -Alcohol content as applicable (For Alcoholic Beverages) -"Flavor Added" in close proximity to the photograph - if flavoring substances have been added to boost the natural flavor	Not limited to: -Submitted label is inconsistent with the product being applied -Use of brand name which is identical to a previously registered food product under a different company without authorization by the same brand owner. -No declared Brand Name -Use of brand name which is misleading, deceptive, confusing, or is likely to create erroneous impression regarding its character or nature in any respect. -Product name does not state the true nature of the product or misleading, confusing or is likely to create erroneous impression regarding its character or nature in any respect -Inconsistent declaration of the manufacturer's name and/or address on the label and data entry -Inconsistent declaration of ingredient on the label and data entry -Inconsistent declaration of the order of ingredients in the data entry and label -No declared list of ingredients -Specific components of multi-component ingredients are not specified -Use of Food Additives which are not included in the Approved List of Food Additives -Use of food additives with different function from the ones declared in Updated List of Food Additives. -Specific name of food additives used are not specified -Inconsistent declaration of the company activity on the label and on the LTO and/or in the data entry under establishment information	Administrative Order 2014-0030

Note: Please make sure that all compliant and complete labels and supporting documents are uploaded for every product application before continuing the application to Pre-Assessment. The Case Number will close upon assessment of initial (or data capture) applications having INCOMPLETE submission of documentary requirements. If the pre-assessment is disapproved, you will need to upload again ALL previous and current documents using a new case number.

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ANNEX D. REFERENCE GUIDE TO STAKEHOLDERS TO ASSESS COMPLIANCE OF SUBMITTED DOCUMENTS AS COMPLETE REQUIREMENTS FOR PRODUCT REGISTRATION

LOW RISK FOOD PRODUCTS
(Imported)

<table>
<tr><th>REQUIREMENTS</th><th>FOR APPROVAL</th><th>GROUNDS FOR DENIAL</th><th>BASIS</th></tr>
<tr><td>1. *Clear and complete loose labels or artworks, as applicable, of all packaging sizes, or equivalents as defined by FDA regulations except for bulk raw materials</td><td>-Readable
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FDA Circular 2016-014</td></tr>
<tr><td>3. As applicable, documents to substantiate claims, but not limited to, such as technical, nutritional or health studies or reports, market-research studies, Certificate of Analysis to confirm compliance to R.A. 8976, R.A. 8172, F.M. 2011-028, quantitative analysis and computations, scientific report or studies published in peer-reviewed scientific journals, certificates or certification to support use of logo/seal on Sangkap Pinoy, Halal, Organic, or Kosher food and in compliance with current labelling regulations.</td><td>For Imported and Locally manufactured SALT/Wheat flour/Cooking Oil/Refined Sugar/Rice product:
-Certificate of Analysis must be signed/verified by QA Analyst/Manager reflecting the specific content of the fortificant used, specific fortificant used, appropriate unit of measurement (ppm, mg/Kg or mcg/g), date of analysis, product description/name, specifications, method of analysis and batch code/ expiry date/ manufacturing date
<table>
<tr><th>Product</th><th>Approved Fortificant</th><th>Tolerable level of Fortificant</th></tr>
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LOW RISK FOOD PRODUCTS (Imported)			
REQUIREMENTS	**FOR APPROVAL**	**GROUNDS FOR DENIAL**	**BASIS**
3. *cont.*	For Imported Sauce product: -Certificate of Analysis must be signed/verified by QA Analyst/Manager reflecting the specific 3-MCPD content (</= to 0.4 ppm), appropriate unit of measurement (ppm, mg/Kg or mcg/g), date of analysis, product description/name, specifications, method of analysis and batch code/ expiry date/ manufacturing date	-No submitted COA -Submitted COA does not meet the tolerable level of 3-MCPD -Submitted COA contains incomplete information	FDA Memorandum 2011-028
	-Valid Certificates or certification to support use of logo/seal on Sangkap Pinoy, Halal, Organic, or Kosher food, etc. issued by reputable issuing body	-No submitted Certificate -Submitted Certificate is not valid -Submitted Certificate is self-issued	Administrative Order 2014-0030
	-Nutrition and Health claims that conform to BC 2007-002	-Non-conformance of Nutrition and Health claims to BC 2007-002	BC 2007-002
	-Conformance of Micronutrient Fortification of Processed Foods to AO 4-A s. 1995	-Non-conformance of Micronutrient Fortification of Processed Foods to AO 4-A s. 1995	Administrative Order 4-A s, 1995
4.*Source Documents a. For Imported products, Foreign Agency Agreement or Certificate of Distributorship or Appointment letter or Proforma Invoice or Memorandum of Agreement from each supplier	For Importer: -Valid, notarized and duly signed Distributorship agreement or Foreign Agency Agreement or Memorandum of Agreement -Product being applied for registration is listed on the Proforma invoice -Applicant company's and Supplier's Name and Address are reflected on the Foreign Agency Agreement or Certificate of Distributorship or Appointment letter or Proforma Invoice or Memorandum of Agreement -In case products are listed on the agreement, then the product being applied should be included in the list - Name and address of supplier should be consistent in data entry and submitted Foreign Agency Agreement or Certificate of Distributorship or Appointment letter or Proforma Invoice or Memorandum of Agreement	For Importer: -No submitted Foreign Agency Agreement or Certificate of Distributorship or Appointment letter or Proforma Invoice or Memorandum of Agreement from each supplier -Not duly signed, invalid and/or not notarized Distributorship agreement or Foreign Agency Agreement -Not duly signed Certificate of Distributorship or Appointment letter or Memorandum of Agreement -Product being applied for registration is NOT listed on the Proforma invoice -Applicant company's and/or Supplier's Name and Address is/are NOT reflected on the Foreign Agency Agreement or Certificate of Distributorship or Appointment letter or Proforma Invoice or Memorandum of Agreement -In case products are listed on the agreement, the product being applied is NOT included in the list	FDA Circular 2016-007

General Requirements for all food categorization

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LOW RISK FOOD PRODUCTS (Imported)			
REQUIREMENTS	**FOR APPROVAL**	**GROUNDS FOR DENIAL**	**BASIS**
b. For Imported products, Certificate of Registration with GMP Compliance or its equivalent or Valid Sanitary Phyto-Sanitary Certificate or Health Certificate or ISO 22000 Certificate or FSSC Certificate or HACCP Certificate or Certificate of Free Sale issued by the Regulatory/ Health Authority/ Attested by recognized Association or duly authenticated by the Philippine Consulate from the country of origin	-Scanned Copy of the Original and Valid Certificate of Registration with GMP Compliance or its equivalent or Valid Sanitary Phyto-Sanitary Certificate or Health Certificate or ISO 22000 Certificate or FSSC Certificate or HACCP Certificate or Certificate of Free Sale; or -Scanned Copy of the Original and Valid Sanitary Phyto-Sanitary Certificate or Health Certificate or Certificate of Free Sale issued by Competent Regulatory/ Health Authority or if issued by Chamber of Commerce or Attested by recognized Association, authentication from the Philippine Consulate or with affixed Apostille from the country of origin must be submitted (from Manufacturer or Supplier); or -Scanned Copy of the Original and Valid GMP Compliance or its equivalent or ISO 22000 Certificate or FSSC Certificate or HACCP Certificate issued by competent Regulatory Authority or Recognized Issuing body (issued to Manufacturer) Note: The Certificate of Free Sale must declare that the product is fit for human consumption and/or is freely sold from the country of origin (see AO and BC on CFS)	-No submitted Certificate of Registration with GMP Compliance or its equivalent or Valid Sanitary Phyto-Sanitary Certificate or Health Certificate or ISO 22000 Certificate or FSSC Certificate or HACCP Certificate or Certificate of Free Sale issued by the Regulatory/ Health Authority/ Attested by recognized Association or duly authenticated by the Philippine Consulate from the country of origin -Expired Certificate of Registration with GMP Compliance or its equivalent or Sanitary Phyto-Sanitary Certificate or Health Certificate or ISO 22000 Certificate or FSSC Certificate or HACCP Certificate or Certificate of Free Sale -Certificate of Free Sale is self-issued or NOT issued by the Regulatory/ Health Authority/ or not attested by recognized Association or duly authenticated by the Philippine Consulate or without affixed Apostille from the country of origin (from Manufacturer or Supplier) -Scanned copy of photocopy of documents stated on the list of requirements stated in FDA Circular 2016-007 are submitted and not scanned copies of the original documents -Submission of documents not stated in FDA Circular 2016-007 (ISO 9001 Certificate and/or ISO 14001 Certificate) -The submitted Certificate of Free Sale does not declare that the product is fit for human consumption or freely sold in the country of origin/supplier (see AO and BC on CFS).	FDA Circular 2016-007

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LOW RISK FOOD PRODUCTS (Imported)			
REQUIREMENTS	**FOR APPROVAL**	**GROUNDS FOR DENIAL**	**BASIS**
4. c. *cont.*	-Name and address of manufacturer should be consistent in data entry and submitted Scanned Copy of the Original and Valid Certificate of Registration with GMP Compliance or its equivalent or Valid Sanitary Phyto-Sanitary Certificate or Health Certificate or ISO 22000 Certificate or FSSC Certificate or HACCP Certificate or Certificate of Free Sale. In case the address of the submitted documents is different from the address on the data entry, clarification in writing that the product is directly sourced from the same company with different head office and plant addresses.		FDA Circular 2016-007
5.* Valid LTO	For Importer/Distributor: -Valid LTO as Food Importer/Distributor and/or Food Importer/Distributor/Wholesaler -Consistent Company information in the data entry and on the LTO	For Importer/Distributor: -Expired and Non-renewal LTO as Food Importer/Distributor and/or Food Importer/Distributor/Wholesaler -Inconsistent Company information in the data entry and on the LTO	FDA Circular 2016-007 Administrative Order No. 2014-0029
6. *Label requirements	Compliant with Administrative Order 2014-0030, Bureau Circular 2007-002, Bureau Circular 2 s. 1999, Department Circular 2008-0006 and RIRR of Executive Order 51 (as applicable): -Brand Name -Product Name -Net Weight and/or Drained Weight -Complete name and address of Importer/ Distributor as per LTO -Country of Origin (If Imported) -Complete List of Ingredients (including common name and function of all food additives used which are listed in Updated List of Food Additives) -Nutrition Information (Energy, Protein, Carbohydrates, Sugar, Total fat, Saturated fat, Trans fat, Cholesterol, Dietary fiber and Sodium) -Expiration date/use by date/consume before date (in prescribed format, eg. dd/mmm/yyyy) -Lot Identification Code	Not limited to: -Submitted label is inconsistent with the product being applied -Use of brand name which is identical to a previously registered food product under a different company without authorization by the same brand owner. -No declared Brand Name -Use of brand name which is misleading, deceptive, confusing, or is likely to create erroneous impression regarding its character or nature in any respect. -Product name does not state the true nature of the product or misleading, confusing or is likely to create erroneous impression regarding its character or nature in any respect -Inconsistent declaration of the manufacturer's name and/or address on the label and data entry -Inconsistent declaration of ingredient on the label and data entry -Inconsistent declaration of the order of ingredients in the	Administrative Order 2014-0030

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LOW RISK FOOD PRODUCTS (Imported)			
REQUIREMENTS	**FOR APPROVAL**	**GROUNDS FOR DENIAL**	**BASIS**
	-Food Allergen Information (As applicable) -Direction for use (As applicable) -Storage Instructions (As applicable) -"Serving Suggestion" (As applicable) -Alcohol content as applicable (For Alcoholic Beverages) -"Flavor Added" in close proximity to the photograph - if flavoring substances have been added to boost the natural flavor -Corresponding English Translation of ALL label information (If Imported)	data entry and label -No declared list of ingredients -Specific components of multi-component ingredients are not specified -Use of Food Additives which are not included in the Approved List of Food Additives -Use of food additives with different function from the ones declared in Updated List of Food Additives. -Specific name of food additives used are not specified -No English translation submitted and/or English translation is declared separately from the label -Inconsistent declaration of the company activity on the label and on the LTO and/or in the data entry under establishment information -Inconsistent declaration of country of origin on the label and in the data entry	
Note: Please make sure that all compliant and complete labels and supporting documents are uploaded for every product application before continuing the application to Pre-Assessment. The Case Number will close upon assessment of initial (or data capture) applications having INCOMPLETE submission of documentary requirements. If the pre-assessment is disapproved, you will need to upload again ALL previous and current documents using a new case number.			

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MEDIUM RISK FOOD PRODUCTS (Locally Manufactured)			
REQUIREMENTS	**FOR APPROVAL**	**GROUNDS FOR DENIAL**	**BASIS**
1. *Clear and complete loose labels or artworks, as applicable, of all packaging sizes, or equivalents as defined by FDA regulations except for bulk raw materials	-Readable -Reflects all sides of packaging -With submitted secondary and/or primary packaging -Reflects product name/code, lot number -Consistent product information in data entry and label/artwork/picture -Complete labels with the proposed packaging sizes	-No submitted complete picture/artwork/label -Unclear/unreadable information on the picture/artwork/label submitted -Inconsistent product information in data entry and label/artwork/picture -Not all labels for proposed packaging sizes are submitted	Administrative Order 2014-0030 Administrative Order 2014-0029 FDA Circular 2016-014
2. Picture of the product in all angles and in different packaging sizes, and from at least two different perspectives allowing visual recognition of a product as the same with the one being registered, as applicable;	-Readable -Consistent to the declared packaging material type in the data entry -Consistent product information in data entry -With submitted secondary and/or primary packaging	-No submitted picture -Inconsistent product information in data entry and label/artwork/picture -Not all labels for proposed packaging sizes are submitted -Unclear/unreadable information on the picture	Administrative Order 2014-0029 FDA Circular 2016-014
3. As applicable, documents to substantiate claims, but not limited to, such as technical, nutritional or health studies or reports, market-research studies, Certificate of Analysis to confirm compliance to R.A. 8976, R.A. 8172, F.M. 2011-028, quantitative analysis and computations, scientific report or studies published in peer-reviewed scientific journals, certificates or certification to support use of logo/seal on Sangkap Pinoy, Halal, Organic, or Kosher food and in compliance with current labelling regulations.	-Valid Certificates or certification to support use of logo/seal on Sangkap Pinoy, Halal, Organic, or Kosher food, etc. issued by reputable issuing body	-No submitted Certificate -Submitted Certificate is not valid -Submitted Certificate is self-issued	Administrative Order 2014-0030
	-Nutrition and Health claims that conform to BC 2007-002	-Non-conformance of Nutrition and Health claims to BC 2007-002	BC 2007-002
	-Conformance of Micronutrient Fortification of Processed Foods to AO 4-A s. 1995	-Non-conformance of Micronutrient Fortification of Processed Foods to AO 4-A s. 1995	Administrative Order 4-A s, 1995

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MEDIUM RISK FOOD PRODUCTS (Locally Manufactured)			
REQUIREMENTS	**FOR APPROVAL**	**GROUNDS FOR DENIAL**	**BASIS**
4.*Source Documents a. For locally produced products, Certificate of Distributorship or Appointment letter or Memorandum of Agreement from each supplier	For Wholesaler: -Valid, notarized and duly signed Distributorship agreement or Memorandum of Agreement -Applicant company's and Supplier's Name and Address are reflected on the Distributorship Agreement or Memorandum of Agreement -In case products are listed on the agreement, then the product being applied should be included in the list -Name and address of distributor should be consistent in data entry and submitted Distributorship Agreement or Memorandum of Agreement.	For Wholesaler: -No submitted Distributorship agreement or Memorandum of Agreement -Not duly signed, invalid, and/or not notarized Distributorship agreement or Memorandum of Agreement -Applicant company's and/or Supplier's Name and Address is/are NOT reflected on the Distributorship agreement or Memorandum of Agreement -In case products are listed on the agreement, the product being applied is NOT included in the list	FDA Circular 2016-007
	For Trader: -Valid, notarized and duly signed Toll Manufacturing agreement -Trader's and Toll Manufacturer's Name and Address are reflected on the Toll Manufacturing agreement -In case products are listed on the agreement, then the product being applied should be included in the list -Name and address of Toll Manufacturer should be consistent in data entry and submitted Toll Manufacturing agreement	For Trader: -No submitted Toll Manufacturing agreement -Not duly signed, invalid, and/or not notarized Toll Manufacturing agreement -Applicant company's and/or Supplier's Name and Address is/are NOT reflected on theToll Manufacturing agreement -In case products are listed on the agreement, the product being applied is NOT included in the list	
5. *Valid LTO	For Manufacturer: -Valid LTO as Food Manufacturer -Product being applied is listed in FDA approved Product Line/ category -Consistent Company information in the data entry and on the LTO	For Manufacturer: -Expired and Non-renewal of LTO as Food Manufacturer -Product being applied is NOT listed in FDA approved Product Line/ category -Inconsistent Company information in the data entry and on the LTO	FDA Circular 2016-007 Administrative Order 2014-0029

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ANNEX D. REFERENCE GUIDE TO STAKEHOLDERS TO ASSESS COMPLIANCE OF SUBMITTED DOCUMENTS AS COMPLETE REQUIREMENTS FOR PRODUCT REGISTRATION

MEDIUM RISK FOOD PRODUCTS (Locally Manufactured)			
REQUIREMENTS	**FOR APPROVAL**	**GROUNDS FOR DENIAL**	**BASIS**
	For Wholesaler/Trader: -Valid LTO as Food Importer/Distributor/Wholesaler and/or Food Wholesaler and/or Food Trader -Consistent Company information in the data entry and on the LTO	For Wholesaler/Trader: -Expired and Non-renewal LTO as Food Importer/Distributor/Wholesaler and/or Food Wholesaler and/or Food Trader -Inconsistent Company information in the data entry and on the LTO	
6. *Label requirements	Compliant with Administrative Order 2014-0030, Bureau Circular 2007-002, Bureau Circular 2 s. 1999, Department Circular 2008-0006 and RIRR of Executive Order 51 (as applicable): -Brand Name -Product Name -Net Weight and/or Drained Weight -Complete name and address of Manufacturer, Wholesaler or Trader as per LTO -Complete List of Ingredients (including common name and function of all food additives used which are listed in Updated List of Food Additives) -Nutrition Information (Energy, Protein, Carbohydrates, Sugar, Total fat, Saturated fat, Trans fat, Cholesterol, Dietary fiber and Sodium) and For Locally manufactured products: RENI values of nutrients based on RENI 2002 -Expiration date/use by date/consume before date (in prescribed format, eg. dd/mmm/yyyy) -Lot Identification Code -Food Allergen Information (As applicable) -Direction for use (As applicable) -Storage Instructions (As applicable) -"Serving Suggestion" (As applicable) -Alcohol content as applicable (For Alcoholic Beverages) -"Flavor Added" in close proximity to the photograph - if flavoring substances have been added to boost the natural flavor	Not limited to: -Submitted label is inconsistent with the product being applied -Use of brand name which is identical to a previously registered food product under a different company without authorization by the same brand owner. -No declared Brand Name -Use of brand name which is misleading, deceptive, confusing, or is likely to create erroneous impression regarding its character or nature in any respect. -Product name does not state the true nature of the product or misleading, confusing or is likely to create erroneous impression regarding its character or nature in any respect -Inconsistent declaration of the manufacturer's name and/or address on the label and data entry -Inconsistent declaration of ingredient on the label and data entry -Inconsistent declaration of the order of ingredients in the data entry and label -No declared list of ingredients -Specific components of multi-component ingredients are not specified -Use of Food Additives which are not included in the Approved List of Food Additives -Use of food additives with different function from the ones declared in Updated List of Food Additives. -Specific name of food additives used are not specified -Inconsistent declaration of the company activity on the label and on the LTO and/or in the data entry under establishment information	Administrative Order 2014-0030

General Requirements for all food categorization

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ANNEX D. REFERENCE GUIDE TO STAKEHOLDERS TO ASSESS COMPLIANCE OF SUBMITTED DOCUMENTS AS COMPLETE REQUIREMENTS FOR PRODUCT REGISTRATION

MEDIUM RISK FOOD PRODUCTS (Locally Manufactured)			
REQUIREMENTS	**FOR APPROVAL**	**GROUNDS FOR DENIAL**	**BASIS**
6. Certificate of Analysis (COA) must be signed/verified by competent technical staff/QA Analyst/Manager, product description/name, specifications, method of analysis/methodology and batch code/ expiry date/ manufacturing date reflecting the specific/actual results of analysis for the required parameters of each finished product.	Please see pages 33 to 43 for the details to ensure compliance of COA.		
Note: Please make sure that all compliant and complete labels and supporting documents are uploaded for every product application before continuing the application to Pre-Assessment. The Case Number will close upon assessment of initial (or data capture) applications having INCOMPLETE submission of documentary requirements. If the pre-assessment is disapproved, you will need to upload again ALL previous and current documents using a new case number.			

General Requirements for all food categorization
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ANNEX D. REFERENCE GUIDE TO STAKEHOLDERS TO ASSESS COMPLIANCE OF SUBMITTED DOCUMENTS AS COMPLETE REQUIREMENTS FOR PRODUCT REGISTRATION

MEDIUM RISK FOOD PRODUCTS (Imported)			
REQUIREMENTS	**FOR APPROVAL**	**GROUNDS FOR DENIAL**	**BASIS**
1. *Clear and complete loose labels or artworks, as applicable, of all packaging sizes, or equivalents as defined by FDA regulations except for bulk raw materials	-Readable -Reflects all sides of packaging -With submitted secondary and/or primary packaging -Reflects product name/code, lot number -Consistent product information in data entry and label/artwork/picture -Complete labels with the proposed packaging sizes	-No submitted complete picture/artwork/label -Unclear/unreadable information on the picture/artwork/label submitted -Inconsistent product information in data entry and label/artwork/picture -Not all labels for proposed packaging sizes are submitted	Administrative Order 2014-0030 Administrative Order 2014-0029 FDA Circular 2016-014
3. Picture of the product in all angles and in different packaging sizes, and from at least two different perspectives allowing visual recognition of a product as the same with the one being registered, as applicable;	-Readable -Consistent to the declared packaging material type in the data entry -Consistent product information in data entry -With submitted secondary and/or primary packaging	-No submitted picture -Inconsistent product information in data entry and label/artwork/picture -Not all labels for proposed packaging sizes are submitted -Unclear/unreadable information on the picture	Administrative Order 2014-0029 FDA Circular 2016-014
3. As applicable, documents to substantiate claims, but not limited to, such as technical, nutritional or health studies or reports, market-research studies, Certificate of Analysis to confirm compliance to R.A. 8976, R.A. 8172, F.M. 2011-028, quantitative analysis and computations, scientific report or studies published in peer-reviewed scientific journals, certificates or certification to support use of logo/seal on Sangkap Pinoy, Halal, Organic, or Kosher food and in compliance with current labelling regulations.	-Valid Certificates or certification to support use of logo/seal on Sangkap Pinoy, Halal, Organic, or Kosher food, etc. issued by reputable issuing body	-No submitted Certificate -Submitted Certificate is not valid -Submitted Certificate is self-issued	Administrative Order 2014-0030
	-Nutrition and Health claims that conform to BC 2007-002	-Non-conformance of Nutrition and Health claims to BC 2007-002	BC 2007-002
	-Conformance of Micronutrient Fortification of Processed Foods to AO 4-A s. 1995	-Non-conformance of Micronutrient Fortification of Processed Foods to AO 4-A s. 1995	Administrative Order 4-A s, 1995

General Requirements for all food categorization

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ANNEX D. REFERENCE GUIDE TO STAKEHOLDERS TO ASSESS COMPLIANCE OF SUBMITTED DOCUMENTS AS COMPLETE REQUIREMENTS FOR PRODUCT REGISTRATION

MEDIUM RISK FOOD PRODUCTS (Imported)			
REQUIREMENTS	**FOR APPROVAL**	**GROUNDS FOR DENIAL**	**BASIS**
4.*Source Documents a. For Imported products, Foreign Agency Agreement or Certificate of Distributorship or Appointment letter or Proforma Invoice or Memorandum of Agreement from each supplier	For Importer: -Valid, notarized and duly signed Distributorship agreement or Foreign Agency Agreement or Memorandum of Agreement -Product being applied for registration is listed on the Proforma invoice -Applicant company's and Supplier's Name and Address are reflected on the Foreign Agency Agreement or Certificate of Distributorship or Appointment letter or Proforma Invoice or Memorandum of Agreement -In case products are listed on the agreement, then the product being applied should be included in the list - Name and address of supplier should be consistent in data entry and submitted Foreign Agency Agreement or Certificate of Distributorship or Appointment letter or Proforma Invoice or Memorandum of Agreement	For Importer: -No submitted Foreign Agency Agreement or Certificate of Distributorship or Appointment letter or Proforma Invoice or Memorandum of Agreement from each supplier -Not duly signed, invalid and/or not notarized Distributorship agreement or Foreign Agency Agreement -Not duly signed Certificate of Distributorship or Appointment letter or Memorandum of Agreement -Product being applied for registration is NOT listed on the Proforma invoice -Applicant company's and/or Supplier's Name and Address is/are NOT reflected on the Foreign Agency Agreement or Certificate of Distributorship or Appointment letter or Proforma Invoice or Memorandum of Agreement -In case products are listed on the agreement, the product being applied is NOT included in the list	FDA Circular 2016-007

General Requirements for all food categorization
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ANNEX D. REFERENCE GUIDE TO STAKEHOLDERS TO ASSESS COMPLIANCE OF SUBMITTED DOCUMENTS AS COMPLETE REQUIREMENTS FOR PRODUCT REGISTRATION

MEDIUM RISK FOOD PRODUCTS (Imported)			
REQUIREMENTS	**FOR APPROVAL**	**GROUNDS FOR DENIAL**	**BASIS**
b. For Imported products, Certificate of Registration with GMP Compliance or its equivalent or Valid Sanitary Phyto-Sanitary Certificate or Health Certificate or ISO 22000 Certificate or FSSC Certificate or HACCP Certificate or Certificate of Free Sale issued by the Regulatory/ Health Authority/ Attested by recognized Association or duly authenticated by the Philippine Consulate from the country of origin	-Scanned Copy of the Original and Valid Certificate of Registration with GMP Compliance or its equivalent or Valid Sanitary Phyto-Sanitary Certificate or Health Certificate or ISO 22000 Certificate or FSSC Certificate or HACCP Certificate or Certificate of Free Sale; or -Scanned Copy of the Original and Valid Sanitary Phyto-Sanitary Certificate or Health Certificate or Certificate of Free Sale issued by Competent Regulatory/ Health Authority or if issued by Chamber of Commerce or Attested by recognized Association, authentication from the Philippine Consulate or with affixed Apostille from the country of origin must be submitted (from Manufacturer or Supplier); or -Scanned Copy of the Original and Valid GMP Compliance or its equivalent or ISO 22000 Certificate or FSSC Certificate or HACCP Certificate issued by competent Regulatory Authority or Recognized Issuing body (issued to Manufacturer) Note: The Certificate of Free Sale must declare that the product is fit for human consumption and/or is freely sold from the country of origin (see AO and BC on CFS)	-No submitted Certificate of Registration with GMP Compliance or its equivalent or Valid Sanitary Phyto-Sanitary Certificate or Health Certificate or ISO 22000 Certificate or FSSC Certificate or HACCP Certificate or Certificate of Free Sale issued by the Regulatory/ Health Authority/ Attested by recognized Association or duly authenticated by the Philippine Consulate from the country of origin -Expired Certificate of Registration with GMP Compliance or its equivalent or Sanitary Phyto-Sanitary Certificate or Health Certificate or ISO 22000 Certificate or FSSC Certificate or HACCP Certificate or Certificate of Free Sale -Certificate of Free Sale is self-issued or NOT issued by the Regulatory/ Health Authority/ or not attested by recognized Association or duly authenticated by the Philippine Consulate or without affixed Apostille from the country of origin (from Manufacturer or Supplier) -Scanned copy of photocopy of documents stated on the list of requirements stated in FDA Circular 2016-007 are submitted and not scanned copies of the original documents -Submission of documents not stated in FDA Circular 2016-007 (ISO 9001 Certificate and/or ISO 14001 Certificate) -The submitted Certificate of Free Sale does not declare that the product is fit for human consumption or freely sold in the country of origin/supplier (see AO and BC on CFS).	FDA Circular 2016-007

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ANNEX D. REFERENCE GUIDE TO STAKEHOLDERS TO ASSESS COMPLIANCE OF SUBMITTED DOCUMENTS AS COMPLETE REQUIREMENTS FOR PRODUCT REGISTRATION

MEDIUM RISK FOOD PRODUCTS (Imported)			
REQUIREMENTS	**FOR APPROVAL**	**GROUNDS FOR DENIAL**	**BASIS**
4. b. *cont.*	-Name and address of manufacturer should be consistent in data entry and submitted Scanned Copy of the Original and Valid Certificate of Registration with GMP Compliance or its equivalent or Valid Sanitary Phyto-Sanitary Certificate or Health Certificate or ISO 22000 Certificate or FSSC Certificate or HACCP Certificate or Certificate of Free Sale. In case the address of the submitted documents is different from the address on the data entry, clarification in writing that the product is directly sourced from the same company with different head office and plant addresses.		FDA Circular 2016-007
5.*Valid LTO	For Importer/Distributor: -Valid LTO as Food Importer/Distributor -Consistent Company information in the data entry and on the LTO	For Importer/Distributor: -Expired and Non-renewal LTO as Food Importer/Distributor -Inconsistent Company information in the data entry and on the LTO	FDA Circular 2016-007 Administrative Order No. 2014-0029
6. *Label requirements	Compliant with Administrative Order 2014-0030, Bureau Circular 2007-002, Bureau Circular 2 s. 1999, Department Circular 2008-0006 and RIRR of Executive Order 51 (as applicable): -Brand Name -Product Name -Net Weight and/or Drained Weight -Complete name and address of Importer, Wholesaler/ Distributor as per LTO -Country of Origin -Complete List of Ingredients (including common name and function of all food additives used which are listed in Updated List of Food Additives) -Nutrition Information (Energy, Protein, Carbohydrates, Sugar, Total fat, Saturated fat, Trans fat, Cholesterol, Dietary fiber and Sodium) -Expiration date/use by date/consume before date (in prescribed format, eg. dd/mmm/yyyy) -Lot Identification Code	Not limited to: -Submitted label is inconsistent with the product being applied -Use of brand name which is identical to a previously registered food product under a different company without authorization by the same brand owner. -No declared Brand Name -Use of brand name which is misleading, deceptive, confusing, or is likely to create erroneous impression regarding its character or nature in any respect. -Product name does not state the true nature of the product or misleading, confusing or is likely to create erroneous impression regarding its character or nature in any respect -Inconsistent declaration of the manufacturer's name and/or address on the label and data entry -Inconsistent declaration of ingredient on the label and data entry -Inconsistent declaration of the order of ingredients in the	Administrative Order 2014-0030

General Requirements for all food categorization

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MEDIUM RISK FOOD PRODUCTS (Imported)			
REQUIREMENTS	**FOR APPROVAL**	**GROUNDS FOR DENIAL**	**BASIS**
6. **cont.*	-Food Allergen Information (As applicable) -Direction for use (As applicable) -Storage Instructions (As applicable) -"Serving Suggestion" (As applicable) -Alcohol content as applicable (For Alcoholic Beverages) -"Flavor Added" in close proximity to the photograph - if flavoring substances have been added to boost the natural flavor -Corresponding English Translation of ALL label information	data entry and label -No declared list of ingredients -Specific components of multi-component ingredients are not specified -Use of Food Additives which are not included in the Approved List of Food Additives -Use of food additives with different function from the ones declared in Updated List of Food Additives. -Specific name of food additives used are not specified -No English translation submitted and/or English translation is declared separately from the label -Inconsistent declaration of the company activity on the label and on the LTO and/or in the data entry under establishment information -Inconsistent declaration of country of origin on the label and in the data entry	

General Requirements for all food categorization
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MEDIUM RISK FOOD PRODUCTS (Imported)			
REQUIREMENTS	**FOR APPROVAL**	**GROUNDS FOR DENIAL**	**BASIS**
7. Certificate of Analysis (COA) must be signed/verified by competent technical staff/QA Analyst/Manager, product description/name, specifications, method of analysis/methodology and batch code/ expiry date/ manufacturing date reflecting the specific/actual results of analysis for the required parameters of each finished product.	Please see pages 33 to 43 for the details to ensure compliance of COA.		
Note: Please make sure that all compliant and complete labels and supporting documents are uploaded for every product application before continuing the application to Pre-Assessment. The Case Number will close upon assessment of initial (or data capture) applications having INCOMPLETE submission of documentary requirements. If the pre-assessment is disapproved, you will need to upload again ALL previous and current documents using a new case number.			

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ANNEX D. REFERENCE GUIDE TO STAKEHOLDERS TO ASSESS COMPLIANCE OF SUBMITTED DOCUMENTS AS COMPLETE REQUIREMENTS FOR PRODUCT REGISTRATION

MEDIUM RISK FOOD PRODUCTS

FOOD CATEGORY	REQUIREMENT/S	STANDARD		APPROVED	DENIED	BASIS
		PARAMETERS	ACCEPTABLE LEVEL			
MRA1a. CONDENSED MILK and sweetened condensed creamer	Certificate of Analysis (COA) must be signed/verified by competent technical staff/QA Analyst/Manager, product description/name, specifications, method of analysis/methodology and batch code/ expiry date/ manufacturing date reflecting the specific/actual results of analysis for the required parameters.	Coliforms, cfu/g Yeast & Mold Count cfu/g *SPC/APC cfu/g	10 10 10	Submitted COA reflecting the product description/name, specifications and batch code/expiry/ manufacturing date and complete required **PARAMETERS** with methodology, actual/specific results (within the acceptable levels) and signed/verified by a competent technical staff/QA Analyst/Manager. **TPC can be considered in lieu of SPC/APC*	Non-submission of COA reflecting the product description/name, specifications and batch code/expiry/ manufacturing date and complete required **PARAMETERS** (whichever is applicable) with methodology, actual/specific results (within the acceptable level) and signed/verified by a competent technical staff/QA Analyst/Manager. The submitted COA does not meet the required requirements/acceptable levels.	FDA Circular 2013-010
		Total Milk Solids Milk Fat	28%, min. 8.5%, min.			Administrative Order No. 132 s. 1970
		Whole Milk pH Protein Fat Milk Solids Milk Fat Moisture	 6.0, min. 26 – 28% 28% 95%, min. 26%, min. 5%, max.			Administrative Order No. 132 s. 1970
MRA3. MILK PRODUCTS FOR SPECIFIC TARGET AGE GROUP	COA for Microbiological parameters for Milk Powder (e.g. whole, nonfat, filled milk, buttermilk, whey & whey protein and milk intended for children more than 36 months of age and adults)	Salmonella/25g (Normal routine and For high risk population) SPC/APC, cfu/g Enterobacteriaceae, cfu/g	0 5x10^3 10	Submitted COA reflecting the complete Microbiological parameters required and with methodology, results and signature of QA Analyst.	Non-submission of COA reflecting the complete Microbiological parameters required and with methodology, results and signature of QA Analyst./ The submitted COA does not meet the acceptable level.	FDA Circular 2013-010
	COA to support Nutrition Information declaration.			Submitted COA reflecting the test result for the nutrient content of the finished product.	Non-submission of COA reflecting the test result for the nutrient content of the finished product.	Administrative Order 2014-0029

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MEDIUM RISK FOOD PRODUCTS						
FOOD CATEGORY	**REQUIREMENT/S**	**STANDARD**		**APPROVED**	**DENIED**	**BASIS**
		PARAMETERS	**ACCEPTABLE LEVEL**			
MRB2. EDIBLE ICES (POPSICLES)	COA must be signed/verified by competent technical staff/QA Analyst/Manager, product description/name, specifications, method of analysis/methodology and batch code/ expiry date/ manufacturing date reflecting the specific/actual results of analysis for the required parameters.	SPC/APC, cfu/g Coliforms, MPN/g YMC, cfu/g Salmonella/25g	10^2 3.0 10^2 0	Submitted COA reflecting the complete Microbiological parameters required and with methodology, results and signature of QA Analyst.	Non-submission of COA reflecting the complete Microbiological parameters required and with methodology, results and signature of QA Analyst./ The submitted COA does not meet the acceptable level.	FDA Circular 2013-010
MRC2. FROZEN FRUITS	COA must be signed/verified by competent technical staff/QA Analyst/Manager, product description/name, specifications, method of analysis/methodology and batch code/ expiry date/ manufacturing date reflecting the specific/actual results of analysis for the required parameters.	E. coli, MPN/g (pH>4.5)	110	Submitted COA reflecting the complete Microbiological parameters required and with methodology, results and signature of QA Analyst.	Non-submission of COA reflecting the complete Microbiological parameters required and with methodology, results and signature of QA Analyst./ The submitted COA does not meet the acceptable level.	FDA Circular 2013-010
MRC3. CANNED OR BOTTLED FRUITS & VEGETABLE PRESERVE IN JUICE, SYRUP & BRINE	COA must be signed/verified by QA Analyst/Manager, product description/name, specifications, method of analysis and batch code/ expiry date/ manufacturing date reflecting the specific results of analysis for Fruits and Vegetable Products in Hermetically Sealed Containers: Commercial Sterility	Commercial Sterility	Commercially sterile	Submitted COA reflecting the complete Microbiological parameters required and with methodology, results and signature of QA Analyst.	Non-submission of COA reflecting the complete Microbiological parameters required and with methodology, results and signature of QA Analyst./ The submitted Certificate of Analysis (COA) does not meet the acceptable level.	FDA Circular 2013-010

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MEDIUM RISK FOOD PRODUCTS						
FOOD CATEGORY	**REQUIREMENT/S**	**STANDARD**		**APPROVED**	**DENIED**	**BASIS**
		PARAMETERS	**ACCEPTABLE LEVEL**			
MRC7. FERMENTED VEGETABLES	COA must be signed/verified by competent technical staff/QA Analyst/Manager, product description/name, specifications, method of analysis/methodology and batch code/ expiry date/ manufacturing date reflecting the specific/actual results of analysis for the required parameters of Fermented Vegetable (Ready to Eat)	YMC, cfu/g Coliforms, MPN/g E. coli, MPN/g Salmonella/25g S. aureus, cfu/g	10^2 3 3 0 10	Submitted COA reflecting the complete Microbiological parameters required and with methodology, results and signature of QA Analyst.	Non-submission of COA reflecting the complete Microbiological parameters required and with methodology, results and signature of QA Analyst./ The submitted Certificate of Analysis (COA) does not meet the acceptable level.	FDA Circular 2013-010
MRD. COCOA POWDER	COA must be signed/verified by competent technical staff/QA Analyst/Manager, product description/name, specifications, method of analysis/methodology and batch code/ expiry date/ manufacturing date reflecting the specific/actual results of analysis for the required parameters of Cocoa Powder.	Molds, cfu/g Salmonella/25g Coliforms, MPN/g SPC/APC, cfu/g	10^2 0 1.8 10^4	Submitted COA reflecting the complete Microbiological parameters required and with methodology, results and signature of QA Analyst.	Non-submission of COA reflecting the complete Microbiological parameters required and with methodology, results and signature of QA Analyst./ The submitted Certificate of Analysis (COA) does not meet the acceptable level.	FDA Circular 2013-010
MRD. CHOCOLATE PRODUCTS	COA must be signed/verified by competent technical staff/QA Analyst/Manager, product description/name, specifications, method of analysis/methodology and batch code/ expiry date/ manufacturing date reflecting the specific/actual results of analysis for the required parameters of Chocolate Products	Molds, cfu/g Salmonella/25g Coliforms, MPN/g SPC/APC, cfu/g	10^2 0 1.8 10^3	Submitted COA reflecting the complete Microbiological parameters required and with methodology, results and signature of QA Analyst.	Non-submission of COA reflecting the complete Microbiological parameters required and with methodology, results and signature of QA Analyst./ The submitted COA does not meet the acceptable level.	FDA Circular 2013-010

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MEDIUM RISK FOOD PRODUCTS

FOOD CATEGORY	REQUIREMENT/S	STANDARD		APPROVED	DENIED	BASIS
		PARAMETERS	ACCEPTABLE LEVEL			
MRF1Ai. CURED (INCLUDING SALTED) NON-HEAT TREATED PROCESSED MEAT, POULTRY AND GAME PRODUCTS	COA must be signed/verified by competent technical staff/QA Analyst/Manager, product description/name, specifications, method of analysis/methodology and batch code/ expiry date/ manufacturing date reflecting the specific/actual results of analysis for the required parameters of Packaged Cooked, Cured/Salted Meat	S. aureus (coagulase +), cfu/g Salmonella/25g Listeria monocytogenes/25g	10^2 0 0	Submitted COA reflecting the complete Microbiological parameters required and with methodology, results and signature of QA Analyst.	Non-submission of COA reflecting the complete Microbiological parameters required and with methodology, results and signature of QA Analyst./ The submitted COA does not meet the acceptable level.	FDA Circular 2013-010
	COA must be signed/verified by competent technical staff/QA Analyst/Manager, product description/name, specifications, method of analysis/methodology and batch code/ expiry date/ manufacturing date reflecting the specific/actual results of analysis for the required parameters of Cured/Smoked Poultry	S. aureus (coagulase +), cfu/g Salmonella/25g	10^3 0	Submitted COA reflecting the complete Microbiological parameters required and with methodology, results and signature of QA Analyst.	Non-submission of COA reflecting the complete Microbiological parameters required and with methodology, results and signature of QA Analyst./ The submitted COA does not meet the acceptable level.	FDA Circular 2013-010
MRF1Ai. ***Cont.***	COA must be signed/verified by QA Analyst/Manager, product description/name, specifications, method of analysis and batch code/ expiry date/ manufacturing date reflecting the specific results of analysis for Nitrate and Nitrite Content (if utilized)	If it contains: Nitrate Nitrite	 500 ppm 200 ppm	Submitted COA reflecting the complete Nitrate and/or Nitrite parameters required and with methodology, results and signature of QA Analyst.	Non-submission of COA reflecting the complete parameters required Nitrate and/or Nitrite and with methodology, results and signature of QA Analyst./ The submitted COA does not meet the acceptable level.	Administrative Order No. 154 s. 1971 Bureau Circular 2006-016.

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MEDIUM RISK FOOD PRODUCTS						
FOOD CATEGORY	**REQUIREMENT/S**	**STANDARD**		**APPROVED**	**DENIED**	**BASIS**
		PARAMETERS	**ACCEPTABLE LEVEL**			
MRF1Aii. CURED (INCLUDING SALTED) DRIED NON-HEAT TREATED PROCESSED MEAT, POULTRY AND GAME PRODUCTS	COA must be signed/verified by competent technical staff/QA Analyst/Manager, product description/name, specifications, method of analysis/methodology and batch code/ expiry date/ manufacturing date reflecting the specific/actual results of analysis for the required parameters of Packaged Cooked, Cured/Salted Meat	S. aureus (coagulase +), cfu/g Salmonella/25g Listeria monocytogenes/25g	10^2 0 0	Submitted COA reflecting the complete Microbiological parameters required and with methodology, results and signature of QA Analyst.	Non-submission of COA reflecting the complete Microbiological parameters required and with methodology, results and signature of QA Analyst./ The submitted COA does not meet the acceptable level.	FDA Circular 2013-010
	COA must be signed/verified by QA Analyst/Manager, product description/name, specifications, method of analysis and batch code/ expiry date/ manufacturing date reflecting the specific results of analysis for Nitrate and Nitrite Content (if utilized)	If it contains: Nitrate Nitrite	 500 ppm 200 ppm	Submitted COA reflecting the complete Nitrate and/or Nitrite parameters required and with methodology, results and signature of QA Analyst.	Non-submission of COA reflecting the complete parameters required Nitrate and/or Nitrite and with methodology, results and signature of QA Analyst./ The submitted COA does not meet the acceptable level.	Administrative Order No. 154 s. 1971 Bureau Circular 2006-016.

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MRF2Ai. FERMENTED NON-HEAT TREATED PROCESSED MEAT, POULTRY AND GAME PRODUCTS	COA must be signed/verified by competent technical staff/QA Analyst/Manager, product description/name, specifications, method of analysis/methodology and batch code/ expiry date/ manufacturing date reflecting the specific/actual results of analysis for the required parameters of Fermented, Comminuted Meat, not cooked (dry & semi-dry fermented sausages)	E. coli, MPN/g S. aureus (coagulase +), cfu/g Salmonella/25g	1.8 10^3 0	Submitted COA reflecting the complete Microbiological parameters required and with methodology, results and signature of QA Analyst.	Non-submission of COA reflecting the complete Microbiological parameters required and with methodology, results and signature of QA Analyst./ The submitted COA does not meet the acceptable level.	FDA Circular 2013-010
	COA must be signed/verified by QA Analyst/Manager, product description/name, specifications, method of analysis and batch code/ expiry date/ manufacturing date reflecting the specific results of analysis for Nitrate and Nitrite Content (if utilized)	If it contains: Nitrate Nitrite	 500 ppm 200 ppm	Submitted COA reflecting the complete Nitrate and/or Nitrite parameters required and with methodology, results and signature of QA Analyst.	Non-submission of COA reflecting the complete parameters required Nitrate and/or Nitrite and with methodology, results and signature of QA Analyst./ The submitted COA does not meet the acceptable level.	Administrative Order No. 154 s. 1971 Bureau Circular 2006-016.
MRJa. FROZEN BAKERY PRODUCTS	COA must be signed/verified by competent technical staff/QA Analyst/Manager, product description/name, specifications, method of analysis/methodology and batch code/ expiry date/ manufacturing date reflecting the specific/actual results of analysis for the required parameters of Frozen Bakery Products	S. aureus (coagulase +), cfu/g Salmonella/25g	10^2 0	Submitted COA reflecting the complete Microbiological parameters required and with methodology, results and signature of QA Analyst.	Non-submission of COA reflecting the complete Microbiological parameters required and with methodology, results and signature of QA Analyst./ The submitted COA does not meet the acceptable level.	FDA Circular 2013-010

All documents submitted must be CLEAR & READABLE. Non-compliance is ground for Letter of Denial (LOD).

ANNEX D. REFERENCE GUIDE TO STAKEHOLDERS TO ASSESS COMPLIANCE OF SUBMITTED DOCUMENTS AS COMPLETE REQUIREMENTS FOR PRODUCT REGISTRATION

MRjb. FROZEN DOUGH	COA must be signed/verified by competent technical staff/QA Analyst/Manager, product description/name, specifications, method of analysis/methodology and batch code/ expiry date/ manufacturing date reflecting the specific/actual results of analysis for the required parameters of Frozen and Refrigerated Doughs	Molds, cfu/g Yeast & Yeastlike Fungi, cfu/g Coliforms, cfu/g Psychrotrophic bacteria, cfu/g SPC/APC, cfu/g	10^2 10^5 10 10 10^3	Submitted COA reflecting the complete Microbiological parameters required and with methodology, results and signature of QA Analyst.	Non-submission of COA reflecting the complete Microbiological parameters required and with methodology, results and signature of QA Analyst./ The submitted COA does not meet the acceptable level.	FDA Circular 2013-010
MRJa. CAKES, COOKIES, PIES, PASTRIES, DOUGHNUTS, SWEET ROLLS, CONES, MUFFINES, WAFFLES-PLAIN /WITHOUT FILLING	COA must be signed/verified by competent technical staff/QA Analyst/Manager, product description/name, specifications, method of analysis/methodology and batch code/ expiry date/ manufacturing date reflecting the specific/actual results of analysis for the required parameters of Baked Goods	S. aureus (coagulase +), cfu/g MYC, cfu/g SPC/APC, cfu/g Coliforms, cfu/g	10^2 10^2 10^4 50	Submitted COA reflecting the complete Microbiological parameters required and with methodology, results and signature of QA Analyst.	Non-submission of COA reflecting the complete Microbiological parameters required and with methodology, results and signature of QA Analyst./ The submitted COA does not meet the acceptable level.	FDA Circular 2013-010

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MRL1a. FRUIT AND VEGETABLE JUICES	COA must be signed/verified by competent technical staff/QA Analyst/Manager, product description/name, specifications, method of analysis/methodology and batch code/ expiry date/ manufacturing date reflecting the specific/actual results of analysis for the required parameters of Non-Alcoholic Beverages	YMC, cfu/mL Coliforms, cfu/mL SPC/APC, cfu/mL.	1 1 10	Submitted COA reflecting the complete Microbiological parameters required and with methodology, results and signature of QA Analyst.	Non-submission of COA reflecting the complete Microbiological parameters required and with methodology, results and signature of QA Analyst./ The submitted COA does not meet the acceptable level.	FDA Circular 2013-010
MRK2a. EMULSIFIED SAUCES AND DIPS (SALAD DRESSING- i.e. MAYONNAISE, THOUSAND ISLAND, RANCH, FRENCH)	COA must be signed/verified by competent technical staff/QA Analyst/Manager, product description/name, specifications, method of analysis/methodology and batch code/ expiry date/ manufacturing date reflecting the specific/actual results of analysis for the required parameters of Salad Dressing	SPC/APC, cfu/g YMC, cfu/g Salmonella/25g Listeria monocytogenes/25g	10 10 0 0	Submitted COA reflecting the complete Microbiological parameters required and with methodology, results and signature of QA Analyst.	Non-submission of COA reflecting the complete Microbiological parameters required and with methodology, results and signature of QA Analyst./ The submitted COA does not meet the acceptable level.	FDA Circular 2013-010
	For Mayonnaise: COA for Fat Content based on Administrative Order No. 235 s. 1975. If salad dressing contains calcium disodium EDTA or disodium EDTA or both, the label shall bear the statement "___ added as preservative" or "___ added to protect flavor", the blank being filled in with the words "calcium disodium EDTA" or "disodium EDTA"	Fat Content	65%	Submitted COA reflecting the complete Fat Content parameters required and with methodology, results and signature of QA Analyst.	Non-submission of COA on the Fat Content analysis signed/verified by competent technical staff.	Administrative Order No. 235 s. 1975

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ANNEX D. REFERENCE GUIDE TO STAKEHOLDERS TO ASSESS COMPLIANCE OF SUBMITTED DOCUMENTS AS COMPLETE REQUIREMENTS FOR PRODUCT REGISTRATION

MRL1c. SPORTS, ENERGY DRINK & ELECTROLYTE DRINKS	COA must be signed/verified by competent technical staff/QA Analyst/Manager, product description/name, specifications, method of analysis/methodology and batch code/ expiry date/ manufacturing date reflecting the specific/actual results of analysis for the required parameters of Non-Alcoholic Beverages	YMC, cfu/mL Coliforms, cfu/mL SPC/APC, cfu/mL.	1 1 10	Submitted COA reflecting the complete Microbiological parameters required and with methodology, results and signature of QA Analyst.	Non-submission of COA reflecting the complete Microbiological parameters required and with methodology, results and signature of QA Analyst./ The submitted COA does not meet the acceptable level.	FDA Circular 2013-010
MRL1c. SPORTS, ENERGY DRINK & ELECTROLYTE DRINKS	COA must be signed/verified by competent technical staff/QA Analyst/Manager, product description/name, specifications, method of analysis/methodology and batch code/ expiry date/ manufacturing date reflecting the specific/actual results of analysis for the required parameters of Caffeine and Vitamin B Assays.	Caffeine Vitamin B	500 ppm Vitamin B content	Submitted COA reflecting the caffeine and vitamin B test result of the finished product.	Non-submission of COA for caffeine and vitamin B test result of the finished product.	Administrative Order No.2014-0029
	Labelling requirement: • Precaution statement: *"Excessive intake of caffeine may cause sleeplessness, palpitation and other similar side effects. Not recommended for children, pregnant and lactating women, people who may have heart problems and/or those sensitive to caffeine."*					
MRL1cii. NON-CARBONATED WATER-BASED FLAVORED DRINKS	COA must be signed/verified by competent technical staff/QA Analyst/Manager, product description/name, specifications, method of analysis/methodology and batch code/ expiry date/ manufacturing date reflecting the specific/actual results of analysis for the required parameters of Non-Alcoholic Beverages	YMC, cfu/mL Coliforms, cfu/mL SPC/APC, cfu/mL.	1 1 10	Submitted COA reflecting the complete Microbiological parameters required and with methodology, results and signature of QA Analyst.	Non-submission of COA reflecting the complete Microbiological parameters required and with methodology, results and signature of QA Analyst./ The submitted COA does not meet the acceptable level.	FDA Circular 2013-010
	For Cola-type Beverage: Certificate of Analyis for Caffeine Content based on Administrative Order 88-A s. 1984.	Caffeine	Not more than 200 ppm	Submitted COA reflecting the complete parameters required and with methodology, results and signature of QA Analyst.	Non-submission of COA reflecting the complete parameters required and with methodology, results and signature of QA Analyst./ The submitted COA does not meet the acceptable level.	Administrative Order 88-A s. 1984

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MRL1ciii. FROZEN CONCENTRATE	COA must be signed/verified by competent technical staff/QA Analyst/Manager, product description/name, specifications, method of analysis/methodology and batch code/ expiry date/ manufacturing date reflecting the specific/actual results of analysis for the required parameters of Frozen Juice Concentrates	SPC/APC, cfu/mL YMC cfu/mL	10^2 10	Submitted COA reflecting the complete Microbiological parameters required and with methodology, results and signature of QA Analyst.	Non-submission of COA reflecting the complete Microbiological parameters required and with methodology, results and signature of QA Analyst./ The submitted COA does not meet the acceptable level.	FDA Circular 2013-010
MRL1ci. CARBONATED WATER-BASED FLAVORED DRINKS	COA must be signed/verified by competent technical staff/QA Analyst/Manager, product description/name, specifications, method of analysis/methodology and batch code/ expiry date/ manufacturing date reflecting the specific/actual results of analysis for the required parameters of Non-Alcoholic Beverages	YMC, cfu/mL Coliforms, cfu/mL SPC/APC, cfu/mL	1 1 10	Submitted COA reflecting the complete Microbiological parameters required and with methodology, results and signature of QA Analyst.	Non-submission of COA reflecting the complete Microbiological parameters required and with methodology, results and signature of QA Analyst./ The submitted COA does not meet the acceptable level.	FDA Circular 2013-010
MRL1d. POWDERED COCOA DRINK MIXES	COA must be signed/verified by competent technical staff/QA Analyst/Manager, product description/name, specifications, method of analysis/methodology and batch code/ expiry date/ manufacturing date reflecting the specific/actual results of analysis for the required parameters of Powdered Beverage	SPC/APC,cfu/g YMC, cfu/g	3x10^3 10	Submitted COA reflecting the complete Microbiological parameters required and with methodology, results and signature of QA Analyst.	Non-submission of COA reflecting the complete Microbiological parameters required and with methodology, results and signature of QA Analyst./ The submitted COA does not meet the acceptable level.	FDA Circular 2013-010

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ANNEX D. REFERENCE GUIDE TO STAKEHOLDERS TO ASSESS COMPLIANCE OF SUBMITTED DOCUMENTS AS COMPLETE REQUIREMENTS FOR PRODUCT REGISTRATION

MRM1. VITAMINS, MINERALS & AMINO ACIDS AS FOOD SUPPLEMENTS	Shelf life study/ stability data containing relevant information on the critical parameters of the finished product, period conducted, conclusion, and signed/verified by competent technical staff to support shelf life declaration.	Contains relevant information on the critical parameters (physical, chemical, microbiological & heavy metals) of the finished product, period conducted, conclusion & signed/verified by competent technical staff to support shelf-life declaration.	Submitted Shelf life study/ stability data containing relevant information on the critical parameters of the finished product, period conducted, conclusion, and signed/verified by competent technical staff to support shelf life declaration.	Non-submission of shelf life study/ stability data containing relevant information on the critical parameters of the finished product, period conducted, conclusion, and signed/verified by competent technical staff to support shelf life declaration.	FDA Circular 2016-014 Administrative Order 2014-0029
	COA of the physico-chemical (Vitamins, Minerals & Amino Acids Assays) and microbiological parameters of the finished product based on Administrative Order 2014-0029.	Contains relevant information on the critical parameters (physical, chemical, microbiological and heavy metals) of the finished product, period conducted and signed/verified by competent technical staff *Fat Soluble Vitamins: < 105% *Water Soluble: <150% *Minerals: 100% of RENI	Submitted COA of the physico-chemical (Vitamins, Minerals & Amino Acids Assays) and microbiological parameters of the finished product should reflect result of the finished product	The amount of Vitamin ___ at (specify amount in %RENI) in the finished product exceeded the maximum amount (specify amount in %RENI) as prescribed by FDA Regulation.	Office Order No 22 s. 1991
	Sample in actual commercial presentation based on Administrative Order 2014-0029.		Submitted product sample at FDAC Starmall Alabang	Non-submission of product sample as initial requirement to Food/Dietary Supplement	FDA Circular 2016-014 Administrative Order 2014-0029
	Label: Clear and complete loose labels or artworks declaring the term "Food Supplement" and the phrase "NO APPROVED THERAPEUTIC CLAIMS"	Brand Name – Not misleading or deceptive or is likely to create erroneous impression regarding the product's character in any respect Product Name – should declare the true nature of the product, "Food/Dietary Supplement" and Form (e.g capsule, powder, etc.) should be indicated after the product name	Labelling requirement: • NO APPROVED THERAPEUTIC CLAIM • Food/Dietary Supplement • Form: Powder, Capsule, Syrup etc. • Nutrition Facts (AO 2014-0030) • List of ingredients including the ingredients of the capsule	Submitted label does not contain anything: • NO APPROVED THERAPEUTIC CLAIM • FOOD/DIETARY SUPPLEMENT	Administrative Order 2014-0030 Bureau Circular No. 2 s 1999

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ANNEX D. REFERENCE GUIDE TO STAKEHOLDERS TO ASSESS COMPLIANCE OF SUBMITTED DOCUMENTS AS COMPLETE REQUIREMENTS FOR PRODUCT REGISTRATION

HIGH RISK FOOD PRODUCTS (Locally Manufactured)			
REQUIREMENTS	**FOR APPROVAL**	**GROUNDS FOR DENIAL**	**BASIS**
1. *Clear and complete loose labels or artworks, as applicable, of all packaging sizes, or equivalents as defined by FDA regulations except for bulk raw materials	-Readable -Reflects all sides of packaging -With submitted secondary and/or primary packaging -Reflects product name/code, lot number -Consistent product information in data entry and label/artwork/picture -Complete labels with the proposed packaging sizes	-No submitted complete picture/artwork/label -Unclear/unreadable information on the picture/artwork/label submitted -Inconsistent product information in data entry and label/artwork/picture -Not all labels for proposed packaging sizes are submitted	Administrative Order 2014-0030 Administrative Order 2014-0029 FDA Circular 2016-014
2.*Picture of the product in all angles and in different packaging sizes, and from at least two different perspectives allowing visual recognition of a product as the same with the one being registered, as applicable;	-Readable -Consistent to the declared packaging material type in the data entry -Consistent product information in data entry -With submitted secondary and/or primary packaging	-No submitted picture -Inconsistent product information in data entry and label/artwork/picture -Not all labels for proposed packaging sizes are submitted -Unclear/unreadable information on the picture	Administrative Order 2014-0029 FDA Circular 2016-014
3. As applicable, documents to substantiate claims, but not limited to, such as technical, nutritional or health studies or reports, market-research studies, Certificate of Analysis to confirm compliance to R.A. 8976, R.A. 8172, F.M. 2011-028, quantitative analysis and computations, scientific report or studies published in peer-reviewed scientific journals, certificates or certification to support use of logo/seal on Sangkap Pinoy, Halal, Organic, or Kosher food and in compliance with current labelling regulations.	-Valid Certificates or certification to support use of logo/seal on Sangkap Pinoy, Halal, Organic, or Kosher food, etc. issued by reputable issuing body	-No submitted Certificate -Submitted Certificate is not valid -Submitted Certificate is self-issued	Administrative Order 2014-0030
	-Nutrition and Health claims that conform to BC 2007-002	-Non-conformance of Nutrition and Health claims to BC 2007-002	BC 2007-002
	-Conformance of Micronutrient Fortification of Processed Foods to AO 4-A s. 1995	-Non-conformance of Micronutrient Fortification of Processed Foods to AO 4-A s. 1995	Administrative Order 4-A s, 1995

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ANNEX D. REFERENCE GUIDE TO STAKEHOLDERS TO ASSESS COMPLIANCE OF SUBMITTED DOCUMENTS AS COMPLETE REQUIREMENTS FOR PRODUCT REGISTRATION

HIGH RISK FOOD PRODUCTS (Locally Manufactured)			
REQUIREMENTS	**FOR APPROVAL**	**GROUNDS FOR DENIAL**	**BASIS**
4.*Source Documents a. For locally produced products, Certificate of Distributorship or Appointment letter or Memorandum of Agreement from each supplier	For Wholesaler: -Valid, notarized and duly signed Distributorship agreement or Memorandum of Agreement -Applicant company's and Supplier's Name and Address are reflected on the Distributorship Agreement or Memorandum of Agreement -In case products are listed on the agreement, then the product being applied should be included in the list -Name and address of distributor should be consistent in data entry and submitted Distributorship Agreement or Memorandum of Agreement.	For Wholesaler: -No submitted Distributorship agreement or Memorandum of Agreement -Not duly signed, invalid, and/or not notarized Distributorship agreement or Memorandum of Agreement -Applicant company's and/or Supplier's Name and Address is/are NOT reflected on the Distributorship agreement or Memorandum of Agreement -In case products are listed on the agreement, the product being applied is NOT included in the list	FDA Circular 2016-007
	For Trader: -Valid, notarized and duly signed Toll Manufacturing agreement -Trader's and Toll Manufacturer's Name and Address are reflected on the Toll Manufacturing agreement -In case products are listed on the agreement, then the product being applied should be included in the list -Name and address of Toll Manufacturer should be consistent in data entry and submitted Toll Manufacturing agreement	For Trader: -No submitted Toll Manufacturing agreement -Not duly signed, invalid, and/or not notarized Toll Manufacturing agreement -Applicant company's and/or Supplier's Name and Address is/are NOT reflected on theToll Manufacturing agreement -In case products are listed on the agreement, the product being applied is NOT included in the list	FDA Circular 2016-007

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ANNEX D. REFERENCE GUIDE TO STAKEHOLDERS TO ASSESS COMPLIANCE OF SUBMITTED DOCUMENTS AS COMPLETE REQUIREMENTS FOR PRODUCT REGISTRATION

HIGH RISK FOOD PRODUCTS (Locally Manufactured)			
REQUIREMENTS	**FOR APPROVAL**	**GROUNDS FOR DENIAL**	**BASIS**
5. *Valid LTO	For Manufacturer: -Valid LTO as Food Manufacturer -Product being applied is listed in FDA approved Product Line/ category -Consistent Company information in the data entry and on the LTO	For Manufacturer: -Expired and Non-renewal of LTO as Food Manufacturer -Product being applied is NOT listed in FDA approved Product Line/ category -Inconsistent Company information in the data entry and on the LTO	FDA Circular 2016-007 Administrative Order 2014-0029
	For Wholesaler/Trader: -Valid LTO as Food Importer/Distributor/Wholesaler and/or Food Wholesaler and/or Food Trader -Consistent Company information in the data entry and on the LTO	For Wholesaler/Trader: -Expired and Non-renewal LTO as Food Importer/Distributor/Wholesaler and/or Food Wholesaler and/or Food Trader -Inconsistent Company information in the data entry and on the LTO	
6. *Label requirements	Compliant with Administrative Order 2014-0030, Bureau Circular 2007-002, Bureau Circular 2 s. 1999, Department Circular 2008-0006 and RIRR of Executive Order 51 (as applicable): -Brand Name -Product Name -Net Weight and/or Drained Weight -Complete name and address of Manufacturer, Wholesaler or Trader as per LTO -Complete List of Ingredients (including common name and function of all food additives used which are listed in Updated List of Food Additives) -Nutrition Information (Energy, Protein, Carbohydrates, Sugar, Total fat, Saturated fat, Trans fat, Cholesterol, Dietary fiber and Sodium) and For Locally manufactured products: RENI values of nutrients based on RENI 2002 -Expiration date/use by date/consume before date (in prescribed format, eg. dd/mmm/yyyy) -Lot Identification Code -Food Allergen Information (As applicable) -Direction for use (As applicable) -Storage Instructions (As applicable) -"Serving Suggestion" (As applicable) -Alcohol content as applicable (For Alcoholic Beverages)	Not limited to: -Submitted label is inconsistent with the product being applied -Use of brand name which is identical to a previously registered food product under a different company without authorization by the same brand owner. -No declared Brand Name -Use of brand name which is misleading, deceptive, confusing, or is likely to create erroneous impression regarding its character or nature in any respect. -Product name does not state the true nature of the product or misleading, confusing or is likely to create erroneous impression regarding its character or nature in any respect -Inconsistent declaration of the manufacturer's name and/or address on the label and data entry -Inconsistent declaration of ingredient on the label and data entry -Inconsistent declaration of the order of ingredients in the data entry and label -No declared list of ingredients -Specific components of multi-component ingredients are not specified -Use of Food Additives which are not included in the Approved List of Food Additives	Administrative Order 2014-0030

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HIGH RISK FOOD PRODUCTS (Locally Manufactured)			
REQUIREMENTS	**FOR APPROVAL**	**GROUNDS FOR DENIAL**	**BASIS**
6. **cont*	-"Flavor Added" in close proximity to the photograph - if flavoring substances have been added to boost the natural flavor	-Use of food additives with different function from the ones declared in Updated List of Food Additives. -Specific name of food additives used are not specified -Inconsistent declaration of the company activity on the label and on the LTO and/or in the data entry under establishment information	
7. Certificate of Analysis (COA) must be signed/verified by competent technical staff/QA Analyst/Manager, product description/name, specifications, method of analysis/methodology and batch code/ expiry date/ manufacturing date reflecting the specific/actual results of analysis for the required parameters of each finished product.	Please see pages 53 to 94 for the details to ensure compliance of COA.		
Note: Please make sure that all compliant and complete labels and supporting documents are uploaded for every product application before continuing the application to Pre-Assessment. The Case Number will close upon assessment of initial (or data capture) applications having INCOMPLETE submission of documentary requirements. If the pre-assessment is disapproved, you will need to upload again ALL previous and current documents using a new case number.			

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ANNEX D. REFERENCE GUIDE TO STAKEHOLDERS TO ASSESS COMPLIANCE OF SUBMITTED DOCUMENTS AS COMPLETE REQUIREMENTS FOR PRODUCT REGISTRATION

HIGH RISK FOOD PRODUCTS (Imported)			
REQUIREMENTS	**FOR APPROVAL**	**GROUNDS FOR DENIAL**	**BASIS**
1. *Clear and complete loose labels or artworks, as applicable, of all packaging sizes, or equivalents as defined by FDA regulations except for bulk raw materials	-Readable -Reflects all sides of packaging -With submitted secondary and/or primary packaging -Reflects product name/code, lot number -Consistent product information in data entry and label/artwork/picture -Complete labels with the proposed packaging sizes	-No submitted complete picture/artwork/label -Unclear/unreadable information on the picture/artwork/label submitted -Inconsistent product information in data entry and label/artwork/picture -Not all labels for proposed packaging sizes are submitted	Administrative Order 2014-0030 Administrative Order 2014-0029 FDA Circular 2016-014
2.*Picture of the product in all angles and in different packaging sizes, and from at least two different perspectives allowing visual recognition of a product as the same with the one being registered, as applicable;	-Readable -Consistent to the declared packaging material type in the data entry -Consistent product information in data entry -With submitted secondary and/or primary packaging	-No submitted picture -Inconsistent product information in data entry and label/artwork/picture -Not all labels for proposed packaging sizes are submitted -Unclear/unreadable information on the picture	Administrative Order 2014-0029 FDA Circular 2016-014
3. As applicable, documents to substantiate claims, but not limited to, such as technical, nutritional or health studies or reports, market-research studies, Certificate of Analysis to confirm compliance to R.A. 8976, R.A. 8172, F.M. 2011-028, quantitative analysis and computations, scientific report or studies published in peer-reviewed scientific journals, certificates or certification to support use of logo/seal on Sangkap Pinoy, Halal, Organic, or Kosher food and in compliance with current labelling regulations.	-Valid Certificates or certification to support use of logo/seal on Sangkap Pinoy, Halal, Organic, or Kosher food, etc. issued by reputable issuing body	-No submitted Certificate -Submitted Certificate is not valid -Submitted Certificate is self-issued	Administrative Order 2014-0030
	-Nutrition and Health claims that conform to BC 2007-002	-Non-conformance of Nutrition and Health claims to BC 2007-002	BC 2007-002
	-Conformance of Micronutrient Fortification of Processed Foods to AO 4-A s. 1995	-Non-conformance of Micronutrient Fortification of Processed Foods to AO 4-A s. 1995	Administrative Order 4-A s, 1995

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HIGH RISK FOOD PRODUCTS (Imported)			
REQUIREMENTS	**FOR APPROVAL**	**GROUNDS FOR DENIAL**	**BASIS**
4.*Source Documents a. For Imported products, Foreign Agency Agreement or Certificate of Distributorship or Appointment letter or Proforma Invoice or Memorandum of Agreement from each supplier	For Importer: -Valid, notarized and duly signed Distributorship agreement or Foreign Agency Agreement or Memorandum of Agreement -Product being applied for registration is listed on the Proforma invoice -Applicant company's and Supplier's Name and Address are reflected on the Foreign Agency Agreement or Certificate of Distributorship or Appointment letter or Proforma Invoice or Memorandum of Agreement -In case products are listed on the agreement, then the product being applied should be included in the list - Name and address of supplier should be consistent in data entry and submitted Foreign Agency Agreement or Certificate of Distributorship or Appointment letter or Proforma Invoice or Memorandum of Agreement	For Importer: -No submitted Foreign Agency Agreement or Certificate of Distributorship or Appointment letter or Proforma Invoice or Memorandum of Agreement from each supplier -Not duly signed, invalid and/or not notarized Distributorship agreement or Foreign Agency Agreement -Not duly signed Certificate of Distributorship or Appointment letter or Memorandum of Agreement -Product being applied for registration is NOT listed on the Proforma invoice -Applicant company's and/or Supplier's Name and Address is/are NOT reflected on the Foreign Agency Agreement or Certificate of Distributorship or Appointment letter or Proforma Invoice or Memorandum of Agreement -In case products are listed on the agreement, the product being applied is NOT included in the list	FDA Circular 2016-007

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ANNEX D. REFERENCE GUIDE TO STAKEHOLDERS TO ASSESS COMPLIANCE OF SUBMITTED DOCUMENTS AS COMPLETE REQUIREMENTS FOR PRODUCT REGISTRATION

HIGH RISK FOOD PRODUCTS (Imported)			
REQUIREMENTS	**FOR APPROVAL**	**GROUNDS FOR DENIAL**	**BASIS**
b. For Imported products, Certificate of Registration with GMP Compliance or its equivalent or Valid Sanitary Phyto-Sanitary Certificate or Health Certificate or ISO 22000 Certificate or FSSC Certificate or HACCP Certificate or Certificate of Free Sale issued by the Regulatory/ Health Authority/ Attested by recognized Association or duly authenticated by the Philippine Consulate from the country of origin	-Scanned Copy of the Original and Valid Certificate of Registration with GMP Compliance or its equivalent or Valid Sanitary Phyto-Sanitary Certificate or Health Certificate or ISO 22000 Certificate or FSSC Certificate or HACCP Certificate or Certificate of Free Sale; or -Scanned Copy of the Original and Valid Sanitary Phyto-Sanitary Certificate or Health Certificate or Certificate of Free Sale issued by Competent Regulatory/ Health Authority or if issued by Chamber of Commerce or Attested by recognized Association, authentication from the Philippine Consulate or with affixed Apostille from the country of origin must be submitted (from Manufacturer or Supplier); or -Scanned Copy of the Original and Valid GMP Compliance or its equivalent or ISO 22000 Certificate or FSSC Certificate or HACCP Certificate issued by competent Regulatory Authority or Recognized Issuing body (issued to Manufacturer) Note: The Certificate of Free Sale must declare that the product is fit for human consumption and/or is freely sold from the country of origin (see AO and BC on CFS)	-No submitted Certificate of Registration with GMP Compliance or its equivalent or Valid Sanitary Phyto-Sanitary Certificate or Health Certificate or ISO 22000 Certificate or FSSC Certificate or HACCP Certificate or Certificate of Free Sale issued by the Regulatory/ Health Authority/ Attested by recognized Association or duly authenticated by the Philippine Consulate from the country of origin -Expired Certificate of Registration with GMP Compliance or its equivalent or Sanitary Phyto-Sanitary Certificate or Health Certificate or ISO 22000 Certificate or FSSC Certificate or HACCP Certificate or Certificate of Free Sale -Certificate of Free Sale is self-issued or NOT issued by the Regulatory/ Health Authority/ or not attested by recognized Association or duly authenticated by the Philippine Consulate or without affixed Apostille from the country of origin (from Manufacturer or Supplier) -Scanned copy of photocopy of documents stated on the list of requirements stated in FDA Circular 2016-007 are submitted and not scanned copies of the original documents -Submission of documents not stated in FDA Circular 2016-007 (ISO 9001 Certificate and/or ISO 14001 Certificate) -The submitted Certificate of Free Sale does not declare that the product is fit for human consumption or freely sold in the country of origin/supplier (see AO and BC on CFS).	FDA Circular 2016-007

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ANNEX D. REFERENCE GUIDE TO STAKEHOLDERS TO ASSESS COMPLIANCE OF SUBMITTED DOCUMENTS AS COMPLETE REQUIREMENTS FOR PRODUCT REGISTRATION

HIGH RISK FOOD PRODUCTS (Imported)			
REQUIREMENTS	**FOR APPROVAL**	**GROUNDS FOR DENIAL**	**BASIS**
4. b. *cont.*	-Name and address of manufacturer should be consistent in data entry and submitted Scanned Copy of the Original and Valid Certificate of Registration with GMP Compliance or its equivalent or Valid Sanitary Phyto-Sanitary Certificate or Health Certificate or ISO 22000 Certificate or FSSC Certificate or HACCP Certificate or Certificate of Free Sale. In case the address of the submitted documents is different from the address on the data entry, clarification in writing that the product is directly sourced from the same company with different head office and plant addresses.		FDA Circular 2016-007
5.*Valid LTO	For Importer/Distributor: -Valid LTO as Food Importer/Distributor and/or Food Importer/Distributor/Wholesaler -Consistent Company information in the data entry and on the LTO	For Importer/Distributor: -Expired and Non-renewal LTO as Food Importer/Distributor and/or Food Importer/Distributor/Wholesaler – -Inconsistent Company information in the data entry and on the LTO	FDA Circular 2016-007 Administrative Order No. 2014-0029
6. *Label requirements 6. **cont.*	Compliant with Administrative Order 2014-0030, Bureau Circular 2007-002, Bureau Circular 2 s. 1999, Department Circular 2008-0006 and RIRR of Executive Order 51 (as applicable): -Brand Name -Product Name -Net Weight and/or Drained Weight -Complete name and address of Importer/ Distributor as per LTO -Country of Origin -Complete List of Ingredients (including common name and function of all food additives used which are listed in Updated List of Food Additives) -Nutrition Information (Energy, Protein, Carbohydrates, Sugar, Total fat, Saturated fat, Trans fat, Cholesterol, Dietary fiber and Sodium) -Expiration date/use by date/consume before date (in prescribed format, eg. dd/mmm/yyyy) -Lot Identification Code -Food Allergen Information (As applicable) -Direction for use (As applicable)	Not limited to: -Submitted label is inconsistent with the product being applied -Use of brand name which is identical to a previously registered food product under a different company without authorization by the same brand owner. -No declared Brand Name -Use of brand name which is misleading, deceptive, confusing, or is likely to create erroneous impression regarding its character or nature in any respect. -Product name does not state the true nature of the product or misleading, confusing or is likely to create erroneous impression regarding its character or nature in any respect -Inconsistent declaration of the manufacturer's name and/or address on the label and data entry -Inconsistent declaration of ingredient on the label and data entry -Inconsistent declaration of the order of ingredients in the data entry and label -No declared list of ingredients -Specific components of multi-component ingredients are not	Administrative Order 2014-0030

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ANNEX D. REFERENCE GUIDE TO STAKEHOLDERS TO ASSESS COMPLIANCE OF SUBMITTED DOCUMENTS AS COMPLETE REQUIREMENTS FOR PRODUCT REGISTRATION

HIGH RISK FOOD PRODUCTS (Imported)			
REQUIREMENTS	**FOR APPROVAL**	**GROUNDS FOR DENIAL**	**BASIS**
	-Storage Instructions (As applicable) -"Serving Suggestion" (As applicable) -Alcohol content as applicable (For Alcoholic Beverages) -"Flavor Added" in close proximity to the photograph - if flavoring substances have been added to boost the natural flavor -Corresponding English Translation of ALL label information	specified -Use of Food Additives which are not included in the Approved List of Food Additives -Use of food additives with different function from the ones declared in Updated List of Food Additives. -Specific name of food additives used are not specified -No English translation submitted and/or English translation is declared separately from the label -Inconsistent declaration of the company activity on the label and on the LTO and/or in the data entry under establishment information -Inconsistent declaration of country of origin on the label and in the data entry	
7. Certificate of Analysis (COA) must be signed/verified by competent technical staff/QA Analyst/Manager, product description/name, specifications, method of analysis/methodology and batch code/ expiry date/ manufacturing date reflecting the specific/actual results of analysis for the required parameters of each finished product.	Please see pages 53 to 94 for the details to ensure compliance of COA.		
Note: Please make sure that all compliant and complete labels and supporting documents are uploaded for every product application before continuing the application to Pre-Assessment. The Case Number will close upon assessment of initial (or data capture) applications having INCOMPLETE submission of documentary requirements. If the pre-assessment is disapproved, you will need to upload again ALL previous and current documents using a new case number.			

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ANNEX D. REFERENCE GUIDE TO STAKEHOLDERS TO ASSESS COMPLIANCE OF SUBMITTED DOCUMENTS AS COMPLETE REQUIREMENTS FOR PRODUCT REGISTRATION

HIGH RISK FOOD PRODUCTS						
FOOD CATEGORY	**REQUIREMENTS**	**STANDARDS**		**FOR APPROVAL**	**GROUNDS FOR DENIAL**	**BASIS**
		PARAMETERS	**ACCEPTABLE LEVEL**			
1. HRA1a. MILK (PLAIN) AND BUTTERMILK PLAIN	COA must be signed/verified by competent technical staff/QA Analyst/Manager, product description/name, specifications, method of analysis/methodology and batch code/ expiry date/ manufacturing date reflecting the specific/actual results of analysis for the required parameters of Liquid Milk (evaporated & ready to drink)-UHT/Sterilized	Commercial Sterility	Commercially Sterile	COA must reflect complete Microbiological parameters required and with methodology, clear results that the product is commercially sterile and signature of QA Analyst. COA with no conclusion however there are results for Mesophilic Thermophilic Aerobic and Mesophilic Thermophilic Anaerobic, C. botulinum and spore-forming microorganisms.	COA does not reflect complete Microbiological parameters, no methodology, clear results that the product is commercially sterile and signature of QA Analyst. COA with no conclusion and no results for Mesophilic Thermophilic Aerobic and Mesophilic Thermophilic Anaerobic, C. botulinum and spore-forming microorganisms.	FDA Circular 2013-010
	COA must be signed/verified by competent technical staff/QA Analyst/Manager, product description/name, specifications, method of analysis/methodology and batch code/ expiry date/ manufacturing date reflecting the specific/actual results of analysis for the required parameters of Pasteurized Milk	Coliforms Salmonella Listeria monocytogenes Psychrotrophic bacteria SPC/APC	10^2 0 0 10 $5x10^4$	COA must reflect the complete Microbiological parameters required and with methodology, results and signature of QA Analyst. TPC is considered in lieu of SPC/APC results.	COA does not reflect complete Microbiological parameters and no methodology, results and signature of QA Analyst. Test results does not conform to acceptable levels.	FDA Circular 2013-010

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ANNEX D. REFERENCE GUIDE TO STAKEHOLDERS TO ASSESS COMPLIANCE OF SUBMITTED DOCUMENTS AS COMPLETE REQUIREMENTS FOR PRODUCT REGISTRATION

HIGH RISK FOOD PRODUCTS						
FOOD CATEGORY	**REQUIREMENTS**	**STANDARDS**		**FOR APPROVAL**	**GROUNDS FOR DENIAL**	**BASIS**
		PARAMETERS	**ACCEPTABLE LEVEL**			
2. HRA1b. DAIRY-BASED DRINKS, FLAVORED AND/OR FERMENTED	COA must be signed/verified by competent technical staff/QA Analyst/Manager, product description/name, specifications, method of analysis/methodology and batch code/ expiry date/ manufacturing date reflecting the specific/actual results of analysis for the required parameters of Liquid Milk (evaporated & ready to drink)-UHT/Sterilized	Commercial Sterility	Commercially Sterile	COA must reflect complete Microbiological parameters required and with methodology, clear results that the product is commercially sterile and signature of QA Analyst. COA with no conclusion however there are results for Mesophilic Thermophilic Areobic and Mesophilic Thermophilic Anaerobic, C. botulinum and spore-forming microorganisms.	COA does not reflect complete Microbiological parameters, no methodology, clear results that the product is commercially sterile and signature of QA Analyst COA with no conclusion and no results for Mesophilic Thermophilic Areobic and Mesophilic Thermophilic Anaerobic, C. botulinum and spore-forming microorganisms.	FDA Circular 2013-010
	COA must be signed/verified by competent technical staff/QA Analyst/Manager, product description/name, specifications, method of analysis/methodology and batch code/ expiry date/ manufacturing date reflecting the specific/actual results of analysis for the required parameters of Pasteurized Milk	Coliforms Salmonella Listeria monocytogenes Psychrotrophic bacteria SPC/APC	10^2 0 0 10 $5x10^4$	COA must reflect the complete Microbiological parameters required and with methodology, results and signature of QA Analyst. TPC is considered in lieu of SPC/APC results.	COA does not reflect complete Microbiological parameters and no methodology, results & signature of QA Analyst. Test results does not conform to acceptable levels.	FDA Circular 2013-010

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ANNEX D. REFERENCE GUIDE TO STAKEHOLDERS TO ASSESS COMPLIANCE OF SUBMITTED DOCUMENTS AS COMPLETE REQUIREMENTS FOR PRODUCT REGISTRATION

HIGH RISK FOOD PRODUCTS						
FOOD CATEGORY	**REQUIREMENTS**	**STANDARDS**		**FOR APPROVAL**	**GROUNDS FOR DENIAL**	**BASIS**
		PARAMETERS	**ACCEPTABLE LEVEL**			
2. HRA 1b. ***cont.***	COA must be signed/verified by competent technical staff/QA Analyst/Manager, product description/name, specifications, method of analysis/methodology and batch code/ expiry date/ manufacturing date reflecting the specific/actual results of analysis for the required parameters of Yogurt and Fermented Milk	S. aureus (coagulase+) Coliforms Salmonella Lactic Acid	10 10 0 -	COA must reflect the complete Microbiological parameters required and with methodology, results and signature of QA Analyst.	COA does not reflect complete Microbiological parameters and no methodology, results and signature of QA Analyst. Test results does not conform to acceptable levels.	
3. HRA3a. PASTEURIZED CREAM	COA must be signed/verified by competent technical staff/QA Analyst/Manager, product description/name, specifications, method of analysis/methodology and batch code/ expiry date/ manufacturing date reflecting the specific/actual results of analysis for the required parameters of Pasteurized Cream	Coliforms Salmonella Listeria monocytogenes Psychrotrophic bacteria SPC/APC	10^2 0 0 10 $5x10^4$	COA must reflect the complete Microbiological parameters required and with methodology, results and signature of QA Analyst. TPC is considered in lieu of SPC/APC results.	COA does not reflect complete Microbiological parameters and no methodology, results and signature of QA Analyst. Test results does not conform to acceptable levels.	FDA Circular 2013-010

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4. HRA3b. STERILIZED AND UHT CREAMS, WHIPPING AND WHIPPED CREAMS, AND REDUCED FAT CREAMS (PLAIN)	COA must be signed/verified by competent technical staff/QA Analyst/Manager, product description/name, specifications, method of analysis/methodology and batch code/ expiry date/ manufacturing date reflecting the specific/actual results of analysis for the required parameters of Cream (UHT/Sterilized)	Commercial Sterility	Commercially Sterile	COA must reflect complete Microbiological parameters required and with methodology, clear results that the product is commercially sterile and signature of QA Analyst. COA with no conclusion however there are results for Mesophilic Thermophilic Areobic and Mesophilic Thermophilic Anaerobic, C. botulinum and spore-forming microorganisms.	COA does not reflect complete Microbiological parameters, no methodology, clear results that the product is commercially sterile and signature of QA Analyst COA with no conclusion and no results for Mesophilic Thermophilic Areobic and Mesophilic Thermophilic Anaerobic, C. botulinum and spore-forming microorganisms.	FDA Circular 2013-010
5. UNRIPENED CHEESE	COA must be signed/verified by competent technical staff/QA Analyst/Manager, product description/name, specifications, method of analysis/methodology and batch code/ expiry date/ manufacturing date reflecting the specific/actual results of analysis for the required parameters of Cheese and Cheese (moisture > 39% & pH)	S. aureus (coagulase+) E. coli Coliforms Psychrotrophic bacteria Salmonella Listeria monocytogenes	10^2 11 11 10^2 0 0	COA must reflect the complete Microbiological parameters required and with methodology, results and signature of QA Analyst.	COA does not reflect complete Microbiological parameters and no methodology, results and signature of QA Analyst. Test results does not conform to acceptable levels.	FDA Circular 2013-010
	COA must be signed/verified by competent technical staff/QA Analyst/Manager, product description/name, specifications, method of analysis/methodology and batch code/ expiry date/ manufacturing date reflecting the specific/actual results of analysis for the required parameters of All Raw Milk Cheese:	Campylobacter Salmonella Listeria monocytogenes S. aureus (coagulase+)	0 0 0 10^2	COA must reflect the complete Microbiological parameters required and with methodology, results and signature of QA Analyst.	COA does not reflect complete Microbiological parameters and no methodology, results and signature of QA Analyst. Test results does not conform to acceptable levels.	FDA Circular 2013-010

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	Certificate of Analysis for Fat in Dry Matter and Moisture Content	a) Cheddar b) Pasteurized Process (PP) Cheese c) PP Cheese Food d) PP Cheese Spread e) Cream Cheese f) Cottage Cheese g) Low Fat Cottage Cheese	*Fat (min) Dry basis* 50% 47% 23% 20% 33% 4% 0.5 to 2%	*Moisture (max)* 39% 43% 44% 55% 55% 80% 82.5%	Result of COA must conform to the specified amount of Fat in Dry Matter and Moisture Content.	Result of COA did not conform to the specified amount of Fat in Dry Matter and Moisture Content.	Administrative Order No. 200-A s. 1973
6. PLAIN PROCESSED CHEESE	COA must be signed/verified by competent technical staff/QA Analyst/Manager, product description/name, specifications, method of analysis/methodology and batch code/ expiry date/ manufacturing date reflecting the specific/actual results of analysis for the required parameters of Processed Cheese Spread	S. aureus (coagulase+) Coliforms SPC/APC	10 10 10^4		COA must reflect the complete Microbiological parameters required and with methodology, results and signature of QA Analyst. TPC is considered in lieu of SPC/APC results.	COA does not reflect complete Microbiological parameters and no methodology, results and signature of QA Analyst. Test result does not conform to acceptable levels.	FDA Circular 2013-010
7. FLAVORED PROCESSED CHEESE	COA must be signed/verified by competent technical staff/QA Analyst/Manager, product description/name, specifications, method of analysis/methodology and batch code/ expiry date/ manufacturing date reflecting the specific/actual results of analysis for the required parameters of Processed Cheese Spread	S. aureus (coagulase+) Coliforms SPC/APC	10 10 10^4		COA must reflect the complete Microbiological parameters required and with methodology, results and signature of QA Analyst. TPC is considered in lieu of SPC/APC results.	COA does not reflect complete Microbiological parameters and no methodology, results and signature of QA Analyst. Test result does not conform to acceptable levels.	FDA Circular 2013-010

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8. DAIRY BASED DESSERT (e.g. Yogurt)	COA must be signed/verified by competent technical staff/QA Analyst/Manager, product description/name, specifications, method of analysis/methodology and batch code/ expiry date/ manufacturing date reflecting the specific/actual results of analysis for the required parameters of Yogurt and Fermented Milk	S. aureus (coagulase+) Coliforms Salmonella Lactic Acid (Required minimum level $\geq 10^{6}$)	10 10 0 -	COA must reflect the complete Microbiological parameters required and with methodology, results and signature of QA Analyst.	COA does not reflect complete Microbiological parameters and no methodology, results and signature of QA Analyst. Test result does not conform to acceptable levels	FDA Circular 2013-010
9. DAIRY BASED FROZEN DESSERT	COA must be signed/verified by competent technical staff/QA Analyst/Manager, product description/name, specifications, method of analysis/methodology and batch code/ expiry date/ manufacturing date reflecting the specific/actual results of analysis for the required parameters of Ice Cream & Sherbet (plain and flavored)	Coliforms Listeria monocytogenes Salmonella SPC/APC S. aureus (coagulase+)	10 0 0 10^{4} 10	COA must reflect the complete Microbiological parameters required and with methodology, results and signature of QA Analyst. TPC is considered in lieu of SPC/APC results.	COA does not reflect complete Microbiological parameters and no methodology, results and signature of QA Analyst. Test result does not conform to acceptable levels	FDA Circular 2013-010
	COA must be signed/verified by competent technical staff/QA Analyst/Manager, product description/name, specifications, method of analysis/methodology and batch code/ expiry date/ manufacturing date reflecting the specific/actual results of analysis for the required parameters of Ice Cream with added ingredients (nuts, fruits, cocoa etc.)	Coliforms S. aureus (coagulase+) Salmonella SPC/APC Listeria monocytogenes	10 10 0 $5x10^{4}$ 0	COA must reflect the complete Microbiological parameters required and with methodology, results and signature of QA Analyst. TPC is considered in lieu of SPC/APC results.	COA does not reflect complete Microbiological parameters and no methodology, results and signature of QA Analyst. Test result does not conform to acceptable levels	FDA Circular 2013-010

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10. DRIED FRUIT	COA must be signed/verified by competent technical staff/QA Analyst/Manager, product description/name, specifications, method of analysis/methodology and batch code/ expiry date/ manufacturing date reflecting the specific/actual results of analysis for the required parameters of Sun Dried Fruits	Molds Osmophilic Yeast E.coli	10^2 10 3	COA must reflect the complete Microbiological parameters required and with methodology, results and signature of QA Analyst.	COA does not reflect complete Microbiological parameters and no methodology, results and signature of QA Analyst. Test result does not conform to acceptable levels	FDA Circular 2013-010
11. DRIED VEGETABLE	COA must be signed/verified by competent technical staff/QA Analyst/Manager, product description/name, specifications, method of analysis/methodology and batch code/ expiry date/ manufacturing date reflecting the specific/actual results of analysis for the required parameters of Dried Vegetable	E.coli	110	COA must reflect the complete Microbiological parameters required and with methodology, results and signature of QA Analyst.	COA does not reflect complete Microbiological parameters and no methodology, results and signature of QA Analyst. Test result does not conform to acceptable levels	FDA Circular 2013-010
12. CHOCOLATE WITH NUTS	COA must be signed/verified by competent technical staff/QA Analyst/Manager, product description/name, specifications, method of analysis/methodology and batch code/ expiry date/ manufacturing date reflecting the specific/actual results of analysis for the required parameters of Chocolate Products	Molds Salmonella Coliforms SPC/APC	10^2 0 1.8 10^4	COA must reflect the complete Microbiological parameters required and with methodology, results and signature of QA Analyst. TPC is considered in lieu of SPC/APC results.	COA does not reflect complete Microbiological parameters and no methodology, results and signature of QA Analyst. Test result does not conform to acceptable levels	FDA Circular 2013-010

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13. HRF1. FINE BAKERY PRODUCTS WITH FILLINGS	COA must be signed/verified by competent technical staff/QA Analyst/Manager, product description/name, specifications, method of analysis/methodology and batch code/ expiry date/ manufacturing date reflecting the specific/actual results of analysis for the required parameters of Baked Goods (microbiologically sensitive types e.g. containing eggs & dairy products)	S. aureus (coagulase+), cfu/g MYC, cfu/g SPC/APC, cfu/g, Coliforms, cfu/g	10^2 10^2 10^4 50	COA must reflect the complete Microbiological parameters required and with methodology, results and signature of QA Analyst. TPC is considered in lieu of SPC/APC results.	COA does not reflect complete Microbiological parameters and no methodology, results and signature of QA Analyst. . Test result does not conform to acceptable levels	FDA Circular 2013-010
	COA must be signed/verified by competent technical staff/QA Analyst/Manager, product description/name, specifications, method of analysis/methodology and batch code/ expiry date/ manufacturing date reflecting the specific/actual results of analysis for the required parameters of Coated or Filled, Dried Shelf-Stable Biscuits.	Coliforms, MPN/g Salmonella /25g	3 0	COA must reflect the complete Microbiological parameters required and with methodology, results and signature of QA Analyst.	COA does not reflect complete Microbiological parameters and no methodology, results and signature of QA Analyst. Test result does not conform to acceptable levels	FDA Circular 2013-010
HRB2. VEGETABLE, SEAWEED AND NUT AND SEED-PUREES, SPREAD	COA must be signed/verified by competent technical staff/QA Analyst/Manager, product description/name, specifications, method of analysis/methodology and batch code/ expiry date/ manufacturing date reflecting the specific/actual results of analysis for the required parameters of Peanut Butter & Other Nut Spreads:	Salmonella/25g	0	COA must reflect the complete Microbiological parameters required and with methodology, results and signature of QA Analyst.	COA does not reflect complete Microbiological parameters and no methodology, results and signature of QA Analyst. Test result does not conform to acceptable levels	FDA Circular 2013-010

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ANNEX D. REFERENCE GUIDE TO STAKEHOLDERS TO ASSESS COMPLIANCE OF SUBMITTED DOCUMENTS AS COMPLETE REQUIREMENTS FOR PRODUCT REGISTRATION

HRG1a./HRG2a. HEAT-TREATED PROCESSED MEAT, POULTRY AND GAME PRODUCTS (CANNED)	COA must be signed/verified by competent technical staff/QA Analyst/Manager, product description/name, specifications, method of analysis/methodology and batch code/ expiry date/ manufacturing date reflecting the specific/actual results of analysis for the required parameters of Meat Products in Hermetically Sealed Containers	Commercial Sterility	Commercially Sterile	Submitted COA with methodology, reflecting the complete parameters, with results and signature of the QA analyst/electronically signed. Submitted Incubation Monitoring Records with conclusion: Commercially Sterile Submitted COA for Mesophilic Thermophilic Aerobic and Mesophilic Thermophilic Anaerobic, C. botulinum and spore-forming microorganisms with conclusion.	Non-submission of COA. Submitted COA is incomplete (no methodology, incomplete parameters/nutrients, no results, no signature of the QA Analyst. Submitted document is only product specifications and not COA.	FDA Circular 2013-010
	Certificate of Analysis for Nitrate and Nitrite Content (if utilized) based on Administrative Order No. 154 s. 1971 and Bureau Circular 2006-016.	Nitrate Content Nitrite Content	Not more than 500 ppm Not more than 200 ppm	Submitted COA for Nitrate/Nitrite with methodology, reflecting the complete parameters, with results and signature of the QA analyst.	Non-submission of COA for Nitrate/Nitrite. Submitted COA is incomplete (no methodology, incomplete parameters/nutrients, no results, no signature of the QA Analyst. Submitted document is only product specifications and not COA	Administrative Order No. 154 s. 1971 and Bureau Circular 2006-016.

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HRG2b. FROZEN PROCESSED MEAT, POULTRY AND GAME PRODUCTS (NUGGETS, PATTIES, DUMPLINGS, SALAMI, MEAT LOAF, HOTDOG)	COA must be signed/verified by competent technical staff/QA Analyst/Manager, product description/name, specifications, method of analysis/methodology and batch code/ expiry date/ manufacturing date reflecting the specific/actual results of analysis for the required parameters of Cold Cuts, Frozen & Chilled Hotdogs	E. coli MPN/g Salmonella/25g S. aureus (coagulase +) cfu/g *SPC/APC cfu/g	1.8 0 10^2 10^5	Submitted COA with methodology, reflecting the complete parameters, with results and signature of the QA analyst. *-*TPC is considered in lieu of SPC/APC*	Non-submission of COA. Submitted COA is incomplete (no methodology, incomplete parameters/nutrients, no results, no signature of the QA Analyst. Submitted document is only product specifications and not COA.	FDA Circular 2013-010
	Certificate of Analysis for Nitrate and Nitrite Content (if utilized) based on Administrative Order No. 154 s. 1971 and Bureau Circular 2006-016.	Nitrate Content Nitrite Content	Not more than 500 ppm Not more than 200 ppm	Submitted COA for Nitrate/Nitrite with methodology, reflecting the complete parameters, with results and signature of the QA analyst.	Non-submission of COA for Nitrate/Nitrite. Submitted COA is incomplete (no methodology, incomplete parameters/nutrients, no results, no signature of the QA Analyst. Submitted document is only product specifications and not COA	Administrative Order No. 154 s. 1971 and Bureau Circular 2006-016.
HRH1A. FROZEN FISH, FISH FILLETS AND FISH PRODUCTS.	COA must be signed/verified by competent technical staff/QA Analyst/Manager, product description/name, specifications, method of analysis/methodology and batch code/ expiry date/ manufacturing date reflecting the specific/actual results of analysis for the required parameters of Fresh Frozen Fish	E. coli MPN/g S. aureus (coagulase +) cfu/g V. parahaemolyticus cfu/g Salmonella/25g *SPC/APC cfu/g	11 10^3 10^2 0 5×10^5	Submitted COA with methodology, reflecting the complete parameters, with results and signature of the QA analyst. **TPC is considered in lieu of SPC/APC*	Non-submission of COA. Submitted COA is incomplete (no methodology, incomplete parameters/nutrients, no results, no signature of the QA Analyst. Submitted document is only product specifications and not COA.	FDA Circular 2013-010

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HRH1B. FROZEN BATTERED FISH, FISH FILLETS AND FISH PRODUCTS, INCLUDING MOLLUSCS, CRUSTACEANS AND ECHINODERMS	COA must be signed/verified by competent technical staff/QA Analyst/Manager, product description/name, specifications, method of analysis/methodology and batch code/ expiry date/ manufacturing date reflecting the specific/actual results of analysis for the required parameters of Pre-Cooked Breaded Fish	E. coli MPN/g S. aureus (coagulase +) cfu/g *SPC/APC cfu/g	11 10^3 5×10^5	Submitted COA with methodology, reflecting the complete parameters, with results and signature of the QA analyst. **TPC is considered in lieu of SPC/APC*	Non-submission of COA. Submitted COA is incomplete (no methodology, incomplete parameters/nutrients, no results, no signature of the QA Analyst. Submitted document is only product specifications and not COA.	FDA Circular 2013-010
HRH1DII. COOKED MOLLUSCS, CRUSTACEANS AND ECHINODERMS	COA must be signed/verified by competent technical staff/QA Analyst/Manager, product description/name, specifications, method of analysis/methodology and batch code/ expiry date/ manufacturing date reflecting the specific/actual results of analysis for the required parameters of Frozen Cooked Crustaceans	E. coli MPN/g S. aureus (coagulase +) cfu/g V. parahaemolyticus cfu/g Salmonella/25g *SPC/APC cfu/g	11 10^3 10^2 0 5×10^5	Submitted COA with methodology, reflecting the complete parameters, with results and signature of the QA analyst. **TPC is considered in lieu of SPC/APC*	Non-submission of COA. Submitted COA is incomplete (no methodology, incomplete parameters/nutrients, no results, no signature of the QA Analyst. Submitted document is only product specifications and not COA.	FDA Circular 2013-010
HRH2. FULLY PRESERVED, INCLUDING CANNED OR FERMENTED FISH AND FISH PRODUCTS	COA must be signed/verified by competent technical staff/QA Analyst/Manager, product description/name, specifications, method of analysis/methodology and batch code/ expiry date/ manufacturing date reflecting the specific/actual results of analysis for the required parameters of Fish & Shellfish Products in Hermetically Sealed Containers (thermally processed)	Commercial Sterility	Commercially Sterile	Submitted COA with methodology, reflecting the complete parameters, with results and signature of the QA analyst/electronically signed. Submitted Incubation Monitoring Records with conclusion: Commercially Sterile Submitted COA for Mesophilic Thermophilic Aerobic and Mesophilic Thermophilic Anaerobic, C. botulinum and spore-forming microorganisms with conclusion.	Non-submission of COA. Submitted COA is incomplete (no methodology, incomplete parameters/nutrients, no results, no signature of the QA Analyst. Submitted document is only product specifications and not COA.	FDA Circular 2013-010

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ANNEX D. REFERENCE GUIDE TO STAKEHOLDERS TO ASSESS COMPLIANCE OF SUBMITTED DOCUMENTS AS COMPLETE REQUIREMENTS FOR PRODUCT REGISTRATION

HRH2. FULLY PRESERVED, INCLUDING CANNED OR FERMENTED FISH AND FISH PRODUCTS (BAGOONG (FISH & SHRIMP)	COA must be signed/verified by competent technical staff/QA Analyst/Manager, product description/name, specifications, method of analysis/methodology and batch code/ expiry date/ manufacturing date reflecting the specific/actual results of analysis for the required parameters.	Total Solid Protein NaCl	<u>*Fish*</u> not less than 40% not less than 12.5% not less than 20% and not more than 25%	<u>*Shrimp*</u> not less than 35% not less than 10% not less than 20% and not more than 25%	Submitted COA with methodology, reflecting the complete parameters, with results and signature of the QA analyst.	Non-submission of COA. Submitted COA is incomplete (no methodology, incomplete parameters/nutrients, no results, no signature of the QA Analyst. Submitted document is only product specifications and not COA.	Administrative Order No. 128 s. 1970
HRH2. FULLY PRESERVED, INCLUDING CANNED OR FERMENTED FISH AND FISH PRODUCTS (BAGOONG (COOKED)	COA must be signed/verified by competent technical staff/QA Analyst/Manager, product description/name, specifications, method of analysis/methodology and batch code/ expiry date/ manufacturing date reflecting the specific/actual results of analysis for the required parameters of Fish & Shellfish Products in Hermetically Sealed Containers (thermally processed)	Commercial Sterility	Commercially Sterile		Submitted COA with methodology, reflecting the complete parameters, with results and signature of the QA analyst/electronically signed. Submitted Incubation Monitoring Records with conclusion: Commercially Sterile Submitted COA for Mesophilic Thermophilic Aerobic and Mesophilic Thermophilic Anaerobic, C. botulinum and spore-forming microorganisms with conclusion.	Non-submission of COA. Submitted COA is incomplete (no methodology, incomplete parameters/nutrients, no results, no signature of the QA Analyst. Submitted document is only product specifications and not COA.	FDA Circular 2013-010
HRIA. LIQUID EGG PRODUCTS	COA must be signed/verified by competent technical staff/QA Analyst/Manager, product description/name, specifications, method of analysis/methodology and batch code/ expiry date/ manufacturing date reflecting the specific/actual results of analysis for the required parameters of Pasteurized Egg Products (Liquid, Frozen, Dried)	Coliforms cfu/g Salmonella/25g YMC cfu/g (for dried products) *SPC/APC cfu/g	10 0 10 2.5×10^4		Submitted COA with methodology, reflecting the complete parameters, with results and signature of the QA analyst. **TPC is considered in lieu of SPC/APC*	Non-submission of COA. Submitted COA is incomplete (no methodology, incomplete parameters/nutrients, no results, no signature of the QA Analyst. Submitted document is only product specifications and not COA.	FDA Circular 2013-010

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ANNEX D. REFERENCE GUIDE TO STAKEHOLDERS TO ASSESS COMPLIANCE OF SUBMITTED DOCUMENTS AS COMPLETE REQUIREMENTS FOR PRODUCT REGISTRATION

HIGH RISK FOOD PRODUCTS								
FOOD CATEGORY	REQUIREMENTS	STANDARDS				FOR APPROVAL	GROUNDS FOR DENIAL	BASIS
		PARAMETERS	MIN ACCEPTABLE LEVEL	MAX ACCEPTABLE LEVEL	GUL			
HRJ1. INFANT FORMULA & FORMULAS FOR SPECIAL MEDICAL PURPOSED INTENDED FOR INFANTS (POWDER) eg. Formulae for special medical purposes intended for infants are specially processed or formulated and presented for the dietary management of infants and may be used only under medical supervision. Infant formulae: A human milk substitute for infants (aged no more than 12 months) that is specifically formulated to provide the sole source of nutrition during the first months of life up to the introduction of	COA for Energy, Protein, Total Fat, Linolenic Acid, Total Carbohydrates per 100 kcal, Vitamins and Minerals, Trace Minerals and Other Substances, Lauric/Mystiric/Trans Fatty Acids, Optional Ingredients-Taurine, DHA and Contaminants (ex. Lead)	Energy	not less than 60 kcal (250kJ) per 100 mL	not more than 70 kcal (295 kJ) of energy	-	Submitted COA with methodology, reflecting the complete parameters, with results meeting the prescribed level per nutrient and signature of the QA analyst.	Non-submission of COA. Submitted COA is incomplete (no methodology, incomplete parameters/nutrients, no results, no signature of the QA Analyst Submitted document is only product specifications and not COA Results in the submitted COA does not meet the prescribed level	Codex Stan 72-1981 Rev. 2007
		Protein	1.8g/100 kcal or 0.45g/100 kJ	3.0g/100 kcal or 0.7g/100 kJ	-			
		Total Fat	4.4g/100 kcal or 10.05g/100 kJ	6.0g/100 kcal or 1.4g/100 kJ	-			
		Linoleic Acid	300mg/100 kcal or 70g/100 kJ	-	1400mg/100 kcal or 330mg/100 kJ			
		a-Linolenic Acid	50mg/100 kcal or 12mg/100 kJ	N.S.	-			
		Total Carbohydrates	9.0g/100 kcal or 2.2g/100 kJ	14.0g/100 kcal or 3.3g/100 kJ	-			
		Vitamin A	60µg RE/100 kcal or 14 µg RE/100 kJ	180µg RE/100 kcal or 43 µg RE/100 kJ	-			
		Vitamin D	1µg/100 kcal or 0.25 µg/100 kJ	2.5µg/100 kcal or 0.6 µg/100 kJ	-			
		Vitamin E	0.5 mg α-TE/100 kcal or 0.12 mg α-TE/100 kJ	-	5 mg α-TE/100 kcal or 1.2 mg α-TE/100 kJ			
		Vitamin K	4µg/100 kcal or 1µg/100 kJ	-	27µg/100 kcal or 6.5µg/100 kJ			
		Thiamin	60µg/100 kcal or 14µg/100 kJ	-	300µg/100 kcal or 72µg/100 kJ			
		Riboflavin	80µg/100 kcal or 19µg/100 kJ	-	500µg/100 kcal or 119µg/100 kJ			
		Niacin	300µg/100 kcal or 70µg/100 kJ	-	1500µg/100 kcal or 360µg/100 kJ			
		Vitamin B6	35µg/100 kcal or 8.5µg/100 kJ	-	175µg/100 kcal or 45µg/100 kJ			
		Vitamin B12	0.1µg/100 kcal or 0.025µg/100 kJ	-	1.5 µg/100 kcal or 0.36µg/100 kJ			
		Pantothenic Acid	400µg/100 kcal or	-	2000µg/100 kcal or			

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HIGH RISK FOOD PRODUCTS								
FOOD CATEGORY	REQUIREMENTS	STANDARDS				FOR APPROVAL	GROUNDS FOR DENIAL	BASIS
		PARAMETERS	MIN ACCEPTABLE LEVEL	MAX ACCEPTABLE LEVEL	GUL			
appropriate complementary feeding. **HRJ1. INFANT**			96µg/100 kJ		478µg/100 kJ			
		Folic Acid	10µg/100 kcal or 2.5µg/100 kJ	-	50µg/100 kcal or 12µg/100 kJ			
		Vitamic C	10µg/100 kcal or 2.5µg/100 kJ	-	70µg/100 kcal or 17µg/100 kJ			
		Biotin	1.5µg/100 kcal or 0.4µg/100 kJ	-	10µg/100 kcal or 2.4µg/100 kJ			
		Iron	0.45mg/100 kcal or 0.1mg/100 kJ	-	-			
		Calcium	50mg/100 kcal or 12mg/100 kJ	-	140mg/100 kcal or 35mg/100 kJ			
		Phosphorus	25mg/100 kcal or 6mg/100 kJ	-	100mg/100 kcal or 24mg/100 kJ			
		Magnesium	5mg/100 kcal or 1.2mg/100 kJ	-	15mg/100 kcal or 3.6mg/100 kJ			
		Sodium	20mg/100 kcal or 5mg/100 kJ	60mg/100 kcal or 14mg/100 kJ	-			
		Chloride	50mg/100 kcal or 12mg/100 kJ	160mg/100 kcal or 38mg/100 kJ	-			
		Potassium	60mg/100 kcal or 14mg/100 kJ	180mg/100 kcal or 43mg/100 kJ	-			
		Manganese	1µg/100 kcal or 0.25µg/100 kJ	-	100µg/100 kcal or 24µg/100 kJ			
		Iodine	10µg/100 kcal or 2.5µg/100 kJ	-	60µg/100 kcal or 14µg/100 kJ			
		Selenium	1µg/100 kcal or 0.24µg/100 kJ	-	9µg/100 kcal or 2.2µg/100 kJ			
		Copper	35µg/100 kcal or 8.5µg/100 kJ	-	120µg/100 kcal or 29µg/100 kJ			
		Zinc	0.5mg/100 kcal or 0.12mg/100 kJ	-	1.5mg/100 kcal or 0.36mg/100 kJ			
		Choline	7mg/100 kcal or	-	50mg/100 kcal or			

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HIGH RISK FOOD PRODUCTS								
FOOD CATEGORY	REQUIREMENTS	STANDARDS				FOR APPROVAL	GROUNDS FOR DENIAL	BASIS
		PARAMETERS	MIN. ACCEPTABLE LEVEL	MAX. ACCEPTABLE LEVEL	GUL			
FORMULA & FORMULAS FOR SPECIAL MEDICAL PURPOSED INTENDED FOR INFANTS (POWDER) ***cont.***			1.7mg/100 kJ		12mg/100 kJ			
		Myo-Inositol	4mg/100 kcal or 1mg/100 kJ	-	40mg/100 kcal or 9.5mg/100 kJ			
		L-Carnitine	1.2mg/100 kcal or 0.3mg/100 kJ	N S	-			
		Taurine (Optional Ingredient)	-	12mg/100 kcal or 3mg/100 kJ	-			
		Total Nucleotides (Optional Ingredient)	-	-	-			
		Docosahexaenoic Acid (% of Fatty Acids)	-	-	0 5			
		Fluoride	-	100µg/100 kcal or 24µg/100 kJ	-			

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HIGH RISK FOOD PRODUCTS					
FOOD CATEGORY	**REQUIREMENTS**	**STANDARDS/ ADDITIONAL LABELLING REQUIREMENTS**	**FOR APPROVAL**	**GROUNDS FOR DENIAL**	**BASIS**
HRJ1. INFANT FORMULA & FORMULAS FOR SPECIAL MEDICAL PURPOSED INTENDED FOR INFANTS (POWDER) ***cont.***	Clear and complete loose labels or artworks compliant with Department Circular 2008-0006 and RIRR of EO 51.	*PRIMARY MESSAGES:* 1.ENGLISH: **BREASTMILK IS THE BEST FOR BABIES UP TO 2 YEARS OF AGE AND BEYOND** FILIPINO: **ANG GATAS NG INA ANG PINAKAMABUTI PARA SA BATA HANGGANG 2 TAON O HIGIT PA** 2.ENGLISH: **IMPORTANT NOTICE: THERE IS NO SUBSTITUTE FOR BREASTMILK** FILIPINO: **MAHALAGANG PAALALA: WALANG ANUMANG GATAS ANG PWEDENG IPALIT SA GATAS NG INA** 3. a. ENGLISH: **THIS PRODUCT MAY CONTAIN PATHOGENIC MICROORGANISMS AND MUST BE PREPARED AND USED APPROPRIATELY** FILIPINO: **ANG PRODUKTONG ITO AY MAARING MAGKAROON NG MIKROBYO NA NAGDUDULOT NG SAKIT AT DAPAT IHANDA AT GAMITIN NG TAMA** Or b. ENGLISH: **THERE IS LIKELIHOOD THAT PATHOGENIC MICROORGANISMS WILL BE IN THIS PRODUCT WHEN IT IS PREPARED AND USED INAPPROPRIATELY** FILIPINO: **ANG PRODUKTONG ITO AY MAARING MAGKAROON NG MIKROBYO NA NAGDUDULOT NG SAKIT KAPAG HINDI TAMA ANG PAGHAHANDA AT PAG-GAMIT** - These three (3) messages shall be printed **bold** in all CAPITAL letters at the center lowermost level of the principal display panel, the font type is Arial and font size of which must be one-third (1/3) of the size of the biggest letter on the label. - Message must be readable and font color must be in contrast with the background. Additional messages: **"Infants six months onwards should be given fresh, indigenous, and natural foods in combination with continued breastfeeding"** - This message shall be printed bold and prominent on the lowermost level of the information display panel of the label	Submitted product label/artwork reflecting the compete mandatory labeling information, primary and secondary messages as per Codex Stan 72-1981 Rev. 2007 and Department Circular 2008-0006 and IRR of EO 51.	Non-submission of clear, readable label or artwork.	Codex Stan 72-1981 Rev. 2007 Department Circular 2008-0006 and RIRR of EO 51
HRJ1. INFANT					

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HIGH RISK FOOD PRODUCTS					
FOOD CATEGORY	**REQUIREMENTS**	**STANDARDS/ ADDITIONAL LABELLING REQUIREMENTS**	**FOR APPROVAL**	**GROUNDS FOR DENIAL**	**BASIS**
FORMULA & FORMULAS FOR SPECIAL MEDICAL PURPOSED INTENDED FOR INFANTS (POWDER) *cont.*		*SECONDARY MESSAGES*: - The information display panel of each container/label shall contain the following messages in both English and Filipino languages: - ENGLISH: **The Use of Infant Formula/Milk Supplements must only be upon the advice of a health professional** FILIPINO: **Ang paggamit ng gatas na ito ay dapat sang-ayon sa payo ng Doctor o health professional** ENGLISH: **The unnecessary and improper use of this product may be dangerous to your child's health.** FILIPINO: **Ang maling paggamit ng gatas na ito ay maaaring makasama sa kalusugan ng bata.** - These messages shall be printed **bold**, font type Arial and font size 1/6 size of the biggest letter at the uppermost level of the information display panel.			
	Scientific Studies indicating safety and benefits of the product for intended medical condition based on Codex Stan Codex Stan 72-1981 Rev. 2007. and Administrative Order 2014-0029.		Submitted clear, readable and complete Peer-reviewed or validated studies by third party organizations (with no conflict of interest) or published Scientific Study specific on the product being applied and its intended use.	Non-submission of clear, readable and complete Peer-reviewed or validated study by a third party or published Scientific Study specific on the product and its intended use. -Only one scientific study was submitted and this was sponsored by the applicant company without validation study from independent organization.	

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HIGH RISK FOOD PRODUCTS						
FOOD CATEGORY	**REQUIREMENTS**	**STANDARDS**		**FOR APPROVAL**	**GROUNDS FOR DENIAL**	**BASIS**
		PARAMETERS	**ACCEPTABLE LEVELS**			
HRJ1. INFANT FORMULA & FORMULAS FOR SPECIAL MEDICAL PURPOSED INTENDED FOR INFANTS (POWDER) ***cont.***	COA must be signed/verified by competent technical staff/QA Analyst/Manager, product description/name, specifications, method of analysis/methodology and batch code/ expiry date/ manufacturing date reflecting the specific/actual results of analysis for the required parameters of Powdered Infant Formula with or without added Lactic acid producing cultures	Cronobacter spp. Salmonella *SPC/APC Enterobacteriaceae	0/10g 0/25g $5x10^2$ cfu/g 0/10g	Submitted COA with methodology, reflecting the complete parameters, with results and signature of the QA analyst. *-*TPC is considered in lieu of SPC/APC*	Non-submission of COA. Submitted COA is incomplete (no methodology, incomplete parameters/nutrients, no results, no signature of the QA Analyst. Submitted document is only product specifications and not COA.	FDA Circular 2013-010

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HIGH RISK FOOD PRODUCTS

FOOD CATEGORY	REQUIREMENTS	STANDARDS				FOR APPROVAL	GROUNDS FOR DENIAL	BASIS
		PARAMETERS	MIN. ACCEPTABLE LEVEL	MAX. ACCEPTABLE LEVEL	GUL			
HRJ1. INFANT FORMULA & FORMULAS FOR SPECIAL MEDICAL PURPOSED INTENDED FOR INFANTS (LIQUID) Eg. Formulae for special medical purposes intended for infants are specially processed or formulated and presented for the dietary management of infants and may be used only under medical supervision. Infant formulae: A human milk substitute for infants (aged no more than 12 months) that is specifically formulated to provide the sole source of nutrition during the first months of life up to	Certificate of Analysis for Energy, Protein, Total Fat, Linolenic Acid, Total Carbohydrates per 100 kcal, Vitamins and Minerals, Trace Minerals and Other Substances, Lauric/Mystiric/Trans Fatty Acids, Optional Ingredients-Taurine, DHA and Contaminants (ex. Lead) based on Codex Stan 72-1981 Rev. 2007.	Energy	not less than 60 kcal (250kJ) per 100 mL	not more than 70 kcal (295 kJ) of energy	-	Submitted clear, readable Certificate of Analysis with methodology, reflecting the complete parameters, with results meeting the prescribed level per nutrient and signature of the QA analyst. Submitted clear, readable Certificate of Analysis with methodology, reflecting the complete parameters, with results meeting the prescribed level per nutrient and electronically signed.	Non-submission of Certificate of Analysis Submitted COA is unreadable Submitted COA is incomplete (no methodology, incomplete parameters/nutrients, no results, no signature of the QA Analyst Submitted document is only product specifications and not COA Results in the submitted COA does not meet the prescribed level	
		Protein	1.8g/100 kcal or 0.45g/100 kJ	3.0g/100 kcal or 0.7g/100 kJ	-			
		Total Fat	4.4g/100 kcal or 10.05g/100 kJ	6.0g/100 kcal or 1.4g/100 kJ	-			
		Linoleic Acid	300mg/100 kcal or 70g/100 kJ	-	1400mg/100 kcal or 330mg/100 kJ			
		a-Lenolenic Acid	50mg/100 kcal or 12mg/100 kJ	N.S.	-			
		Total Carbohydrates	9.0g/100 kcal or 2.2g/100 kJ	14.0g/100 kcal or 3.3g/100 kJ	-			
		Vitamin A	60µg RE/100 kcal or 14 µg RE/100 kJ	180µg RE/100 kcal or 43 µg RE/100 kJ	-			
		Vitamin D	1µg/100 kcal or 0.25 µg/100 Kj	2.5µg/100 kcal or 0.6 µg/100 kJ	-			
		Vitamin E	0.5 mg α-TE/100 kcal or 0.12 mg α-TE/100 kJ	-	5 mg α-TE/100 kcal or 1.2 mg α-TE/100 kJ			
		Vitamin K	4µg/100 kcal or 1µg/100 kJ	-	27µg/100 kcal or 6.5µg/100 kJ			
		Thiamin	60µg/100 kcal or 14µg/100 kJ	-	300µg/100 kcal or 72µg/100 kJ			
		Riboflavin	80µg/100 kcal or 19µg/100 kJ	-	500µg/100 kcal or 119µg/100 kJ			
		Niacin	300µg/100 kcal or 70µg/100 kJ	-	1500µg/100 kcal or 360µg/100 kJ			
		Vitamin B6	35µg/100 kcal or 8.5µg/100 kJ	-	175µg/100 kcal or 45µg/100 kJ			
		Vitamin B12	0.1µg/100 kcal or 0.025µg/100 kJ	-	1.5 µg/100 kcal or 0.36µg/100 kJ			

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HIGH RISK FOOD PRODUCTS								
FOOD CATEGORY	**REQUIREMENTS**	**STANDARDS**				**FOR APPROVAL**	**GROUNDS FOR DENIAL**	**BASIS**
		PARAMETERS	**MIN. ACCEPTABLE LEVEL**	**MAX. ACCEPTABLE LEVEL**	**GUL**			
the introduction of appropriate complementary feeding.		Pantothenic Acid	400µg/100 kcal or 96µg/100 kJ	-	2000µg/100 kcal or 478µg/100 kJ			
		Folic Acid	10µg/100 kcal or 2.5µg/100 kJ	-	50µg/100 kcal or 12µg/100 kJ			
		Vitamic C	10µg/100 kcal or 2.5µg/100 kJ	-	70µg/100 kcal or 17µg/100 kJ			
		Biotin	1.5µg/100 kcal or 0.4µg/100 kJ	-	10µg/100 kcal or 2.4µg/100 kJ			
		Iron	0.45mg/100 kcal or 0.1mg/100 kJ	-	-			
		Calcium	50mg/100 kcal or 12mg/100 kJ	-	140mg/100 kcal or 35mg/100 kJ			
		Phosphorus	25mg/100 kcal or 6mg/100 kJ	-	100mg/100 kcal or 24mg/100 kJ			
		Magnesium	5mg/100 kcal or 1.2mg/100 kJ	-	15mg/100 kcal or 3.6mg/100 kJ			
		Sodium	20mg/100 kcal or 5mg/100 kJ	60mg/100 kcal or 14mg/100 kJ	-			
		Chloride	50mg/100 kcal or 12mg/100 kJ	160mg/100 kcal or 38mg/100 kJ	-			
		Potassium	60mg/100 kcal or 14mg/100 kJ	180mg/100 kcal or 43mg/100 kJ	-			
		Manganese	1µg/100 kcal or 0.25µg/100 kJ	-	100µg/100 kcal or 24µg/100 kJ			
		Iodine	10µg/100 kcal or 2.5µg/100 kJ	-	60µg/100 kcal or 14µg/100 kJ			
		Selenium	1µg/100 kcal or 0.24µg/100 kJ	-	9µg/100 kcal or 2.2µg/100 kJ			
		Copper	35µg/100 kcal or 8.5µg/100 kJ	-	120µg/100 kcal or 29µg/100 kJ			
		Zinc	0.5mg/100 kcal or 0.12mg/100 kJ	-	1.5mg/100 kcal or 0.36mg/100 kJ			

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HIGH RISK FOOD PRODUCTS								
FOOD CATEGORY	**REQUIREMENTS**	**STANDARDS**				**FOR APPROVAL**	**GROUNDS FOR DENIAL**	**BASIS**
		PARAMETERS	**MIN. ACCEPTABLE LEVEL**	**MAX. ACCEPTABLE LEVEL**	**GUL**			
HRJ1. INFANT FORMULA & FORMULAS FOR SPECIAL MEDICAL PURPOSED INTENDED FOR INFANTS (LIQUID) ***Cont.***		Choline	7mg/100 kcal or 1.7mg/100 kJ	-	50mg/100 kcal or 12mg/100 kJ			
		Myo-Inositol	4mg/100 kcal or 1mg/100 kJ	-	40mg/100 kcal or 9.5mg/100 kJ			
		L-Carnitine	1.2mg/100 kcal or 0.3mg/100 kJ	N.S.	-			
		Taurine (Optional Ingredient)	-	12mg/100 kcal or 3mg/100 kJ	-			
		Total Nucleotides (Optional Ingredient)	-	-	-			
		Docosahexaenoic Acid (% of Fatty Acids)	-	-	0.5			
		Fluoride	-	100µg/100 kcal or 24µg/100 kJ	-			

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HIGH RISK FOOD PRODUCTS					
FOOD CATEGORY	**REQUIREMENTS**	**STANDARDS/ ADDITIONAL LABELLING REQUIREMENTS**	**FOR APPROVAL**	**GROUNDS FOR DENIAL**	**BASIS**
HRJ1. INFANT FORMULA & FORMULAS FOR SPECIAL MEDICAL PURPOSED INTENDED FOR INFANTS (LIQUID) ***Cont.***	Clear and complete loose labels or artworks compliant with Department Circular 2008-0006 and RIRR of EO 51.	*PRIMARY MESSAGES:* 1.ENGLISH: **BREASTMILK IS THE BEST FOR BABIES UP TO 2 YEARS OF AGE AND BEYOND** FILIPINO: **ANG GATAS NG INA ANG PINAKAMABUTI PARA SA BATA HANGGANG 2 TAON O HIGIT PA** 2.ENGLISH: **IMPORTANT NOTICE: THERE IS NO SUBSTITUTE FOR BREASTMILK** FILIPINO: **MAHALAGANG PAALALA: WALANG ANUMANG GATAS ANG PWEDENG IPALIT SA GATAS NG INA** 3. a. ENGLISH: **THIS PRODUCT MAY CONTAIN PATHOGENIC MICROORGANISMS AND MUST BE PREPARED AND USED APPROPRIATELY** FILIPINO: **ANG PRODUKTONG ITO AY MAARING MAGKAROON NG MIKROBYO NA NAGDUDULOT NG SAKIT AT DAPAT IHANDA AT GAMITIN NG TAMA** Or b. ENGLISH: **THERE IS LIKELIHOOD THAT PATHOGENIC MICROORGANISMS WILL BE IN THIS PRODUCT WHEN IT IS PREPARED AND USED INAPPROPRIATELY** FILIPINO: **ANG PRODUKTONG ITO AY MAARING MAGKAROON NG MIKROBYO NA NAGDUDULOT NG SAKIT KAPAG HINDI TAMA ANG PAGHAHANDA AT PAG-GAMIT** - These three (3) messages shall be printed **bold** in all CAPITAL letters at the center lowermost level of the principal display panel, the font type is Arial and font size of which must be one-third (1/3) of the size of the biggest letter on the label. - Message must be readable and font color must be in contrast with the background. Additional messages: **"Infants six months onwards should be given fresh, indigenous, and natural foods in combination with continued breastfeeding"** - This message shall be printed bold and prominent on the lowermost level of the information display panel of the label	Submitted product label/artwork reflecting the compete mandatory labeling information, primary and secondary messages as per Codex Stan 72-1981 Rev. 2007 and Department Circular 2008-0006 and IRR of EO 51.	Non-submission of clear, readable label or artwork.	Codex Stan 72-1981 Rev. 2007 Department Circular 2008-0006 and RIRR of EO 51

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HIGH RISK FOOD PRODUCTS					
FOOD CATEGORY	**REQUIREMENTS**	**STANDARDS/ ADDITIONAL LABELLING REQUIREMENTS**	**FOR APPROVAL**	**GROUNDS FOR DENIAL**	**BASIS**
HRJ1. INFANT FORMULA & FORMULAS FOR SPECIAL MEDICAL PURPOSED INTENDED FOR INFANTS (LIQUID) ***Cont.***		*SECONDARY MESSAGES*: - The information display panel of each container/label shall contain the following messages in both English and Filipino languages: - ENGLISH: **The Use of Infant Formula/Milk Supplements must only be upon the advice of a health professional** FILIPINO: **Ang paggamit ng gatas na ito ay dapat sang-ayon sa payo ng Doctor o health professional** ENGLISH: **The unnecessary and improper use of this product may be dangerous to your child's health.** FILIPINO: **Ang maling paggamit ng gatas na ito ay maaaring makasama sa kalusugan ng bata.** - These messages shall be printed **bold**, font type Arial and font size 1/6 size of the biggest letter at the uppermost level of the information display panel.			
	Scientific Studies indicating safety and benefits of the product for intended medical condition based on Codex Stan Codex Stan 72-1981 Rev. 2007. and Administrative Order 2014-0029.		Submitted clear, readable and complete Peer-reviewed or validated studies by third party organizations (with no conflict of interest) or published Scientific Study specific on the product being applied and its intended use.	Non-submission of clear, readable and complete Peer-reviewed or validated study by a third party or published Scientific Study specific on the product and its intended use. -Only one scientific study was submitted and this was sponsored by the applicant company without validation study from independent organization.	

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ANNEX D. REFERENCE GUIDE TO STAKEHOLDERS TO ASSESS COMPLIANCE OF SUBMITTED DOCUMENTS AS COMPLETE REQUIREMENTS FOR PRODUCT REGISTRATION

HIGH RISK FOOD PRODUCTS						
FOOD CATEGORY	**REQUIREMENTS**	**STANDARDS**		**FOR APPROVAL**	**GROUNDS FOR DENIAL**	**BASIS**
		PARAMETERS	**ACCEPTABLE LEVEL**			
HRJ1. INFANT FORMULA & FORMULAS FOR SPECIAL MEDICAL PURPOSED INTENDED FOR INFANTS (LIQUID) ***Cont.***	COA must be signed/verified by competent technical staff/QA Analyst/Manager, product description/name, specifications, method of analysis/methodology and batch code/ expiry date/ manufacturing date reflecting the specific/actual results of analysis for the required parameters of Infant Formula- Liquid (UHT/Sterilized) cultures	Commercial Sterility	Commercially Sterile	Submitted COA with methodology, reflecting the complete parameters, with results and signature of the QA analyst/electronically signed. Submitted Incubation Monitoring Records with conclusion: Commercially Sterile Submitted Certificate of Analysis for Mesophilic Thermophilic Aerobic and Mesophilic Thermophilic Anaerobic, C. botulinum and spore-forming microorganisms with conclusion.	Non-submission of COA. Submitted COA is incomplete (no methodology, incomplete parameters/nutrients, no results, no signature of the QA Analyst. Submitted document is only product specifications and not COA.	FDA Circular 2013-010

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ANNEX D. REFERENCE GUIDE TO STAKEHOLDERS TO ASSESS COMPLIANCE OF SUBMITTED DOCUMENTS AS COMPLETE REQUIREMENTS FOR PRODUCT REGISTRATION

HIGH RISK FOOD PRODUCTS							
FOOD CATEGORY	**REQUIREMENTS**	**STANDARDS**			**FOR APPROVAL**	**GROUNDS FOR DENIAL**	**BASIS**
		PARAMETERS	**MIN. ACCEPTABLE LEVEL**	**MAX. ACCEPTABLE LEVEL**			
HRJ1. FOLLOW-UP FORMULA/ MILK SUPPLEMENT **Eg.** Follow-up formulae: Food intended for use as a liquid part of the complementary feeding of infants (aged at least 6 months) and for young children (aged 1-3 years).	Certificate of Analysis for Energy, Protein, Total Fat, Linolenic Acid, Total Carbohydrates per 100 kcal, Vitamins and Minerals, Trace Minerals and Other Substances, Lauric/Mystiric/Trans Fatty Acids, Optional Ingredients-suitable for 6 months onwards and scientifically proven based on Codex Stan 156-1987.	Energy Content	not less than 60 kcal (or 250 kJ) per 100 mL	not more than 85 kcal (or 355 kJ) per 100 mL	Submitted COA with methodology, reflecting the complete parameters, with results meeting the prescribed level per nutrient and signature of the QA analyst. Submitted COA with methodology, reflecting the complete parameters, with results meeting the prescribed level per nutrient and electronically signed.	Non-submission of COA Submitted COA is incomplete (no methodology, incomplete parameters/nutrients, no results, no signature of the QA Analyst Submitted document is only product specifications and not COA Results in the submitted COA does not meet the prescribed level	Codex Stan 156-1987
		Protein	not less than 3.0g per 100 available calories (or 0.7 g per 100 available kilojoules)	not more than 5.5 g per 100 available calories (or 1.3 g per 100 available kilojoules)			
		Fat	not less than 3 g per 100 calories (or 0.7 g per 100 available kilojoules)	not more than 6g per 100 calories (or 1.4 g per 100 available kilojoules)			
		Linoleic Acid (in the form of a glyceride)	not less than 300 mg per 100 calories (or 71.7 mg per 100 available kilojoules)				
		Vitamin A	250 I.U. or 75 ug expressed as retinol per 100 available calories (or 60 I.U. or 18 ug expressed as retinol per 100 available kilojoules)	750 I.U. or 225 ug expressed as retinol per 100 available calories (or 180 I.U. or 54 ug expressed as retinol per 100 available kilojoules)			
		Vitamin D	40 I.U. or 1 ug per 100 available calories (or 10 I.U. or 0.25 ug per 100 available kilojoules)	120 I.U. or 3 ug per 100 available calories (or 30 I.U. or 0.75 ug per 100 available kilojoules)			
		Ascorbic Acid (Vitamin C)	8 mg per 100 available calories (or 1.9 mg per 100 available kilojoules)	N.S.			
		Thiamine (Vitamin B1)	40ug mg per 100 available calories (or 10ug per 100 available kilojoules)	N.S.			
		Riboflavin (Vitamin B2)	60 ug per 100 available calories (or 14 ug per 100 available kilojoules)	N.S.			
		Nicotinamide	250 ug per 100 available calories (or 60 ug per 100 available kilojoules)	N.S.			
		Vitamin 6	45 ug per 100 available calories (or 11 ug per 100 available kilojoules)	N.S.			
		Folic Acid	4 ug per 100 available calories (or 1 ug per 100 available kilojoules)	N.S.			
		Pantothenic Acid	300 ug per 100 available calories (or 70 ug per 100 available kilojoules)	N.S.			
HRJ1. FOLLOW-							

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ANNEX D. REFERENCE GUIDE TO STAKEHOLDERS TO ASSESS COMPLIANCE OF SUBMITTED DOCUMENTS AS COMPLETE REQUIREMENTS FOR PRODUCT REGISTRATION

HIGH RISK FOOD PRODUCTS					
FOOD CATEGORY	**REQUIREMENTS**	**STANDARDS/ ADDITIONAL LABELLING REQUIREMENTS**	**FOR APPROVAL**	**GROUNDS FOR DENIAL**	**BASIS**
HRJ1. FOLLOW-UP FORMULA/ MILK SUPPLEMENT *Cont.*	Clear and complete loose labels or artworks compliant with Department Circular 2008-0006 and RIRR of EO 51.	*PRIMARY MESSAGES:* 1.ENGLISH: **BREASTMILK IS THE BEST FOR BABIES UP TO 2 YEARS OF AGE AND BEYOND** FILIPINO: **ANG GATAS NG INA ANG PINAKAMABUTI PARA SA BATA HANGGANG 2 TAON O HIGIT PA** 2.ENGLISH: **IMPORTANT NOTICE: THERE IS NO SUBSTITUTE FOR BREASTMILK** FILIPINO: **MAHALAGANG PAALALA: WALANG ANUMANG GATAS ANG PWEDENG IPALIT SA GATAS NG INA** 3. a. ENGLISH: **THIS PRODUCT MAY CONTAIN PATHOGENIC MICROORGANISMS AND MUST BE PREPARED AND USED APPROPRIATELY** FILIPINO: **ANG PRODUKTONG ITO AY MAARING MAGKAROON NG MIKROBYO NA NAGDUDULOT NG SAKIT AT DAPAT IHANDA AT GAMITIN NG TAMA** Or b. ENGLISH: **THERE IS LIKELIHOOD THAT PATHOGENIC MICROORGANISMS WILL BE IN THIS PRODUCT WHEN IT IS PREPARED AND USED INAPPROPRIATELY** FILIPINO: **ANG PRODUKTONG ITO AY MAARING MAGKAROON NG MIKROBYO NA NAGDUDULOT NG SAKIT KAPAG HINDI TAMA ANG PAGHAHANDA AT PAG-GAMIT** - These three (3) messages shall be printed **bold** in all CAPITAL letters at the center lowermost level of the principal display panel, the font type is Arial and font size of which must be one-third (1/3) of the size of the biggest letter on the label. - Message must be readable and font color must be in contrast with the background. Additional messages: **"Infants six months onwards should be given fresh, indigenous, and natural foods in combination with continued breastfeeding"** - This message shall be printed bold and prominent on the lowermost level of the information display panel of the label	Submitted product label/artwork reflecting the compete mandatory labeling information, primary and secondary messages as per Codex Stan 72-1981 Rev. 2007 and Department Circular 2008-0006 and IRR of EO 51.	Non-submission of clear, readable label or artwork.	Codex Stan 72-1981 Rev. 2007 Department Circular 2008-0006 and RIRR of EO 51
HRJ1. FOLLOW-UP FORMULA/					

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ANNEX D. REFERENCE GUIDE TO STAKEHOLDERS TO ASSESS COMPLIANCE OF SUBMITTED DOCUMENTS AS COMPLETE REQUIREMENTS FOR PRODUCT REGISTRATION

HIGH RISK FOOD PRODUCTS							
FOOD CATEGORY	**REQUIREMENTS**	**STANDARDS**			**FOR APPROVAL**	**GROUNDS FOR DENIAL**	**BASIS**
		PARAMETERS	**MIN. ACCEPTABLE LEVEL**	**MAX. ACCEPTABLE LEVEL**			
UP FORMULA/ MILK SUPPLEMENT ***Cont.***		Vitamin B12	0.15 ug per 100 available calories (or 0.04 ug per 100 available kilojoules)	N.S.			
		Vitamin K1	4 ug per 100 available calories (or 1 ug per 100 available kilojoules)	N.S.			
		Vitamin E (a-tocopherol compounds)	0.7 I.U./g linoleic acid but in no case less than 0.7 I.U./100 available calories (0.7 I.U./g linoleic acid but in no case less than 0.15 I.U./100 available kilojoules)	N.S.			
		Sodium (Na)	20 mg per 100 available calories (or 5g mg per 100 available kilojoules)	85 mg per 100 available calories (or 21 mg per 100 available kilojoules)			
		Potassium (K)	80 mg per 100 available calories (or 20 mg per 100 available kilojoules)	N.S.			
		Chloride (Cl)	55 mg per 100 available calories (or 14 mg per 100 available kilojoules)	N.S.			
		Calcium (Ca)	90 mg per 100 available calories 9or 22 mg per 100 available kilojoules)	N.S.			
		Phosphorus (P)	60 mg per 100 available calories (or 14 mg per 100 available kilojoules)	N.S.			
		Magnesium (Mg)	6 mg per 100 available calories (or 1.4 mg per 100 available kilojoules)	N.S.			
		Iron (Fe)	1 mg per 100 available calories (or 0.25 mg per 100 available kilojoules)	N.S.			
		Iodine (I)	5 ug per 100 available calories (or 1.2 ug per 100 available kilojoules)	N.S.			
		Zinc (Zn)	0.5 mg per 100 available calories (or 0.12 mg per 100 available kilojoules)	N.S.			

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HIGH RISK FOOD PRODUCTS							
FOOD CATEGORY	**REQUIREMENTS**	**STANDARDS**			**FOR APPROVAL**	**GROUNDS FOR DENIAL**	**BASIS**
		PARAMETERS	**MIN. ACCEPTABLE LEVEL**	**MAX. ACCEPTABLE LEVEL**			
HRJ2. CEREAL-BASED FOODS FOR INFANTS & YOUNG CHILDREN **Eg.** Includes cereal, acteal flour, biscuits and rusks that are intended for infants 6 months of age and older, and for progressive adaptation of infants and children to ordinary food.	COA for Energy, Protein, Carbohydrates, Lipids, Minerals and Vitamins per 100 kcal based on Codex Stan 074-1981, Rev 1-2006.	Energy Density	not less than 3.3 kJ/g (0.8 kcal/g)	-	Submitted COA with methodology, reflecting the complete parameters, with results meeting the prescribed level per nutrient and signature of the QA analyst. Submitted COA with methodology, reflecting the complete parameters, with results meeting the prescribed level per nutrient and electronically signed.	Non-submission of COA Submitted COA is incomplete (no methodology, incomplete parameters/nutrients, no results, no signature of the QA Analyst Submitted document is only product specifications and not COA	Codex Stan 074-1981, Rev 1-2006.
		Protein of Cereals with an added high protein food which are or have to be prepared for consumption with water or other appropriate protein-free liquid (2.1.2)	not less than 0.4 g/100 kJ (or 2 g/100 kcal)	not more than 1.3 g/100 kJ (or 5.5 g/100 kcal)			
		Protein of Rusks and biscuits which are to be used either directly or, after pulverization, with the addition of water, milk or other suitable liquids (2.1.4)	not less than 0.36 g/100 kJ (or 1.5 g/100 kcal)	not more than 1.3 g/100 kJ (or 5.5 g/100 kcal)			
		Carbohydrates of Products consisting of cereals which are or have to be prepared for consumption with milk or other appropriate nutritious liquids (2.1.1)	-	the amount of added carbohydrates from these sources shall not exceed 1.8 g/100 kJ (7.5 g/100 kcal) and the amount of added fructose shall not exceed 0.9 g/100 kJ (3.75 g/100 kcal)			
		Carbohydrates of Rusks and biscuits which are to be used either directly or, after pulverization, with the addition of water, milk or other suitable liquids (2.1.4)	-	the amount of added carbohydrates from these sources shall not exceed 1.8 g/100 kJ (7.5 g/100 kcal) and the amount of added fructose shall not exceed 0.9 g/100 kJ (3.75 g/100 kcal)			
		Carbohydrates of Cereals with an added high protein food which are or have to be prepared for consumption with water or other appropriate protein-free liquid (2.1.2)	-	the amount of added carbohydrates from these sources shall not exceed 1.2 g/100 kJ (5 g/100 kcal) and the amount of added fructose shall not exceed 0.6 g/100 kJ (2.5 g/100 kcal)			
		Lipids of Cereals with an added high protein food which are or have to be prepared for consumption with water or other appropriate protein-free liquid (2.1.2)	-	shall not exceed 1.1g/100 kJ (4.5 g/100 kcal)			
HRJ2. CEREAL-							

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ANNEX D. REFERENCE GUIDE TO STAKEHOLDERS TO ASSESS COMPLIANCE OF SUBMITTED DOCUMENTS AS COMPLETE REQUIREMENTS FOR PRODUCT REGISTRATION

HIGH RISK FOOD PRODUCTS

FOOD CATEGORY	REQUIREMENTS	STANDARDS/ ADDITIONAL LABELLING REQUIREMENTS	FOR APPROVAL	GROUNDS FOR DENIAL	BASIS
MILK SUPPLEMENT ***Cont.***		*SECONDARY MESSAGES*: - The information display panel of each container/label shall contain the following messages in both English and Filipino languages: - ENGLISH: **The Use of Infant Formula/Milk Supplements must only be upon the advice of a health professional** FILIPINO: **Ang paggamit ng gatas na ito ay dapat sang-ayon sa payo ng Doctor o health professional** ENGLISH: **The unnecessary and improper use of this product may be dangerous to your child's health.** FILIPINO: **Ang maling paggamit ng gatas na ito ay maaaring makasama sa kalusugan ng bata.** - These messages shall be printed **bold**, font type Arial and font size 1/6 size of the biggest letter at the uppermost level of the information display panel.			
	COA must be signed/verified by competent technical staff/QA Analyst/Manager, product description/name, specifications, method of analysis/methodology and batch code/ expiry date/ manufacturing date reflecting the specific/actual results of analysis for the required parameters of Powdered Infant Formula with or without added Lactic acid producing cultures	**PARAMETERS** / **ACCEPTABLE LEVELS** Cronobacter spp. — 0/10g Salmonella — 0/25g *SPC/APC — $5x10^2$ cfu/g Enterobacteriaceae — 0/10g	Submitted COA with methodology, reflecting the complete parameters, with results and signature of the QA analyst. -**TPC is considered in lieu of SPC/APC*	Non-submission of COA. Submitted COA is incomplete (no methodology, incomplete parameters/nutrients, no results, no signature of the QA Analyst. Submitted document is only product specifications and not COA.	FDA Circular 2013-010

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HIGH RISK FOOD PRODUCTS							
FOOD CATEGORY	**REQUIREMENTS**	**STANDARDS**			**FOR APPROVAL**	**GROUNDS FOR DENIAL**	**BASIS**
		PARAMETERS	**MIN. ACCEPTABLE LEVEL**	**MAX. ACCEPTABLE LEVEL**			
HRJ2. CEREAL-BASED FOODS FOR INFANTS & YOUNG CHILDREN **Eg.** Includes cereal, acteal flour, biscuits and rusks that are intended for infants 6 months of age and older, and for progressive adaptation of infants and children to ordinary food.	COA for Energy, Protein, Carbohydrates, Lipids, Minerals and Vitamins per 100 kcal based on Codex Stan 074-1981, Rev 1-2006.	Energy Density	not less than 3 3 kJ/g (0.8 kcal/g)	-	Submitted COA with methodology, reflecting the complete parameters, with results meeting the prescribed level per nutrient and signature of the QA analyst. Submitted COA with methodology, reflecting the complete parameters, with results meeting the prescribed level per nutrient and electronically signed.	Non-submission of COA Submitted COA is incomplete (no methodology, incomplete parameters/nutrients, no results, no signature of the QA Analyst Submitted document is only product specifications and not COA	Codex Stan 074-1981, Rev 1-2006.
		Protein of Cereals with an added high protein food which are or have to be prepared for consumption with water or other appropriate protein-free liquid (2 1 2)	not less than 0 4 g/100 kJ (or 2 g/100 kcal)	not more than 1 3 g/100 kJ (or 5 5 g/100 kcal)			
		Protein of Rusks and biscuits which are to be used either directly or, after pulverization, with the addition of water, milk or other suitable liquids (2 1 4)	not less than 0 36 g/100 kJ (or 1 5 g/100 kcal)	not more than 1 3 g/100 kJ (or 5 5 g/100 kcal)			
		Carbohydrates of Products consisting of cereals which are or have to be prepared for consumption with milk or other appropriate nutritious liquids (2 1 1)	-	the amount of added carbohydrates from these sources shall not exceed 1 8 g/100 kJ (7 5 g/100 kcal) and the amount of added fructose shall not exceed 0 9 g/100 kJ (3 75 g/100 kcal)			
		Carbohydrates of Rusks and biscuits which are to be used either directly or, after pulverization, with the addition of water, milk or other suitable liquids (2 1 4)	-	the amount of added carbohydrates from these sources shall not exceed 1 8 g/100 kJ (7 5 g/100 kcal) and the amount of added fructose shall not exceed 0 9 g/100 kJ (3 75 g/100 kcal)			
		Carbohydrates of Cereals with an added high protein food which are or have to be prepared for consumption with water or other appropriate protein-free liquid (2 1 2)	-	the amount of added carbohydrates from these sources shall not exceed 1 2 g/100 kJ (5 g/100 kcal) and the amount of added fructose shall not exceed 0 6 g/100 kJ (2 5 g/100 kcal)			
		Lipids of Cereals with an added high protein food which are or have to be prepared for consumption with water or other appropriate protein-free liquid (2 1 2)	-	shall not exceed 1 1g/100 kJ (4 5 g/100 kcal)			
HRJ2. CEREAL-							

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ANNEX D. REFERENCE GUIDE TO STAKEHOLDERS TO ASSESS COMPLIANCE OF SUBMITTED DOCUMENTS AS COMPLETE REQUIREMENTS FOR PRODUCT REGISTRATION

HIGH RISK FOOD PRODUCTS							
FOOD CATEGORY	REQUIREMENTS	STANDARDS			FOR APPROVAL	GROUNDS FOR DENIAL	BASIS
		PARAMETERS	MIN. ACCEPTABLE LEVEL	MAX. ACCEPTABLE LEVEL			
BASED FOODS FOR INFANTS & YOUNG CHILDREN *Cont.*		Lipids of Products consisting of cereals which are or have to be prepared for consumption with milk or other appropriate nutritious liquids (2.1.1) and Rusks and biscuits which are to be used either directly or, after pulverization, with the addition of water, milk or other suitable liquids (2.1.4)	-	shall not exceed a maximum lipid content of 0.8 g /100 kJ (3.3 g/100 kcal)			
		Sodium of Products under 2.1.1 to 2.1.4	-	shall not exceed 24 mg/100 kJ (100 mg/100 kcal) of the ready-to-eat product			
		Calcium of Product under 2.1.2	shall not be less than 20 mg/100 kJ (80 mg/100 kcal)	-			
		Calcium of Product under 2.1.4	shall not be less than 12 mg/100 kJ (50 mg/100 kcal)	-			
		Vitamin B1 of Products under 2.1.1 to 2.1.4	shall not be less than 12.5µg/100 kJ (50µg/100 kcal)	-			
		Vitamin A of Product under 2.1.2	14 µg/100kJ (or 60 µg/100kcal)	43 µg/100kJ (or 180 µg/100kcal)			
		Vitamin D of Product under 2.1.2	0.25 µg/100kJ (or 1 µg/100kcal)	0.75 µg/100kJ (or 3 µg/100kcal)			

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HIGH RISK FOOD PRODUCTS						
FOOD CATEGORY	**REQUIREMENTS**	**STANDARDS**		**FOR APPROVAL**	**GROUNDS FOR DENIAL**	**BASIS**
		PARAMETERS	**ACCEPTABLE LEVEL**			
HRJ2. CEREAL-BASED FOODS FOR INFANTS & YOUNG CHILDREN *Cont.*	COA must be signed/verified by competent technical staff/QA Analyst/Manager, product description/name, specifications, method of analysis/methodology and batch code/ expiry date/ manufacturing date reflecting the specific/actual results of analysis for the required parameters of Infants	Bacillus cereus cfu/g Clostridium perfringes cfu/g SPC/APC cfu/g Salmonella/25g Coliforms MPN/g	10^2 10 10^3 0 3	Submitted COA with methodology, reflecting the complete parameters, with results meeting the acceptable level per parameter and signature of the QA analyst. Submitted clear, readable Certificate of Analysis with methodology, reflecting the complete parameters, with results meeting the prescribed level per nutrient and electronically signed.	Non-submission of COA Submitted COA is incomplete (no methodology, incomplete parameters/nutrients, no results, no signature of the QA Analyst Submitted document is only product specifications and not COA	FDA Circular 2013-010.
	Clear and complete loose labels or artworks based on Department Circular 2008-0006 and RIRR EO 51	Additional message/statement: **"Infants six months onwards should be given fresh, indigenous and natural food in combination with continued breastfeeding"** - This message shall be printed bold and prominent on the lowermost level of the information display panel of the label		Submitted clear and complete loose labels or artworks declaring the additional message/statement based on Department Circular 2008-0006.	Non-submission of clear and complete loose labels or artworks declaring the additional message/statement based on Department Circular 2008-0006.	Department Circular 2008-0006 and RIRR EO 51

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HIGH RISK FOOD PRODUCTS						
FOOD CATEGORY	REQUIREMENTS	STANDARDS		FOR APPROVAL	GROUNDS FOR DENIAL	BASIS
		PARAMETERS	ACCEPTABLE LEVEL			
HRJ2. CANNED BABY FOODS **Eg.** Includes fruit, vegetable-, and meat based "baby foods" for infants, "toddler foods," and "junior foods" in can and in pouch (pureed)	COA to support Nutrition Information based on Codex Stan 73-1981 amended 1989.	Vitamins and minerals Sodium	may only be added in accordance with the legislation of the country in which the food is sold. shall not exceed 200 mg Na/100 g calculated on the ready-to-eat basis	Submitted COA with methodology, reflecting the complete parameters, with results meeting the prescribed level per nutrient and signature of the QA analyst. Submitted COA with methodology, reflecting the complete parameters, with results meeting the prescribed level per nutrient and electronically signed.	Non-submission of COA Submitted COA is incomplete (no methodology, incomplete parameters/nutrients, no results, no signature of the QA Analyst Submitted document is only product specifications and not COA	Codex Stan 73-1981 amended 1989
	COA must be signed/verified by competent technical staff/QA Analyst/Manager, product description/name, specifications, method of analysis/methodology and batch code/ expiry date/ manufacturing date reflecting the specific/actual results of analysis for the required parameters of Baby Foods in Hermetically Sealed Containers	Commercial Sterility	Commercially Sterile	Submitted COA with methodology, reflecting the complete parameters, with results and signature of the QA analyst/electronically signed. Submitted Incubation Monitoring Records with conclusion: Commercially Sterile Submitted Certificate of Analysis for Mesophilic Thermophilic Aerobic and Mesophilic Thermophilic Anaerobic, C. botulinum and spore-forming microorganisms with conclusion.	Non-submission of COA Submitted COA is incomplete (no methodology, incomplete parameters/nutrients, no results, no signature of the QA Analyst. Submitted document is only product specifications and not COA.	FDA Circular 2013-010
	Clear and complete loose labels or artworks based on Department Circular 2008-0006	Additional message/statement: **"Infants six months onwards should be given fresh, indigenous and natural food in combination with continued breastfeeding"** - This message shall be printed bold and prominent on the lowermost level of the information display panel of the label		Submitted clear and complete loose labels or artworks declaring the additional message/statement based on Department Circular 2008-0006.	Non-submission of clear and complete loose labels or artworks declaring the additional message/statement based on Department Circular 2008-0006.	Department Circular 2008-0006

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HIGH RISK FOOD PRODUCTS					
FOOD CATEGORY	**REQUIREMENTS**	**STANDARDS/ADDITIONAL LABELLING REQUIREMENTS**	**FOR APPROVAL**	**GROUNDS FOR DENIAL**	**BASIS**
HRJ3. FOODS FOR SPECIAL MEDICAL PURPOSES **Eg.** Foods for special dietary use that are specially processed or formulated and presented for the dietary management of patients and may be used only under medical supervision.	Scientific Studies indicating safety and benefits of the product for intended medical condition based on Codex Stan 180-1991 and Administrative Order 2014-0029.		Submitted clear, readable and complete Peer-reviewed or validated studies by third party organizations (with no conflict of interest) or published Scientific Study specific on the product being applied and its intended use.	Non-submission of clear, readable and complete Peer-reviewed or validated study by a third party or published Scientific Study specific on the product and its intended use. -Only one scientific study was submitted and this was sponsored by the applicant company without validation study from independent organization.	Codex Stan 180-1991 and Administrative Order 2014-0029.
	COA to support Nutrition Information based on Codex Stan 180-1991.		Submitted clear, readable COA with methodology, reflecting the complete parameters, with results per nutrient and signature of the QA analyst/ electronically signed.	Non-submission of COA Submitted COA is incomplete (no methodology, incomplete parameters/nutrients, no results, no signature of the QA Analyst Submitted document is only product specifications and not COA	Codex Stan 180-1991.
HRJ3. FOODS FOR SPECIAL	Clear and complete loose labels or artworks compliant with Codex Stan 180-1991.	1. Nutrition Labelling: Energy, Vitamins and Minerals per 100 g or per 100 mL of the food as sold or as applicable, per serving as suggested for consumption. 2. Osmolality or osmolarity and/or acid base balance when appropriate 3.Nature of the animal or plant proteins or protein hydrolysates 4. Modification of the content or nature of proteins, fats or carbohydrates, other nutrients with rationale for such modification. 5. USE UNDER MEDICAL SUPERVISION shall be declared in bold in an area separated from other written, printed or graphic information 6. Additional warning statement in bold letters if the product poses a health hazard when it is consumed by individuals who do not have the disease. Additional Requirements: 7.A statement that the product is not to be used for parenteral administration. 8.A prominent statement indicating whether the product is or is not intended as the sole source of nutrition	Submitted clear and complete loose labels or artworks compliant to the labelling requirements of Codex Stan 180-1991.	Non-submission of clear and complete loose labels or artworks compliant to the labelling requirements of Codex Stan 180-1991	

All documents submitted must be CLEAR & READABLE. Non-compliance is ground for Letter of Denial (LOD).

ANNEX D. REFERENCE GUIDE TO STAKEHOLDERS TO ASSESS COMPLIANCE OF SUBMITTED DOCUMENTS AS COMPLETE REQUIREMENTS FOR PRODUCT REGISTRATION

HIGH RISK FOOD PRODUCTS					
FOOD CATEGORY	**REQUIREMENTS**	**STANDARDS/ADDITIONAL LABELLING REQUIREMENTS**	**FOR APPROVAL**	**GROUNDS FOR DENIAL**	**BASIS**
MEDICAL PURPOSES *Cont.*		9. The statement "For the dietary management of ___" with specific disease, disorder or medical condition for which the product is intended and for which it has been shown to be effective. 10. Adequate precautions, known side effects, contraindication and product-drug interaction, as applicable. 11. Rationale for the use of the product and a description of the properties or characteristics that make it useful. 12. Specific age group if the product is formulated for this age group 13. Feeding instruction, including method of administration and serving size			
HRJ5. FOODS FOR SPECIAL DIETARY USE	Scientific Studies indicating safety and suitability of the product to specific disease and disorder to which it is intended based on Codex Stan146-1985 and Administrative Order 2014-0029.		Submitted clear, readable and complete Peer-reviewed or validated studies by third party organizations (with no conflict of interest) or published Scientific Study specific on the product being applied and its intended use.	Non-submission of clear, readable and complete Peer-reviewed or validated study by a third party or published Scientific Study specific on the product and its intended use. -Only one scientific study was submitted and this was sponsored by the applicant company without validation study from independent organization.	Codex Stan146-1985 and Administrative Order 2014-0029.
	COA to support Nutrition Information based on Codex Stan146-1985		Submitted COA with methodology, reflecting the complete parameters, with results per nutrient and signature of the QA analyst/ electronically signed.	Non-submission of COA Submitted COA is incomplete (no methodology, incomplete parameters/nutrients, no results, no signature of the QA Analyst Submitted document is only product specifications and not COA	Codex Stan146-1985
HRJ5. FOODS FOR SPECIAL DIETARY USE *cont.*	Clear and complete loose labels or artworks compliant with Codex Stan146-1985.	1. Product Name: The designation "Special dietary" or "Special dietetic" or an appropriate equivalent term shall be declared; characterizing essential feature but not the condition shall be stated in appropriate description near the product name. 2. List of ingredients 3. Nutrition labeling: Energy, Protein, CHO, Fats, Vitamins and Minerals per 100 g or per 100 ml of the food as sold, or as	Submitted clear and complete loose labels or artworks compliant to the labelling requirements of Codex Stan 146-1985:	Non-submission of clear and complete loose labels or artworks compliant to the labelling requirements of Codex Stan 146-1985.	Codex Stan146-1985

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HIGH RISK FOOD PRODUCTS					
FOOD CATEGORY	**REQUIREMENTS**	**STANDARDS/ADDITIONAL LABELLING REQUIREMENTS**	**FOR APPROVAL**	**GROUNDS FOR DENIAL**	**BASIS**
		applicable, per serving as suggested for consumption. 4. Net content 5. Storage of opened food 6. Claims should conform with Guidelines on Health and Nutrition Claims 7. Claims on prevention, alleviation, treatment, or cure of a disease, disorder or particular physiological condition are not allowed. 8. Advise statement indicating that advice from a qualified medical person is needed.			
HRJ4. FORMULA FOODS FOR WEIGHT CONTROL DIETS	COA to support Nutrition Information based on Codex Stan 181-1991.		Submitted COA with methodology, reflecting the complete parameters, with results per nutrient and signature of the QA analyst/ electronically signed.	Non-submission of COA Submitted COA is incomplete (no methodology, incomplete parameters/nutrients, no results, no signature of the QA Analyst Submitted document is only product specifications and not COA	Codex Stan 181-1991.
HRJ4. FORMULA FOODS FOR WEIGHT CONTROL DIETS *cont.*	Clear and complete loose labels or artworks compliant with Codex Stan 181-1991.	1. Product name: Meal Replacement for Weight Control 2. List of ingredients 3. Nutrition labeling: Energy, Protein, CHO, Fats, Vitamins and Minerals per 100 g or per 100 ml of the food as sold or as applicable, per serving as suggested for consumption 4. Date Marking 5. Storage Instructions for opened and unopened food 6. If direction for use indicate that the food should be combined with other ingredients, the nutritive value of the final combination should be declared. Additional Provisions: 7. The label shall not make reference to the rate or amount of weight loss which result from the use of the food or to reduction inhunder an increase in the sense of satiety. 8. Statement on the importance of maintaining an adequate fluid intake when the product is used. 9. If there is sugar alcohol in excess of 20 g, a statement on the	Submitted clear and complete loose labels or artworks compliant to the labelling requirements of Codex Stan 181--1991:	Non-submission of clear and complete loose labels or artworks compliant to the labelling requirements of Codex Stan 181-1991.	Codex Stan 181-1991.

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HIGH RISK FOOD PRODUCTS					
FOOD CATEGORY	**REQUIREMENTS**	**STANDARDS/ADDITIONAL LABELLING REQUIREMENTS**	**FOR APPROVAL**	**GROUNDS FOR DENIAL**	**BASIS**
		label that the food may have a laxative effect. 10. Statement that the food maybe useful in weight control only as a part of an energy- controlled diet. 11. The label shall have a prominent statement recommending that if the food is used for more than 6 weeks, medical advice should be sought.			

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HIGH RISK FOOD PRODUCTS

FOOD CATEGORY	REQUIREMENTS	STANDARDS			FOR APPROVAL	GROUNDS FOR DENIAL	BASIS
		PARAMETERS	GUIDE LEVEL	MAXIMUM ACCEPTABLE LEVEL			
HRJ. BOTTLED WATER	COA for Physico-Chemical Properties (Turbidity, Color, Odor, Taste, pH, TDS, Conductivity, Calcium. Magnesium, Sodium, Potassium, Chloride, Sulfate), Contaminants (Nitrates, Nitrites, Iron, manganese, Copper, Zinc, Aluminum, Fluoride, organic Matter, Surfactants), Toxic Contaminants (Arsenic, Cadmium, Cyanide, Chromium, Lead, Mercury, Selenium, Phenolic Substances), Volatile Organic Compounds (Carbon tetrachloride, Benzene, Trihalomethanes), Pesticides & Related Substances (Carbamates, Organochlorines, Organophosphates, Herbicides, Fungicides, PCB), Radionuclides (Gross Alpha Activity, Gross Beta Activity) and Microbiological Parameters (Coliforms, Fecal Strepcocci, Pseudomonas Aeruginosa, HPC) based on Administrative Order No. 18-A s. 1993.	Turbidity	5 NTU Purified/Distilled: 1 NTU	-	Submitted COA with methodology, reflecting the complete parameters, with results per parameter and signature of the QA analyst. Submitted COA with methodology, reflecting the complete parameters, with results meeting the prescribed level per parameter and electronically signed.	Non-submission of COA Submitted COA is incomplete (no methodology, incomplete parameters/nutrients, no results, no signature of the QA Analyst Submitted document is only product specifications and not COA	Administrative Order No. 18-A s. 1993
		Color	15 TCU	-			
		Odor	not objectionable	-			
		Taste	not objectionable	-			
		pH	6.5-8.5 Puridied/Distilled: 5-7	9			
		TDS	Mineral: >200 mg/l (ppm) Spring: >100 mg/L (ppm) Purified: <10 mg/L (ppm) Distilled: < 10 mg/L (ppm)	Mineral: 1000 mg/L (ppm) Spring: 500 mg/L (ppm) Purified: 500 mg/L (ppm) Distilled: 500 mg/L (ppm)			
		Conductivity	Distilled: <5 uS/cm Mineral: >200 uS/cm	- -			
		Calcium	100 mg/L (ppm)	-			
		Magnesium	30 mg/L (ppm)	50 mg/L (ppm)			
		Sodium	20 mg/L (ppm)	175 mg/L (ppm)			
		Potassium	10 mg/L (ppm)	12 mg/L (ppm)			
		Chloride	25 mg/L (ppm)	200 mg/L (ppm)			
		Sulfate	25 mg/L (ppm)	250 mg/L (ppm)			
		Nitrates	25 mg/L (ppm)	45 mg/L (ppm)			
		Nitrites	not detected	0.1 mg/L (ppm)			
		Iron	0.3 mg/L (ppm)	1.0 mg/L (ppm)			
		Manganese	0.05 mg/L (ppm)	0.1 mg/L (ppm)			
		Copper	0.1 mg/L (ppm)	1 mg/L (ppm)			
		Zinc	0.5 mg/L (ppm)	5 mg/L (ppm)			
		Aluminum	0.05 mg/L (ppm)	0.2 mg/L (ppm)			
		Fluoride	>0.8 mg/L (ppm)	2 mg/L (ppm)			

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HIGH RISK FOOD PRODUCTS							
FOOD CATEGORY	REQUIREMENTS	STANDARDS			FOR APPROVAL	GROUNDS FOR DENIAL	BASIS
		PARAMETERS	GUIDE LEVEL	MAXIMUM ACCEPTABLE LEVEL			
			(flouridated water)				
		Organic Matter (mg O2/L)	2	5			
		Surfactants (as lauryl sulfate)	not detected	2 mg/L (ppm)			
		Arsenic	0.05 mg/L (ppm)	-			
		Cadmium	0.01 mg/L (ppm)	-			
		Cyanide	0.01 mg/L (ppm)	-			
		Chromium	0.05 mg/L (ppm)	-			
		Lead	0.05 mg/L (ppm)	-			
		Mercury	0.001 mg/L (ppm)	-			
		Selenium	0.01 mg/L (ppm)	-			
		Phenolic Substances	0.001 mg/L (ppm)	-			
		Carbon tetrachloride	0.005 mg/L (ppm)	-			
		Benzene	0.005 mg/L (ppm)	-			
		Trihalomethanes	0.01 mg/L (ppm)	-			
		Carbamates	0.1 ppb	-			
		Organochlorines	0.1 ppb	-			
		Organophosphates	0.1 ppb	-			
		Herbicides	0.5 ppb	-			
		Fungicides	0.5 ppb	-			
		PCB	0.5 ppb	-			
		Gross alpha activity Gross beta activity	0.1 Bq/L 1.0 Bq/L	- -			

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HIGH RISK FOOD PRODUCTS							
FOOD CATEGORY	**REQUIREMENTS**	**STANDARDS**			**FOR APPROVAL**	**GROUNDS FOR DENIAL**	**BASIS**
		PARAMETERS	**GUIDE LEVEL**	**MAXIMUM ACCEPTABLE LEVEL**			
		Coliforms	0 MPN/100 mL	1 MPN/100 mL (shall not be E.coli)			
		Fecal Streptococci	0 cfu/100 mL	1 cfu/100 mL (more samples should be analyzed)			
		Pseudomonas aeruginosa	0 cfu/100 mL	-			
		HPC	10^4 cfu/mL Purified/Distilled: 10^3 cfu/mL	10^6 cfu/mL Purified/Distilled: 10^5 cfu/mL			
	Clear and complete loose labels or artworks compliant with Administrative Order No. 39 s. 1996 and Administrative Order No. 18-A s. 1993.				Submitted clear and complete loose labels or artworks compliant to the labelling requirements of Administrative Order No. 39 s. 1996 and Administrative Order No. 18-A s. 1993.	Non-submission of clear and complete loose labels or artworks compliant to the labelling requirements of Administrative Order No. 39 s. 1996 and Administrative Order No. 18-A s. 1993.	

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HIGH RISK FOOD PRODUCTS					
FOOD CATEGORY	**REQUIREMENTS**	**CRITICAL PARAMETERS**	**FOR APPROVAL**	**GROUNDS FOR DENIAL**	**BASIS**
HRK1. HERBS AND BOTANICALS AND/OR PRODUCTS WITH OTHER NUTRITIONAL SUBSTANCES AND/OR COMBINATION AS FOOD SUPPLEMENTS **Eg.** Food Supplements in capsule, tablet, liquid and powder form.	Shelf life study with stability data based on Administrative Order 2014-0029.	Physical Chemical Micro Assays Heavy Metals	Submitted shelf life study/ stability data containing relevant information on the critical parameters (Physical, Chemical, Micro, Assays and Heavy Metals) of the finished product, period conducted, conclusion, with at least 6 months inputs (with certification that the study is on-going) and signed/verified by competent technical staff to support shelf life declaration. (In-house or Third-Party Lab)	Non-submission of shelf life study/ stability data containing relevant information on the critical parameters of the finished product, period conducted, conclusion, and signed/verified by competent technical staff to support shelf life declaration. Submitted study/ stability data is incomplete (no methodology, incomplete parameters/nutrients, no results, no signature of the QA Analyst	
	COA of the physico-chemical and microbiological parameters of the finished product based on Administrative Order 2014-0029.	Physical Chemical Micro Assays Heavy Metals	Submitted COA with methodology, reflecting the complete parameters, with results meeting the prescribed level per parameter and signature of the QA analyst/electronically signed.	Non-submission of COA Submitted COA is incomplete (no methodology, incomplete parameters/nutrients, no results, no signature of the QA Analyst Submitted document is only product specifications and not COA	
	Sample in actual commercial presentation based on Administrative Order 2014-0029. (to be submitted at FDA Action Center)		Submitted actual commercial presentation within 10 days from the date of filing for pre-assessment based on Administrative Order 2014-0029. (to be submitted at FDA Action Center)	Non-submission of actual commercial presentation based on Administrative Order 2014-0029. (to be submitted at FDA Action Center)	
	For Dried Plants: Certificate of Analysis for Heavy Metals in the finished product based on Administrative Order 184 s. 2004.	Heavy Metals	Submitted COA with methodology, reflecting the complete parameters, with results meeting the prescribed level per parameter and signature of the QA analyst/electronically signed.	Non-submission of COA Submitted COA is incomplete (no methodology, incomplete parameters/nutrients, no results, no signature of the QA Analyst Submitted document is only product specifications and not COA	
	Clear and complete loose labels or artworks declaring the term "Food Supplement" and the phrase "NO APPROVED THERAPEUTIC CLAIMS"		Submitted clear and complete loose labels or artworks declaring the term "Food Supplement" and the phrase "NO APPROVED THERAPEUTIC CLAIMS" based on Bureau Circular No. 2 s 1999.	Non-submission of clear and complete loose labels or artworks declaring the term "Food Supplement" and the phrase "NO APPROVED THERAPEUTIC CLAIMS" based on Bureau Circular No. 2 s 1999.	

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HIGH RISK FOOD PRODUCTS					
FOOD CATEGORY	**REQUIREMENTS**	**CRITICAL PARAMETERS**	**FOR APPROVAL**	**GROUNDS FOR DENIAL**	**BASIS**
	based on Bureau Circular No. 2 s 1999.				
	For Innovations/Herbs which are not listed on Pharmacopea (Specify): 1. Additional documents for Safety Data (e.g. LD50, Toxicity Test, etc)	Acute Toxicity Test or LD-50 Test	Submitted safety data (e.g. Acute Toxicity Test or LD-50 Test) of the finished product issued by a Recognized Issuing body.	Non-submission of safety data (e.g. Acute Toxicity Test or LD-50 Test) of the finished product	
	Additional Note: Products containing banned ingredients are not acceptable for food use			Use of banned ingredients. Use of ingredients/components	

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ANNEX D. REFERENCE GUIDE TO STAKEHOLDERS TO ASSESS COMPLIANCE OF SUBMITTED DOCUMENTS AS COMPLETE REQUIREMENTS FOR PRODUCT REGISTRATION

HIGH RISK FOOD PRODUCTS						
FOOD CATEGORY	REQUIREMENTS	STANDARDS		FOR APPROVAL	GROUNDS FOR DENIAL	BASIS
		PARAMETERS	ACCEPTABLE LEVELS			
HRK2. HERBS AND BOTANICALS AND/OR PRODUCTS WITH OTHER NUTRITIONAL SUBSTANCES AS CONVENTIONAL FOOD PRODUCT	Certificate of Analysis for Microbiological parameters for Non-Alcoholic Beverages: YMC cfu/mL, Coliforms cfu/mL & SPC/APC cfu/mL based on FDA Circular 2013-010.	YMC cfu/mL Coliforms cfu/mL SPC/APC cfu/mL*	1 1 10	Submitted clear, readable Certificate of Analysis with methodology, reflecting the complete parameters, with results and signature of the QA analyst. **TPC is considered in lieu of SPC/APC*	Non-submission of COA Submitted COA is incomplete (no methodology, incomplete parameters/nutrients, no results, no signature of the QA Analyst. Submitted document is only product specifications and not COA.	
	Certificate of Analysis for Microbiological parameters for Powdered Beverages: SPC/APC cfu/g & Coliforms cfu/g.	SPC/APC cfu/g Coliforms cfu/g	3×10^3 10	Submitted COA with methodology, reflecting the complete parameters, with results and signature of the QA analyst. **TPC is considered in lieu of SPC/APC*	Non-submission of COA Submitted COA is incomplete (no methodology, incomplete parameters/nutrients, no results, no signature of the QA Analyst. Submitted document is only product specifications and not COA.	

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ANNEX D. REFERENCE GUIDE TO STAKEHOLDERS TO ASSESS COMPLIANCE OF SUBMITTED DOCUMENTS AS COMPLETE REQUIREMENTS FOR PRODUCT REGISTRATION

AMENDMENT		
REQUIREMENTS	**APPROVED**	**DENIED**
1. CHANGE IN BRAND NAME		
*LETTER OF INTENT	*It should state the specific change/s made from the previously approved product and the proposed change/s.	*It does not clearly state specific change/s made. *Made change/s not included in the letter of intent.
· Clear and complete loose labels or artworks reflecting the change, as applicable, of all packaging sizes, or equivalents as defined by FDA regulations	* readable, clear, complete label of all previously approved SKUs * no changes in label design * proposed label reflecting new brand name * proposed brand name does not exist in the same classification * no reformulation * no change in manufacturer/ manufacturing site * proposed brand name is not misleading or deceptive or is likely to create erroneous impression regarding the product's character in any respect	*incomplete submission of label (e.g. only Principal Display Panel only or front label only) *unreadable and unclear label information specifically list of ingredients, country of origin and/or complete name and address of manufacturer *there is a change on the proposed label (design and/or information) vs. previously approved label unless there is change in label design application *non submission of labels reflecting the proposed brand name * the proposed brand name is already registered in CFRR * the proposed brand name is unacceptable because it is misleading, deceptive and may cause erroneous interpretation * incomplete submission of labels for the previously approved SKUs *if the proposed brand name is offensive, obscene, scandalous or otherwise contrary to public morals and policy.
· Authority from the source or the owner of the brand (if local)	*identical brand name may be allowed provided that it is authorized by the same brand owner	*identical to a previously registered food product under a different company without authorization by the same brand owner.
· Authority from the source or the owner of the brand (if imported)	*identical brand name may be allowed provided that it is authorized by the same brand owner	*identical to a previously registered food product under a different company without authorization by the same brand owner.

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ANNEX D. REFERENCE GUIDE TO STAKEHOLDERS TO ASSESS COMPLIANCE OF SUBMITTED DOCUMENTS AS COMPLETE REQUIREMENTS FOR PRODUCT REGISTRATION

AMENDMENT		
REQUIREMENTS	**APPROVED**	**DENIED**
· IPO registration, if available	* proposed brand name is not yet registered with the FDA in the same product classification (Food) * proposed brand name is acceptable if it is not misleading, deceptive, and may cause erroneous impression regardless if the brand name has an IPO * if the proposed brand name has additional or change in logo (Example: ™ ®)	*proposed brand name is already registered under CFRR * the proposed brand name is unacceptable because it is misleading, deceptive and may cause erroneous impression regardless if the brand name has an IPO Certificate
2. CHANGE IN PRODUCT NAME/ ADDITIONAL PRODUCT DESCRIPTION		
A. Change in Product Name		
*LETTER OF INTENT	*It should state the specific change/s including justification for the change (indicate changes/ amendments to be made and the name should describe the true identity of the product).	*It does not clearly state specific change/s made. *Made change/s not included in the letter of intent. *There is no justification for the proposed change.
· Clear and complete loose labels or artworks reflecting the change, as applicable, of all packaging sizes, or equivalents as defined by FDA regulations	* readable, clear, complete label of all previously approved SKUs * no changes in label design except the proposed change * proposed label reflecting new product name * proposed product name is specific, not generic and indicates the true nature of the product * no reformulation * no change in manufacturer/ manufacturing site	*incomplete submission of label (e.g. only Principal Display Panel only or front label only) *unreadable and unclear label information specifically list of ingredients, country of origin and/or complete name and address of manufacturer *there is a change on the proposed label (design and/or information) vs. previously approved label unless there is change in label design application *non submission of labels reflecting the proposed product name * the proposed product name is unacceptable because it is generic and does not indicate the true nature of the product * incomplete submission of label for the previously approved SKUs

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B. Additional Product Description		
*LETTER OF INTENT	*It should state the specific change/s including justification for the change (indicate changes/ amendments to be made and the name should describe the true identity of the product).	*It does not clearly state specific change/s made. *Made change/s not included in the letter of intent. *There is no justification for the proposed change.
· Clear and complete loose labels or artworks reflecting the change, as applicable, of all packaging sizes, or equivalents as defined by FDA regulations	* readable, clear, complete label of all previously approved SKUs * proposed additional product description should be based on the true nature of the products * no changes in label design except the proposed change * proposed label reflecting new product name * no reformulation * no change in manufacturer/ manufacturing site	*incomplete submission of label (e.g. only PDP) *there is a change on the proposed label design vs. previously approved *non submission of labels reflecting the proposed product name * the proposed product name is unacceptable because it is generic and does not indicate the true nature of the product *unreadable and unclear labels specifically list of ingredients, country of origin and/or complete name and address of manufacturer * incomplete submission of label for the previously approved SKUs
3. CHANGE IN BUSINESS/COMPANY NAME		
*LETTER OF INTENT	*It should state the specific change/s made from the previously approved product.	*It does not clearly state specific change/s made. *Made change/s not included in the letter of intent.
· Proof of change in business name	* Valid LTO reflecting the new business name	* The LTO variation application is still on-going * No valid LTO * with valid LTO but does not reflect the new business name

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ANNEX D. REFERENCE GUIDE TO STAKEHOLDERS TO ASSESS COMPLIANCE OF SUBMITTED DOCUMENTS AS COMPLETE REQUIREMENTS FOR PRODUCT REGISTRATION

· Clear and complete loose labels or artworks reflecting the change, as applicable, of all packaging sizes, or equivalents as defined by FDA regulations	* readable, clear, complete label of all previously approved SKUs * no changes in label design except the proposed change * proposed label reflecting new business name * no reformulation * no change in manufacturer/ manufacturing site	*incomplete submission of label (e.g. only Principal Display Panel only or front label only) *unreadable and unclear label information specifically list of ingredients, country of origin and/or complete name and address of manufacturer *there is a change on the proposed label (design and/or information) vs. previously approved label unless there is change in label design application *non submission of labels reflecting the new business name * incomplete submission of label for the previously approved SKUs
4. CHANGE IN/ ADDITIONAL SUPPLIER		
*LETTER OF INTENT	*It should state the specific change/s made from the previously approved product and the proposed change/s.	*It does not clearly state specific change/s made. *Made change/s not included in the letter of intent.
· Any of the following 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 new supplier.	***Please see specifications based on general requirements for SOURCE DOCUMENTS (FDA Circular No.2016-007)** (Foreign Agency Agreement and Memorandum of Agreement) *Notarized, signed by the supplier and importer/applicant company and reflecting the correct address. (Proforma Invoice) *It indicates the product being applied *Reflecting the complete name and address of the new/ additional supplier and the name of the applicant company	*There is no source document submitted to support the change/s.
5. CHANGE IN/ ADDITIONAL PACKAGING TYPE/ MATERIAL		
*LETTER OF INTENT	*It should state the specific change/s made from the previously approved product and the proposed change/s.	*It does not clearly state specific change/s made. Made change/s not included in the letter of intent.

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· Clear and complete proposed loose labels or artworks, as applicable, of all packaging sizes, or equivalents as defined by FDA regulations	* readable, clear, complete label of all previously approved SKUs * no reformulation * no change in manufacturer/ manufacturing site	*incomplete submission of label (e.g. only Principal Display Panel only or front label only) *unreadable and unclear label information specifically list of ingredients, country of origin and/or complete name and address of manufacturer *there is a change on the proposed label (design and/or information) vs. previously approved label unless there is change in label design application *non submission of proposed loose labels or artworks, as applicable, of all packaging sizes, or equivalents as defined by FDA regulations * incomplete submission of label for the previously approved SKUs
· Pictures of the product in all angles and in different packaging sizes, and from at least two different perspectives allowing visual recognition of a product as the same with the one being registered.	* pictures should show the commercial presentation of the product in the proposed packaging material	* non-submission of pictures showing the commercial presentation of the product in the proposed packaging material per approved SKU * incomplete submission of pictures in commercial presentation of the product in the proposed packaging material per approved SKU
· Proof of suitability of packaging material for food, including stability of the product in the new packaging.	* if the primary packaging was changed, stability study result should be submitted reflecting the new shelf life of the product verified by competent staff. * for Raw Material, this is not applicable	* for change in primary packaging, non submission of stability study result reflecting the new shelf life of the product verified by competent staff.
6. CHANGE OF PACKAGING IN COMMERCIAL PRESENTATION (CHANGE/ADDITIONAL PACKAGING SIZE)		
*LETTER OF INTENT	*It should state the specific change/s made from the previously approved product and the proposed change/s.	*It does not clearly state specific change/s made. Made change/s not included in the letter of intent.

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ANNEX D. REFERENCE GUIDE TO STAKEHOLDERS TO ASSESS COMPLIANCE OF SUBMITTED DOCUMENTS AS COMPLETE REQUIREMENTS FOR PRODUCT REGISTRATION

· Clear and complete loose labels or artworks, as applicable, of all packaging sizes, or equivalents, reflecting the change/s, as defined by FDA Regulations	(Additional or Change in SKU) * readable, clear, complete label of the new packaging in all/ new sizes * no reformulation * no change in manufacturer/ manufacturing site (Change in Commercial Presentation but with same material) * pictures showing the commercial presentation of the product to determine the propose change	*incomplete submission of label (e.g. only Principal Display Panel only or front label only) *unreadable and unclear label information specifically list of ingredients, country of origin and/or complete name and address of manufacturer *there is a change on the proposed label (design and/or information) except size/s vs. previously approved label unless there is change in label design application *non submission of proposed loose labels or artworks, as applicable, of all packaging sizes, or equivalents as defined by FDA regulations * incomplete submission of label for the proposed SKUs *For change in commercial presentation but with the same material, non-submission of scanned copy of picture in commercial presentation
7. CHANGE OR EXTENSION IN SHELF-LIFE		
*LETTER OF INTENT	*It should state the specific change/s made from the previously approved product and the proposed change/s.	*It does not clearly state specific change/s made. Made change/s not included in the letter of intent.

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· Stability study results with conclusion to support extension or change in shelf-life	* duly signed by competent technical staff including the complete name with appropriate parameters and conclusion * results should reflect the new shelf life	* non-submission of stability study/data * submitted stability study/data was not duly signed by competent technical staff * submitted stability study/data does not include appropriate parameters and conclusion * submitted stability study/data results does not reflect the declared new shelf life
8. CHANGE IN/ADDITIONAL PACKAGING DESIGN		
· Letter of Intent	*It should state the specific change/s made from the previously approved product and the proposed change/s.	*It does not clearly state specific change/s made. Made change/s not included in the letter of intent.
· Clear and complete loose labels or artworks, as applicable, of all packaging sizes, or equivalents, reflecting the change/s, as defined by FDA Regulations		
* claims for Logos	* readable, clear, complete label reflecting the proposed change * Valid Certificate (e.g. HALAL, Sangkap pinoy seal, Organic, Kosher, etc.)	*non-submission of proposed loose labels reflecting the changes/additional of logos * non-submission of certificate to justify logo *incomplete submission of label (e.g. only Principal Display Panel or front label) *unreadable and unclear label information specifically list of ingredients, country of origin and/or complete name and address of manufacturer * incomplete submission of label for the previously approved SKUs

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* change in label color	* readable, clear, complete label reflecting the proposed change	*non-submission of proposed loose labels reflecting the changes *incomplete submission of label (e.g. only Principal Display Panel or front label) *unreadable and unclear labels specifically list of ingredients, country of origin and/or complete name and address of manufacturer * incomplete submission of label for the previously approved SKUs
* change in font size for product information	* readable, clear, complete label reflecting the proposed change	*non-submission of proposed loose labels reflecting the changes *incomplete submission of label (e.g. only Principal Display Panel or front label) *unreadable and unclear label information specifically list of ingredients, country of origin and/or complete name and address of manufacturer *there is a change on the proposed label design vs. previously approved label * incomplete submission of label for the previously approved SKUs
* claims for source of vitamins/minerals and health and nutrition claims (change/additional)	* readable, clear, complete label reflecting the proposed change * Certificate of Analysis (duly signed by competent technical staff including the complete name with appropriate parameters and result) -documents to substantiate claims	*non submission of proposed loose labels reflecting the changes *incomplete submission of label (e.g. only PDP) *unreadable and unclear labels specifically list of ingredients, country of origin and/or complete name and address of manufacturer * non-submission of Certificate of Analysis *the submitted COA is not duly signed by the competent technical staff and has no complete name *the submitted CoA has no result *Result of test results for vitamin/ mineral did not conform to required levels.

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ANNEX D. REFERENCE GUIDE TO STAKEHOLDERS TO ASSESS COMPLIANCE OF SUBMITTED DOCUMENTS AS COMPLETE REQUIREMENTS FOR PRODUCT REGISTRATION

* change /update nutrition information (vitamin and mineral)	* readable, clear, complete label reflecting the proposed change * Certificate of Analysis (duly signed by competent technical staff including the complete name with appropriate parameters and result)	*non submission of proposed loose labels reflecting the changes/additional of logos *incomplete submission of label (e.g. only Principal Display Panel or front label) *unreadable and unclear labels specifically list of ingredients, country of origin and/or complete name and address of manufacturer *there is a change on the proposed label design vs. previously approved * incomplete submission of label for the previously approved SKUs * non-submission of Certificate of Analysis *the submitted COA is not duly signed by the competent technical staff and has no complete name *the submitted CoA has no result
* change/additional menu or serving suggestion (photograph)	* readable, clear, complete label reflecting the proposed change	*non-submission of proposed loose labels reflecting the changes/additional menu (photograph) *incomplete submission of label (e.g. only PDP) *unreadable and unclear labels specifically list of ingredients, country of origin and/or complete name and address of manufacturer * incomplete submission of label for the previously approved SKUs
* compliance remarks	* readable, clear, complete label in compliance to CPR remarks	*non-submission of proposed loose labels reflecting the compliance to the CPR remarks *incomplete submission of label (e.g. only PDP) *unreadable and unclear labels specifically list of ingredients, country of origin and/or complete name and address of manufacturer * incomplete submission of label for the previously approved SKUs

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ANNEX D. REFERENCE GUIDE TO STAKEHOLDERS TO ASSESS COMPLIANCE OF SUBMITTED DOCUMENTS AS COMPLETE REQUIREMENTS FOR PRODUCT REGISTRATION

* declaration of distributor	* readable, clear, complete label reflecting the new/ additional/ inclusion of distributor * Distributorship Agreement (Notarized, signed by the MAH/ Applicant Company and distributor reflecting the correct address)	*non-submission of proposed loose labels reflecting the changes/additional of logos *incomplete submission of label (e.g. only Principal Display Panel or front label) *unreadable and unclear labels specifically list of ingredients, country of origin and/or complete name and address of manufacturer * incomplete submission of label for the previously approved SKUs
* change of manufacturer's name	* readable, clear, complete label reflecting the proposed change (if the manufacturer is declared on the previously approved label) *submit attestation letter from the manufacturer stating the reason for change in manufacturer's name *ANY of the scanned copy of the original document issued by the Regulatory/ Health Authority/Recognized Issuing body/ Attested by recognized Association or duly authenticated by the Philippine Consulate from the country of origin: Certificate of Registration with GMP Compliance or its equivalent or Valid Sanitary Phyto-Sanitary Certificate or Health Certificate or ISO 22000 Certificate or FSSC Certificate or HACCP Certificate or Certificate of Free Sale. (if available)	* non-submission of proposed loose labels reflecting the new manufacturer's name *Non-submission of ANY of the scanned copy of the original document issued by the Regulatory/ Health Authority/Recognized Issuing body/ Attested by recognized Association or duly authenticated by the Philippine Consulate from the country of origin: Certificate of Registration with GMP Compliance or its equivalent or Valid Sanitary Phyto-Sanitary Certificate or Health Certificate or ISO 22000 Certificate or FSSC Certificate or HACCP Certificate or Certificate of Free Sale. (if available) or supporting documents attesting reflecting/ attesting the new manufacturer's name
* locally produced with additional activity for export	* readable, clear and complete loose label if there is change in the design/ label information *LTO as food exporter if the company is not manufacturer	* non-submission of readable, clear and complete loose label if there is change in the design/ label information
* declaration of "Exclusively Distributed by"	* Valid LTO of the declared Distributor * Terms of Agreement/exclusive distributorship agreement	* No valid LTO
* declaration of manufacturer's office address on the label	* readable, clear, complete label reflecting the proposed change	* non-submission of label reflecting the address

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ANNEX D. REFERENCE GUIDE TO STAKEHOLDERS TO ASSESS COMPLIANCE OF SUBMITTED DOCUMENTS AS COMPLETE REQUIREMENTS FOR PRODUCT REGISTRATION

9. EXPORTATION OF CURRENTLY REGISTERED PRODUCT INITIALLY FOR LOCAL DISTRIBUTION/ ADDITIONAL DESIGN OF THE PRODUCT INTENDED FOR LOCAL DISTRIBUTION INITIALLY REGISTERED FOR EXPORTATION		
· Letter of Intent	It should state the specific changes made from the previously approved to proposed change/s.	It does not clearly state specific change/s made. Made change/s not included in the letter of intent.
· License to Operate	The applicant company should have a valid LTO with activity as Food Exporter except for manufacturer.	* No valid LTO with activity as Food Exporter
· Clear and complete loose labels or artworks reflecting the change, as applicable, of all packaging sizes, or equivalents, reflecting the change/s, as defined by FDA regulations or reflecting compliance to labeling requirements of importing country (If for Export) - · Clear and complete loose labels or artworks reflecting the change, as applicable, of all packaging sizes, or equivalents, reflecting the change/s, as defined by FDA regulations or reflecting compliance to mandatory labeling requirements (For Local Distribution)	* readable, clear, complete label of all previously approved SKUs * no reformulation * no change in manufacturer/ manufacturing site	*incomplete submission of label (e.g. only Principal Display Panel only or front label only) *unreadable and unclear label information specifically list of ingredients, country of origin and/or complete name and address of manufacturer *no English translation of information written in foreign language * incomplete submission of labels for the previously approved SKUs
*May include other changes on label information without affecting the formulation and manufacturing plant address of the registered product.		
10. TRANSFER OF OWNERSHIP OF A REGISTERED PRODUCT *notification to CFRR Data Controller (authorization letter and valid LTO)		
· Letter of Intent	*It should state the specific changes made from the previously approved to proposed change/s.	It does not clearly state specific change/s made. Made change/s not included in the letter of intent.
· Proof of Agreement between previous and current owners of the product transferring ownership	*Agreement must be signed by the previous and current owners and clearly states that there is transferring of ownership	*Non-submission of signed Agreement by the previous and current owners and does not clearly stating that there is transferring of ownership

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· Clear and complete loose labels or artworks, as applicable, of all packaging sizes, or equivalents, reflecting the change/s, as defined by FDA Regulations	* readable, clear, complete label of all previously approved SKUs * no changes in label design * proposed label reflecting new brand name * proposed brand name does not exist in the same classification * no reformulation * no change in manufacturer/ manufacturing site	*incomplete submission of label (e.g. only Principal Display Panel only or front label only) *unreadable and unclear label information specifically list of ingredients, country of origin and/or complete name and address of manufacturer *there is a change on the proposed label (design and/or information) vs. previously approved label unless there is change in label design application *non-submission of labels reflecting the proposed change/s
Transfer of Account from Old Owner (Company) to the New Owner/ Company (This is for the approval of the e-reg account database controller)	*Agreement must be signed by the previous and current owners and clearly states that there is transferring of ownership of the company *with Valid License-to-Operate	*Non-submission of signed Agreement by the previous and current owners and does not clearly stating that there is transferring of ownership *No Valid LTO
11. CHANGE IN IMPORTER/DISTRIBUTOR/ TRADER		
· Letter of Intent	It should state the specific changes made from the previously approved to proposed change/s.	It does not clearly state specific change/s made. Made change/s not included in the letter of intent.
· Termination of agreement/Deed of assignment	*must be duly signed by the manufacturer and the previous importer/ distributor/ trader stating that there is a termination of their product contract and assigning the new importer *complete documents with complete details	*not duly signed by the manufacturer and the previous importer stating that there is a termination of their contract. *did not mention the new importer/distributor/ trader *complete documents with complete details
· Agreement of New Importer/ Distributor/ Trader or Appointment Letter	*must be duly signed by the manufacturer and the new importer/ distributor/ trader *complete documents with complete details	*not duly signed by the manufacturer and the new importer/ distributor/ trader *complete documents with complete details
· Clear and complete loose labels or artworks, as applicable, of all packaging sizes, or equivalents, reflecting the change/s, as defined by FDA Regulations	*must be clear and readable reflecting the new name and address of importer/distributor	*not clear and unreadable
12. CHANGE IN BUSINESS / COMPANY ADDRESS (NOT APPLICABLE TO MANUFACTURER AND REPACKER)		
· Letter of Intent	It should state the specific changes made from the previously approved to proposed change/s.	It does not clearly state specific change/s made. Made change/s not included in the letter of intent.

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· Proof of change in business name	*Must have valid LTO	* No valid LTO * with valid LTO but does not reflect the new business address *has valid LTO but with different activity from previously approved CPR
· Clear and complete loose labels or artworks reflecting the change, as applicable, of all packaging sizes, or equivalents as defined by FDA regulations	* readable, clear, complete label of all previously approved SKUs reflecting the new address * no changes in label design * no reformulation * no change in manufacturer/ manufacturing site	*incomplete submission of label (e.g. only Principal Display Panel only or front label only) *unreadable and unclear label information specifically list of ingredients, country of origin and/or complete name and address of manufacturer *there is a change on the proposed label (design and/or information) vs. previously approved label unless there is change in label design application *Non-submission of proposed label reflecting the new address.
OTHER CASES AS DECLARED IN SUCCEEDING FDA ISSUANCES (not limited to the following):		
13. CHANGE IN LTO NUMBER AND/OR LTO VALIDITY		
· Letter of Intent	It should state the specific changes made from the previously approved to proposed change/s.	It does not clearly state specific change/s made. Made change/s not included in the letter of intent.
· Copy of updated License to Operate	* Valid LTO reflecting the new LTO Number and/or LTO Validity	* No valid LTO * with valid LTO but does not reflect the new business address *has valid LTO but with different activity from previously approved CPR
14. CHANGE IN PRODUCT SPECIFICATION		
· Letter of Intent	It should state the specific changes made from the previously approved to proposed change/s.	It does not clearly state specific change/s made. Made change/s not included in the letter of intent.
· Copy of updated Product Specification Sheet	* Updated Product Specification Sheet	No submitted updated product specifications

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15. CHANGE IN LOT IDENTIFICATION CODE AND INTERPRETATION		
· Letter of Intent	It should state the specific changes made from the previously approved to proposed change/s indicating the new lot code format and interpretation	It does not clearly state specific change/s made. Made change/s not included in the letter of intent.
· Clear and complete loose labels or artworks reflecting the change, as applicable, of all packaging sizes, or equivalents as defined by FDA regulations	* readable, clear, complete label of all previously approved SKUs reflecting the new lot id code format or picture of the product in commercial presentation. * no changes in label design * no reformulation * no change in manufacturer/ manufacturing site	*incomplete submission of label (e.g. only Principal Display Panel only or front label only) *unreadable and unclear label information specifically list of ingredients, country of origin and/or complete name and address of manufacturer *there is a change on the proposed label (design and/or information) vs. previously approved label unless there is change in label design application * incomplete submission of labels for the previously approved SKUs

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