DEPARTMENT OF HEALTH

FOOD AND DRUG ADMINISTRATION

CITIZEN'S CHARTER

CENTER FOR FOOD REGULATION AND RESEARCH (CFRR)

2022 (3rd Edition)

Effectivity Date: 31 MARCH 2022

Profile

I. Mandate:

To protect the general public by ensuring the safety, efficacy, and quality of health products.

II. Vision:

To be an internationally recognized center of excellence in health product regulation by 2026.

III. Mission:

To guarantee the safety, quality, purity, efficacy of health products in order to protect and promote the right to health of the general public.

IV. Service Pledge:

Ensure the safety, efficacy, quality, and purity of health products by fostering integrity, transparency, and excellence-based standards and policies, in a healthy and safe work environment.

Center for Food Regulation and Research

LIST OF EXTERNAL SERVICES

Field Regulatory Operations Office Inspection Agenda

CENTER FOR FOOD REGULATION AND RESEARCH

A. E-REGISTRATION PORTAL USER ACCOUNT

Center/Office/Division	**:**	Center for Food Regulation and Research (CFRR)
Classification	**:**	Government to Business
Type of Transaction	**:**	Simple
Who May Avail	**:**	All FOOD Manufacturers/Traders/Distributors (Importers/ Wholesalers/ Exporters)
Fees to be Paid	**:**	NONE

CHECKLIST OF REQUIREMENTS	**WHERE TO SECURE**
GENERAL GUIDELINE/S *1. Submit **ONE** (1) scanned copy of the required document.*	
A. ISSUANCE OF E-REGISTRATION USER ACCOUNT 1. Send a request for username and password to cfrr@fda.gov.ph with SUBJECT: CFRR: E-Registration (Body) Email Address: Last name: First Name: Middle Name: Company Name: LTO No.: LTO validity: 2. The email must contain an attached scanned copy notarized authorization letter (please see Annex B of FDA Circular No. 2016-014 or updated/existing issuance set by FDA) from company with a valid License-to-Operate (LTO). Note: ***(Please refer to current FDA regulation on the use of the e-Registration Portal/e-Services)***	**Applicant company** **FDA Website (www.fda.gov.ph)**

FOR RE-VALIDATION OF ACCOUNT (FOR THOSE INITIALLY GRANTED ACCESS THROUGH E-PORTAL FOR LICENSING PURPOSES) 1. If the issued username is cfrruser**, email must be sent to fdac@fda.gov.ph; 2. If the issued username is fdauser**, email must be sent to cfrr@fda.gov.ph with SUBJECT: CFRR: E-Registration (Body) Email Address: Last name: First Name: Middle Name: Company Name: LTO No.: LTO validity: 3. The email must contain an attached scanned copy notarized authorization letter (please see Annex B of FDA Circular No. 2016-014 or updated/existing issuance set by FDA) from company with a valid License-to-Operate (LTO). Note: ***(Please refer to current FDA regulation on the use of the e-Registration Portal/e-Services)*** FOR RENEWAL OF ACCOUNT 1. If the issued username is cfrruser**, email must be sent to cfrr@fda.gov.ph; 2. If the issued username is fdauser**, email must be sent to fdac@fda.gov.ph with SUBJECT: CFRR: E-Registration (Body) Email Address: Last name: First Name: Middle Name: Company Name: LTO No.: LTO validity: 3. The email must contain an attached scanned copy notarized authorization letter (please see Annex B of FDA Circular No. 2016-014 or	**FDA** **FDA Website (www.fda.gov.ph)** **Applicant company** **FDA Website (www.fda.gov.ph)**

updated/existing issuance set by FDA) from company with a valid License-to-Operate (LTO). Note: ***(Please refer to current FDA regulation on the use of the e-Registration Portal/e-Services)*** B. CHANGE OF REPRESENTATIVE OF THE APPLICANT COMPANY 1. Send a request for username and password to cfrr@fda.gov.ph with SUBJECT: CFRR: E-Registration (Body) Email Address: Last name: First Name: Middle Name: Company Name: LTO No.: LTO validity: 2. The email must contain an attached scanned copy notarized authorization letter (please see Annex C of FDA Circular No. 2016-014 or updated/existing issuance set by FDA) from company with a valid License-to-Operate (LTO). Note: ***(Please refer to current FDA regulation on the use of the e-Registration Portal/e-Services)***	**Applicant company** **FDA Website (www.fda.gov.ph)**

CLIENT STEPS	AGENCY ACTION	PROCESSING TIME	PERSON RESPONSIBLE
1) The authorized representative submits documents/information to the above-mentioned e-mail address.	1) The FDA Personnel checks e-mail request. If compliant, user name and password will be issued to the client, via e-mail. Otherwise, the personnel will send e-mail to the applicant to request for lacking document(s)/ clarify information.	3 Working Days	Administrative Staff, Center for Food Regulation and Research (CFRR) or Food Drug Action Center (FDAC)
	Total:	3 Working Days	

Please be advised that as per RA 11032 IRR, page 22 of 48, Section 3, b) ***The maximum time prescribed in Section 9 (b) (1) of the Act may be extended only once for the same number of days, which shall be indicated in the Citizen's Charter.***

B. CERTIFICATE OF PRODUCT REGISTRATION (CPR)

(COVERING ALL TYPES OF FOOD PRODUCTS/FOOD CATEGORIZATION: RAW MATERIALS, LOW RISK, MEDIUM RISK AND HIGH RISK FOOD PRODUCTS)

I. TITLE OF CERTIFICATION/PERMIT: CERTIFICATE OF PRODUCT REGISTRATION (CPR) – INITIAL/ RENEWAL DATA CAPTURE (REGULAR)/ AMENDMENT DATA CAPTURE/ RE-APPLICATION DATA CAPTURE

(DATA CAPTURE in the modified e-Registration System/Portal refers to applications processed in the old e-Registration Portal (Version 1) or thru manual registration system)

RENEWAL DATA CAPTURE (REGULAR) in the modified e-Registration System/Portal refers to applications processed in the old e-Registration Portal (Version 1) or thru manual registration system) which is not qualified to the General Guideline/s of AUTOMATIC RENEWAL.

Center/Office/Division	**:**	Center for Food Regulation and Research (CFRR)
Classification	**:**	Government to Business
Type of Transaction	**:**	Highly Technical
Who May Avail	**:**	All FOOD Manufacturers/Traders/Distributors (Importers/ Wholesalers/ Exporters)
Fees to be Paid	**:**	In accordance to Administrative Order 50 s. 2001 + Legal Research Fee (LRF). Conventional Food (Category 1): Php 200.00/year of validity + 1% LRF Conventional Food (Category 2): Php 250.00/year of validity + 1% LRF Food Supplement: Php 1,000.00/year of validity + 1% LRF Bottled Water: Php 1,000.00/year of validity + 1% LRF

GENERAL GUIDELINE/S *1. Submit **ONE (1)** scanned copy of the required document in the e-Registration Portal* *2. Product labels and pictures of the product in commercial presentation for upload should be scanned in 200-dpi setting* *3. Documents for upload should be scanned in 150-dpi setting* *4. Limit the total size of attachments to 25 MB with a limit of 2 MB per file using the format ".png" or ".pdf"* *5. Provide an appropriate file name for each scanned copy of documents to be uploaded in the E-registration*	

system. For product labels, follow the format: "Label_(Case Number)" e.g. Label_12345.png or Label_12345.pdf *6. The validity and contents of the Certificate of Analysis to be uploaded/attached must conform to FDA Circular 2020-033 and/or current FDA regulation (e.g. for Assessment of Microbiological Quality of Processed Food, the COA must indicate the methodology/ies used to verify test result/s for each parameter. The methodologies may be obtained from internationally recognized references as stated in FDA Circular 2013-010).* Note: ***(Please refer to current FDA regulation on the use of the e-Registration Portal/e-Services)***	
CHECKLIST OF REQUIREMENTS **FOR ALL TYPES OF FOOD PRODUCTS/FOOD CATEGORIZATION: RAW MATERIALS, LOW RISK, MEDIUM RISK AND HIGH RISK FOOD PRODUCTS** I. General requirements for Application of Certificate of Product Registration based on Administrative Order 2014-0029	**WHERE TO SECURE**
1. Accomplished Initial Application Form as prescribed by current FDA regulations (e-Registration e-Portal; please refer to FDA Circular No.2020-033, FDA Circular No.2020-033-A or current FDA regulation).	FDA Website (www.fda.gov.ph)
2. Proof of Payment of Fees as prescribed by FDA regulations (e.g. A.O. 50 s. 2001 or current FDA regulation).	FDA Cashier/Other FDA Authorized Payment Portals or Banks
3. Clear and complete loose labels or artworks, as applicable, of all packaging sizes, or equivalents as defined by FDA regulations (Refer to AO 2014-0030 or current FDA regulation).	Applicant Company/ Manufacturer/Source/Supplier
4. 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, as applicable.	Applicant Company/ Manufacturer/Source/Supplier
5. For FOOD SUPPLEMENT, a sample in actual commercial presentation shall be submitted.	Applicant Company/ Manufacturer/Source/Supplier
6. As applicable, documents to substantiate claims, such as technical, nutritional or health studies or reports, market-research studies, Certificate of	Applicant Company/ Manufacturer/Source/Supplier For the Certificate of Analysis:

Analysis, 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 labeling regulations.	a) Manufacturer/Supplier/Source; **OR** b) Laboratory analysis issued/conducted by FDA accredited laboratories.
II. Valid and appropriate FDA License to Operate (required for all types of CPR application)	
III. General Requirements based on FDA Circular 2016-007 • For Locally Manufactured Products: (in cases when the source is not directly the manufacturer) Distributorship agreement or contract agreement, whichever is applicable, signed by the duly authorized representative of the establishment as reflected in the records of CFRR (FDA Circular 2016-007). • For Imported Products: a. **ONE** scanned copy of the original copy of **ANY** of the following documents: Distributorship agreement **OR** contract agreement **OR** Sales Invoice or Proforma Invoice **OR** Appointment letter issued by the supplier/manufacturer appointing the applicant company to distribute the product being applied in the local market, whichever is applicable, signed by the duly authorized representative of the establishment as reflected in the records of CFRR (FDA Circular 2016-007). b. **ONE** scanned Certified true copy or certified photocopy of **ANY** of the following original documents issued to the source by the regulatory or health authority from the country of origin per source: ✓ Valid manufacturer's certificate of registration with GMP compliance or its equivalent; **OR** ✓ Valid Phytosanitary Certificate/ Health Certificate; **OR** ✓ Valid ISO 22000 Certification; **OR** ✓ Valid HACCP Certificate; **OR** ✓ Certificate of Free Sale (CFS issued by a regulatory agency or duly authenticated by the Philippine consulate from the country of origin)	Manufacturer/Source/Supplier
IV. **ADDITIONAL** REQUIREMENTS PER FOOD CATEGORY	1) For the Certificate of Analysis: a) Applicant Company/ Manufacturer/Source/Supplier; **OR**

1. **RAW MATERIALS** ADDITIONAL requirements for raw materials in bulk or for further & processing based on Administrative Order 2014-0029: As applicable, certification to support use of logo/seal on Sangkap Pinoy, Halal, Organic, or Kosher food and in compliance with current labelling regulations. COOKING OIL (i.e. Coconut, Palm, Soybean, Corn). • Certificate of Analysis for Vitamin A based on Republic Act 8976 & Implementing Rules and Regulation of RA 8976 or current FDA regulation. WHEAT FLOUR • Certificate of Analysis for Vitamin A and Iron based on Republic Act 8976 & Implementing Rules and Regulation of RA 8976 or current FDA regulation. REFINED SUGAR • Certificate of Analysis for Vitamin A based on Republic Act 8976 & Implementing Rules and Regulation of RA 8976 or current FDA regulation. IODIZED SALT • Certificate of Analysis for Iodine Content based on Republic Act 8172 & FDA Circular 2013-007 or current FDA regulation. SOY SAUCE • Certificate of Analysis for 3-MCPD based on FDA Memorandum 2011-028. PRE-PACKED RICE • Certificate of Analysis for Iron based on Republic Act 8976 & Implementing Rules and Regulation of RA 8976 or current FDA regulation. 2. **LOW-RISK FOOD PRODUCTS** A. FATS OILS AND FAT EMULSIONS	b) Laboratory analysis issued/conducted by FDA accredited laboratories. 2) For other technical document(s): a) Applicant Company/ Manufacturer/Source/Supplier

	A.1. COOKING OIL (i.e. Coconut, Palm, Soybean, Corn). • Certificate of Analysis for Vitamin A based on Republic Act 8976 & Implementing Rules and Regulation of RA 8976 or current FDA regulation. • In the Electronic Registration Data Entry – Product Specifications Physical/Chemical/Microbiological, declare the results (under specification) for the following Parameters: Saponification Value; Iodine Value for LARD based on Administrative Order No. 231 s. 1974 • In the Electronic Registration Data Entry – Product Specifications Physical/Chemical/Microbiological, declare the results (under specification) for the following Parameters: %Milk Fat by weight; % Milk Solids not fat by weight; % water by weight; Salt (optional) for BUTTER (Whipped, Pasteurized) based on Administrative Order 132 s. 1970. • In the Electronic Registration Data Entry – Product Specifications Physical/Chemical/Microbiological, declare the results (under specification) for the following Parameters: %Milk Fat by weight; % Milk Solids not fat by weight; % water by weight; Salt (optional) for WHEY BUTTER based on Administrative Order 132 s. 1970. • In the Electronic Registration Data Entry – Product Specifications Physical/Chemical/Microbiological, declare the results (under specification) for the following Parameters: % Fat; % Moisture for MARGARINE based on Administrative Order No. 232 s. 1974.	
	B. PROCESSED FRUITS, VEGETABLE AND EDIBLE FUNGI (including mushrooms and fungi, roots and tubers, pulses and legumes, and alovera) SEAWEEDS, AND NUTS AND SEEDS • In the Electronic Registration Data Entry – Product Specifications Physical/Chemical/Microbiological, declare the results (under specification) for the following	

	Parameters: Soluble Solids for JELLY/JELLIES based on Administrative Order No. 239 s. 1975. • In the Electronic Registration Data Entry – Product Specifications Physical/Chemical/Microbiological, declare the results (under specification) for the following Parameters: Soluble Solids for PRESERVES OR JAMS based on Administrative Order No. 238 s. 1975.	
	D.1. WHEAT FLOUR • Certificate of Analysis for Vitamin A and Iron based on Republic Act 8976 & Implementing Rules and Regulation of RA 8976 or current FDA regulation.	
	D.6. PRE-PACKED RICE • Certificate of Analysis for Iron based on Republic Act 8976 & Implementing Rules and Regulation of RA 8976 or current FDA regulation.	
	G.1. REFINED SUGAR • Certificate of Analysis for Vitamin A based on Republic Act 8976 & Implementing Rules and Regulation of RA 8976 or current FDA regulation.	
	I. SALT, SPICES, SOUPS, SALADS AND PROTEIN PRODUCTS I.1. IODIZED SALT & SALT SUBSTITUTES • Certificate of Analysis for Iodine Content based on Republic Act 8172 & FDA Circular 2013-007 or current FDA regulation. * "*All food manufacturers processors using food-grade salt are also required to use iodized salt in the processing of their products and must comply with the provisions of this Act not later than one (1) year from its effectivity. Provided, That the use of iodized salt shall not prejudice the quality and safety of their food products: Provided, however, That the burden of proof and testing for any prejudicial effects due to iodized salt fortification lies on the said food manufacturers/processor."* – **RA 8172**	

	• In the Electronic Registration Data Entry – Product Specifications Physical/Chemical/Microbiological, declare the results (under specification) for the following Parameters: % Acidity; % Total Solids; % Ash; Lead Content; Copper Content and Arsenic Content; *Additional for Malt Vinegar: Phosphorus Pentoxide and Nitrogen Contents for VINEGAR based on Order No. 134 s. 1970. • In the Electronic Registration Data Entry – Product Specifications Physical/Chemical/Microbiological, declare the results (under specification) for the following Parameters: Specific Gravity; Total Solids; Salt Content; Protein Content for PATIS based on Administrative Order No. 325 s. 1977		
	I.8. SOY SAUCE • Certificate of Analysis for 3-MCPD based on FDA Memorandum 2011-028.		
	J. BEVERAGES excluding dairy products • In the Electronic Registration Data Entry – Product Specifications Physical/Chemical/Microbiological, declare the results (under specification) for the following Parameters: Moisture Content (%w/w); Caffeine (%w/w dry basis); Ash (%w/w dry basis; Water-insoluble Solids (%w/w, dry basis); pH; Solubility; Sensory Attributes; Arsenic Content; Lead Content for INSTANT COFFEE based on Administrative Order No. 136-A s. 1985 • In the Electronic Registration Data Entry – Product Specifications Physical/Chemical/Microbiological, declare the results (under specification) for the following Parameters: Moisture Content (%w/w); Caffeine (%w/w, dry basis); Ash (%w/w, dry basis; Water-insoluble Solids (%w/w, dry basis); Carbohydrates (% w/w, dry basis); pH; Solubility; Sensory Attributes; Arsenic Content; Lead Content for SOLUBLE COFFEE WITH ADDED CARBOHYDRATES based on Administrative Order No. 136-B s. 1985 • For IMPORTED ALCOHOLIC BEVERAGES: a) Technical specifications of raw materials and finished product (including methanol content); b) a certificate of		

	compliance with the country of origin's standards and regulation for alcoholic beverages; c) copy of standards and regulation stated in (b) based on Memorandum Circular No. 13 s. 1989. • For LOCALLY MANUFACTURED ALCOHOLIC BEVERAGE: a) Technical specifications of raw materials and finished product (including methanol content); b) source of ethyl alcohol, used as raw material for compounded alcoholic beverages based on Memorandum Circular No. 13 s. 1989.	
3.	**MEDIUM-RISK FOOD PRODUCTS**	
	MRA1a. CONDENSED MILK • Certificate of Analysis for Microbiological parameters for SWEETENED CONDENSED MILK: Coliforms cfu/g, Yeast & Mold Count cfu/g & SPC/APC cfu/g based on FDA Circular 2013-010. • Certificate of Analysis for Total Milk Solids and Milk Fat based on Administrative Order No. 132 s. 1970.	
	MRA2. MILK POWDER • Certificate of Analysis 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, SPC/APC cfu/g & Enterobacteriaceae cfu/g based on FDA Circular 2013-010. • Certificate of Analysis for pH, Protein, Fat, Milk Solids, Milk Fat and Moisture (whichever is applicable) based on Administrative Order No. 132 s. 1970.	
	MRA3. MILK PRODUCTS FOR SPECIFIC TARGET AGE GROUP • Certificate of Analysis 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, SPC/APC cfu/g & Enterobacteriaceae cfu/g based on FDA Circular 2013-010. • Certificate of Analysis for pH, Protein, Fat, Milk Solids, Milk Fat and Moisture (whichever is applicable) based on Administrative Order No. 132 s. 1970. • Certificate of Analysis to support Nutrition Information declaration.		
	MRB2. EDIBLE ICES (POPSICLES) • Certificate of Analysis for Microbiological parameters for FLAVORED ICE: SPC/APC cfu/g, Coliforms MPN/g, YMC cfu/g & Salmonella/25g based on FDA Circular 2013-010.		
	MRC1. TOMATO CATSUP • Certificate of Analysis for Total Soluble Solids and Titratable Acidity based on Administrative Order No. 233 s. 1974.		
	MRC2. FROZEN FRUITS • Certificate of Analysis for Microbiological parameters for FROZEN FRUITS: E. coli MPN/g based on FDA Circular 2013-010.		
	MRC3. CANNED OR BOTTLED FRUITS & VEGETABLE PRESERVE IN JUICE, SYRUP & BRINE • Certificate of Analysis for Microbiological parameters for FRUITS AND VEGETABLE PRODUCTS IN HERMETICALLY SEALED CONTAINERS: Commercial Sterility based on FDA Circular 2013-010.		
	MRC7. FERMENTED VEGETABLES • Certificate of Analysis for Microbiological parameters for FERMENTED VEGETABLE (READY TO EAT): YMC cfu/g, Coliforms MPN/g, E. coli MPN/g, Salmonella/25g & S. aureus cfu/g based on FDA Circular 2013-010.		
	MRD. COCOA POWDER • Certificate of Analysis for Microbiological parameters for COCOA POWDER: Molds cfu/g, Salmonella/25g, Coliforms, MPN/g & SPC/APC cfu/g based on FDA Circular 2013-010.		

	MRD. CHOCOLATE PRODUCTS • Certificate of Analysis for Microbiological parameters for CHOCOLATE PRODUCTS: Molds cfu/g, Salmonella/25g, Coliforms, MPN/g & SPC/APC cfu/g based on FDA Circular 2013-010.	
	MRF1Ai. CURED (INCLUDING SALTED) NON-HEAT TREATED PROCESSED MEAT, POULTRY AND GAME PRODUCTS • Certificate of Analysis for Microbiological parameters for PACKAGED COOKED, CURED/SALTED MEAT: S. aureus (coagulase +) cfu/g, Salmonella/25g & Listeria monocytogenes/25g based on FDA Circular 2013-010. • Certificate of Analysis for Microbiological parameters for CURED/SMOKED POULTRY: S. aureus (coagulase +) cfu/g & Salmonella/25g based on 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.	
	MRF1Aii. CURED (INCLUDING SALTED) DRIED NON-HEAT TREATED PROCESSED MEAT, POULTRY AND GAME PRODUCTS • Certificate of Analysis for Microbiological parameters for PACKAGED COOKED, CURED/SALTED MEAT: S. aureus (coagulase +) cfu/g, Salmonella/25g & Listeria monocytogenes/25g based on 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.	
	MRF2Ai. FERMENTED NON-HEAT TREATED PROCESSED MEAT, POULTRY AND GAME PRODUCTS • Certificate of Analysis for Microbiological parameters for FERMENTED, COMMINUTED MEAT, NOT COOKED (DRY & SEMI-DRY FERMENTED SAUSAGES): E. coli MPN/g, S. aureus (coagulase +) cfu/g & Salmonella/25g based on 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.	
	MRJa. CAKES, COOKIES, PIES, PASTRIES, DOUGHNUTS, SWEET ROLLS, CONES, MUFFINES, WAFFLES-PLAIN /WITHOUT FILLING • Certificate of Analysis for Microbiological parameters for Baked Goods: S. aureus (coagulase +) cfu/g, MYC cfu/g, SPC/APC cfu/g & Coliforms cfu/g) based on FDA Circular 2013-010.	
	MRJa. FROZEN BAKERY PRODUCTS • Certificate of Analysis for Microbiological parameters for FROZEN BAKERY PRODUCTS: S. aureus (coagulase +) cfu/g & Salmonella/25g based on FDA Circular 2013-010.	
	MRjb. FROZEN DOUGH • Certificate of Analysis for Microbiological parameters for FROZEN AND REFRIGERATED DOUGHS: Molds cfu/g, Yeast & Yeastlike Fungi cfu/g, Coliforms cfu/g, Psychrotrophic bacteria cfu/g & SPC/APC cfu/g based on FDA Circular 2013-010.	
	MRK2a. EMULSIFIED SAUCES AND DIPS (SALAD DRESSING- i.e. MAYONNAISE, THOUSAND ISLAND, RANCH, FRENCH) • Certificate of Analysis for Microbiological parameters for SALAD DRESSING: SPC/APC cfu/g, YMC cfu/g, Salmonella/25g & Listeria monocytogenes/25g based on FDA Circular 2013-010. • For MAYONNAISE: Certificate of Analysis for Fat Content based on Administrative Order No. 235 s. 1975.	
	MRK2b. NON-EMULSIFIED SAUCES (ketchup, cheese sauce, cream sauce, brown gravy) • Certificate of Analysis for Total Solids; Titratable Acidity; pH for BANANA SAUCE based on Administrative Order No. 123-A s. 1985.	
	MRL1a. FRUIT AND VEGETABLE JUICES	

	• 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.	
	MRL1c. SPORTS, ENERGY DRINK & ELECTROLYTE DRINKS • 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. • Certificate of Analysis for Caffeine and Vitamin Assays based on Administrative Order 2014-0029. • Label bearing the 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."*	
	MRL1ci. CARBONATED WATER-BASED FLAVORED DRINKS • 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. • For COLA-TYPE BEVERAGE: Certificate of Analysis for Caffeine Content based on Administrative Order 88-A s. 1984.	
	MRL1cii. NON-CARBONATED WATER-BASED FLAVORED DRINKS • 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.	
	MRL1ciii. FROZEN CONCENTRATE • Certificate of Analysis for Microbiological parameters for FROZEN JUICE CONCENTRATES: SPC/APC cfu/mL & YMC cfu/mL based on FDA Circular 2013-010.	
	MRL1d. POWDERED COCOA DRINK MIXES	

	• Certificate of Analysis for Microbiological parameters for POWDERED BEVERAGE: SPC/APC cfu/g & YMC cfu/g based on FDA Circular 2013-010.	
	MRM1. VITAMINS, MINERALS & AMINO ACIDS AS FOOD SUPPLEMENTS • Shelf life study with stability data based on Administrative Order 2014-0029. • Certificate of Analysis of the physico-chemical (Vitamins, Minerals & Amino Acids Assays) and microbiological parameters of the finished product based on Administrative Order 2014-0029. • 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. • Sample in actual commercial presentation based on Administrative Order 2014-0029. For **FOOD SUPPLEMENTS**, 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: • Personal Delivery to FDAC, Starmall, Alabang, Muntinlupa City or • 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.

Note:

Please refer to current FDA regulation (e.g. FDA Circular 2020-026: Food and Drug Action Center (FDAC) New Normal Operational Guidelines of the Food and Drug Administration). Updates on FDAC Operational Guidelines will be announced/published accordingly.

4. **HIGH-RISK FOOD PRODUCTS**

HRA1a. MILK (PLAIN) AND BUTTERMILK PLAIN

- Certificate of Analysis for Microbiological parameters for LIQUID MILK (EVAPORATED & READY TO DRINK)-UHT/STERILIZED: Commercial Sterility based on FDA Circular 2013-010.

- Certificate of Analysis for Microbiological parameters for PASTEURIZED MILK: Coliforms cfu/mL, Salmonella/25mL, Listeria monocytogenes/25mL, Psychrotrophic bacteria cfu/mL & SPC/APC cfu/mL based on FDA Circular 2013-010.

- Certificate of Analysis for % Total Milk Solids; % Milk Fat; Vitamin D (If Vitamin D is added) for EVAPORATED MILK, EVAPORATED WHOLE MILK, EVAPORATED FULL CREAM MILK, UNSWEETENED CONDENSED WHOLE MILK, AND UNSWEETENED FULL CREAM CONDENSED MILK based on Administrative Order 132 s. 1970.

- Certificate of Analysis for % Total Milk Solids and % Milk Fat for SWEETENED CONDENSED MILK, SWEETENED CONDENSED WHOLE MILK, AND SWEETENED FULL CREAM CONDENSED MILK based on Administrative Order 132 s. 1970.

	• Certificate of Analysis for % Milk Solids, % Milk Fat and % Water for WHOLE MILK POWDER (DRIED FULL CREAM MILK, FULL CREAM MILK POWDER, DRY WHOLE MILK AND MILK POWDER, DRIED MILK based on Administrative Order 132 s. 1970. • Certificate of Analysis for % Milk Fat; % Milk Solids Not Fat for SKIM MILK AND SKIMMED MILK based on Administrative Order 132 s. 1970. • Certificate of Analysis for % Milk Solids for EVAPORATED SKIMMED MILK, UNSWEETENED CONDENSED SKIMMED MILK based on Administrative Order 132 s. 1970. • Certificate of Analysis for % Milk Solids for SWEETENED CONDENSED SKIMMED MILK based on Administrative Order 132 s. 1970. • Certificate of Analysis for % Solids, % Fat and % Water for SKIMMED MILK POWDER (NON-FAT DRIED MILK, DRIED SKIMMED MILK) based on Administrative Order 132 s. 1970. • Certificate of Analysis for % Milk Solids, % Milk Fat and % Water for PARTLY SKIMMED MILK POWDER (PARTLY SKIMMED DRIED MILK) based on Administrative Order 132 s. 1970. • Certificate of Analysis for Milk Fat; Solids-Not-Fat; Vitamin A content; Vitamin D Content (if added) for RECONSTITUTED, RECONSTRUCTED OR RECOMBINED EVAPORATE MILK based on Administrative Order 132 s. 1970. • Certificate of Analysis for % Milk Solid-Not-Fat for RECONSTITUTED, RECONSTRUCTED OR RECOMBINED SKIMMED MILK based on Administrative Order 132 s. 1970. • Certificate of Analysis for % Milk Solids for RECONSTITUTED, RECONSTRUCTED OR RECOMBINED EVAPORATED SKIM MILK based on Administrative Order 132 s. 1970.		

	• Certificate of Analysis for % Milk Solids-Not-Fat for BUTTERMILK based on Administrative Order 132 s. 1970. • Certificate of Analysis for % Butterfat, %Total Milk Solids and % Moisture for BUTTERMILK POWDER (DRIED BUTTERMILK) based on Administrative Order 132 s. 1970. • Certificate of Analysis for % Milk Fat Content for LOWFAT MILK based on Administrative Order 132 s. 1970. • Certificate of Analysis for % Milk Fat Content for RECONSTITUTED, RECONSTRUCTED OR RECOMBINED LOW FAT MILK based on Administrative Order 132 s. 1970. • Certificate of Analysis for % Total Oil Content; % Non-Milk Fat Solids; Vitamin A & D Content (The addition of Vitamin D is optional) for FILLED MILK based on Administrative Order 132 s. 1970. • Certificate of Analysis for % Total Oil Content; % Non-Milk Fat Solids; Vitamin A & D Content for EVAPORATED FILLED MILK based on Administrative Order 132 s. 1970. • Certificate of Analysis for % Total Oil Content; % Non-Fat Milk Solids; Vitamin A & D Content (Vitamin D is optional) for SWEETENED CONDENSED FILLED MILK based on Administrative Order 132 s. 1970.		
	HRA1b. DAIRY-BASED DRINKS, FLAVORED AND/OR FERMENTED • Certificate of Analysis for Microbiological parameters for LIQUID MILK (EVAPORATED & READY TO DRINK)-UHT/STERILIZED: Commercial Sterility based on FDA Circular 2013-010. • Certificate of Analysis for Microbiological parameters for PASTEURIZED MILK: Coliforms cfu/mL, Salmonella/25mL, Listeria monocytogenes/25mL, Psychrotrophic bacteria cfu/mL & SPC/APC cfu/mL based on FDA Circular 2013-010.		

	• Certificate of Analysis for Microbiological parameters for YOGURT AND FERMENTED MILK: S. aureus (coagulase +) cfu/mL, Coliforms cfu/mL, Salmonella/25mL & Lactic acid cfu/mL based on FDA Circular 2013-010. • Certificate of Analysis for % Milk Fat and % Moisture for MALTED MILK POWDER based on Administrative Order 132 s. 1970. • Certificate of Analysis for % Milk Fat Content by weight; % Milk Solids Non-Fat Content by weight; Acidity of the product when solid for YOGURT AND FLAVORED YOGURT based on Administrative Order 132 s. 1970.		
	HRA3a. PASTEURIZED CREAM • Certificate of Analysis for Microbiological parameters for Pasteurized Cream: Coliforms cfu/g, Salmonella/25g, Listeria monocytogenes/25g, Psychrotrophic bacteria cfu/g & SPC/APC cfu/g based on FDA Circular 2013-010.		
	HRA3b. STERILIZED AND UHT CREAMS, WHIPPING AND WHIPPED CREAMS, AND REDUCED FAT CREAMS (PLAIN) • Certificate of Analysis for Microbiological parameters for CREAM (UHT/STERILIZED): Commercial Sterility based on FDA Circular 2013-010. • Certificate of Analysis for % Butterfat for CREAM based on Administrative Order 132 s. 1970. • Certificate of Analysis for % Butterfat for LIGHT CREAM TABLE CREAM OR COFFEE CREAM based on Administrative Order 132 s. 1970. • Certificate of Analysis for % Milk Fat for WHIPPING CREAM based on Administrative Order 132 s. 1970. • Certificate of Analysis for % Butterfat for LIGHT WHIPPING CREAM based on Administrative Order 132 s. 1970. • Certificate of Analysis for % Milk Fat for HEAVY CREAM OR HEAVY WHIPPING CREAM based on Administrative Order 132 s. 1970.		

	• Certificate of Analysis for % Milk Fat for HALF-AND HALF based on Administrative Order 132 s. 1970.	
	HRA4a. UNRIPENED CHEESE • Certificate of Analysis for Microbiological parameters for CHEESE AND CHEESE PRODUCTS (MOISTURE ≥ 39% & PH > 5): S. aureus (coagulase +) cfu/g, E. coli MPN/g, Coliforms MPN/g, Psychrotrophic bacteria cfu/g, Salmonella/25g & Listeria monocytogenes/25g based on FDA Circular 2013-010. • Certificate of Analysis for Microbiological parameters for ALL RAW MILK CHEESE: Campylobacter/25g, Salmonella/25g, Listeria monocytogenes/25g and S. aureus (coagulase +) cfu/g based on FDA Circular 2013-010. • Certificate of Analysis for Fat in Dry Matter and Moisture Content based on Administrative Order No. 200-A s. 1973	
	HRA4di. PLAIN PROCESSED CHEESE • Certificate of Analysis for Microbiological parameters for PROCESSED CHEESE SPREAD: S. aureus (coagulase +) cfu/g, Coliforms cfu/g & SPC /APC cfu/g based on FDA Circular 2013-010.	
	HRA4di. FLAVORED PROCESSED CHEESE • Certificate of Analysis for Microbiological parameters for Processed Cheese Spread: S. aureus (coagulase +) cfu/g, Coliforms cfu/g & SPC /APC cfu/g based on FDA Circular 2013-010.	
	HRA5. DAIRY BASED DESSERT (e.g. Yogurt) • Certificate of Analysis for Microbiological parameters for YOGURT AND FERMENTED MILK: S. aureus (coagulase +) cfu/mL, Coliforms cfu/mL, Salmonella/25mL & Lactic acid cfu/mL based on FDA Circular 2013-010.	
	HRA8. DAIRY BASED FROZEN DESSERT • Certificate of Analysis for Microbiological parameters for ICE CREAM & SHERBET (PLAIN AND FLAVORED): Coliforms cfu/g, Listeria monocytogenes/25g, Salmonella/25g,	

	SPC/APC cfu/g & S. aureus (coagulase +) cfu/g based on FDA Circular 2013-010. • Certificate of Analysis for Microbiological parameters for ICE CREAM WITH ADDED INGREDIENTS (NUTS, FRUITS, COCOA ETC.): Coliforms cfu/g, Listeria monocytogenes/25g, Salmonella/25g, SPC/APC cfu/g & S. aureus (coagulase +) cfu/g based on FDA Circular 2013-010.		
	HRB1. DRIED FRUIT • Certificate of Analysis for Microbiological parameters for SUN DRIED FRUITS: Mold cfu/g, OsmophilicYeasts cfu/g & E. coli MPN/g based on FDA Circular 2013-010.		
	HRB1. DRIED VEGETABLE • Certificate of Analysis for Microbiological parameters for DRIED VEGETABLE: E. coli MPN/g based on FDA Circular 2013-010.		
	HRB2. VEGETABLE, SEAWEED AND NUT AND SEED- PUREES, SPREADS • Certificate of Analysis for Microbiological parameters for PEANUT BUTTER & OTHER NUT SPREADS: Salmonella/25g based on FDA Circular 2013-010.		
	HRD. CHOCOLATE WITH NUTS • Certificate of Analysis for Microbiological parameters for CHOCOLATE PRODUCTS: Molds cfu/g, Salmonella/25g, Coliforms MPN/g & SPC/APC cfu/g based on FDA Circular 2013-010.		
	HRF1. FINE BAKERY PRODUCTS WITH FILLINGS • Certificate of Analysis for Microbiological parameters for 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) based on FDA Circular 2013-010. • Certificate of Analysis for Microbiological parameters for COATED OR FILLED, DRIED SHELF-STABLE BISCUITS: Coliforms MPN/g & Salmonella/25g based on FDA Circular 2013-010.		

	HRG1a./HRG2a. HEAT-TREATED PROCESSED MEAT, POULTRY AND GAME PRODUCTS (CANNED) • Certificate of Analysis for Microbiological parameters for MEAT PRODUCTS IN HERMETICALLY SEALED CONTAINERS: Commercial Sterility based on 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.	
	HRG2b. FROZEN PROCESSED MEAT, POULTRY AND GAME PRODUCTS (NUGGETS, PATTIES, DUMPLINGS, SALAMI, MEAT LOAF, HOTDOG) • Certificate of Analysis for Microbiological parameters for COLD CUTS, FROZEN & CHILLED HOTDOGS: E. coli MPN/g, Salmonella/25g, S. aureus (coagulase +) cfu/g & SPC/APC cfu/g based on 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.	
	HRH1A. FROZEN FISH, FISH FILLETS AND FISH PRODUCTS • Certificate of Analysis for Microbiological parameters for FRESH FROZEN FISH: E. coli MPN/g, S. aureus (coagulase +) cfu/g, V. parahaemolyticus cfu/g, Salmonella/25g & SPC/APC cfu/g based on FDA Circular 2013-010.	
	HRH1B. FROZEN BATTERED FISH, FISH FILLETS AND FISH PRODUCTS, INCLUDING MOLLUSCS, CRUSTACEANS AND ECHINODERMS • Certificate of Analysis for Microbiological parameters for PRE-COOKED BREADED FISH: E. coli MPN/g, S. aureus (coagulase +) cfu/g & SPC/APC cfu/g based on FDA Circular 2013-010.	
	HRH1DII. COOKED MOLLUSCS, CRUSTACEANS AND ECHINODERMS • Certificate of Analysis for Microbiological parameters for FROZEN COOKED	

	CRUSTACEANS: E. coli MPN/g, S. aureus (coagulase +) cfu/g, V. parahaemolyticus cfu/g, Salmonella/25g & SPC/APC cfu/g based on FDA Circular 2013-010.		
	HRH2. Fully preserved, including canned or fermented fish and fish products • Certificate of Analysis for Microbiological parameters for FISH & SHELLFISH PRODUCTS IN HERMETICALLY SEALED CONTAINERS (THERMALLY PROCESSED): commercial sterility based on FDA Circular 2013-010.		
	HRH2. FULLY PRESERVED, INCLUDING CANNED OR FERMENTED FISH AND FISH PRODUCTS (BAGOONG (FISH & SHRIMP)) • Certificate of Analysis for Total Solids, Protein and NaCl based on Administrative Order No. 128 s. 1970		
	HRH2. FULLY PRESERVED, INCLUDING CANNED OR FERMENTED FISH AND FISH PRODUCTS (BAGOONG (COOKED)) • Certificate of Analysis for Microbiological parameters for FISH & SHELLFISH PRODUCTS IN HERMETICALLY SEALED CONTAINERS (THERMALLY PROCESSED): commercial sterility based on FDA Circular 2013-010.		
	HRIA. LIQUID EGG PRODUCTS • Certificate of Analysis for Microbiological parameters for PASTEURIZED EGG PRODUCTS (LIQUID, FROZEN, DRIED): Coliforms cfu/g, Salmonella/25g, YMC cfu/g (for dried products) & SPC/APC cfu/g based on FDA Circular 2013-010.		
	HRJ1. INFANT FORMULA & FORMULAS FOR SPECIAL MEDICAL PURPOSED INTENDED FOR INFANTS (POWDER) • Certificate of Analysis for Energy, Protein, Total Fat, Linolenic Acid, Total Carbohydrates per 100g, Vitamins and Minerals, Trace Minerals and Other Substances, Lauric/Mystiric/Trans Fatty Acids, Optional Ingredients- Taurine, DHA and Contaminants based on Codex Stan 72-1981 Rev. 2007. • Certificate of Analysis for Microbiological parameters for POWDERED INFANT FORMULA WITH OR WITHOUT ADDED		

	LACTIC ACID PRODUCING CULTURES: Cronobacter spp./10g, Salmonella/25g, SPC/APC cfu/g & Enterobacteriaceae/10g based on FDA Circular 2013-010. • Clear and complete loose labels or artworks compliant with Department Circular 2008-0006. • For FSMP: Scientific Studies indicating safety and benefits of the product for intended medical condition based Codex Stan 180-1991 and Administrative Order 2014-0029.		
	HRJ1. INFANT FORMULA & FORMULAS FOR SPECIAL MEDICAL PURPOSED INTENDED FOR INFANTS (LIQUID) • Certificate of Analysis for Energy, Protein, Total Fat, Linolenic Acid, Total Carbohydrates per 100g, Vitamins and Minerals, Trace Minerals and Other Substances, Lauric/Mystiric/Trans Fatty Acids, Optional Ingredients- Taurine, DHA and Contaminants based on Codex Stan 72-1981 Rev. 2007. • Certificate of Analysis for Microbiological parameters for INFANT FORMULA- LIQUID (UHT/STERILIZED) CULTURES: commercial sterility based on FDA Circular 2013-010. • Clear and complete loose labels or artworks compliant with Department Circular 2008-0006. • For FSMP: Scientific Studies indicating safety and benefits of the product for intended medical condition based Codex Stan 180-1991 and Administrative Order 2014-0029.		
	HRJ1. FOLLOW-UP FORMULA/MILK SUPPLEMENT • Certificate of Analysis for Energy, Protein, Total Fat, Linolenic Acid, Total Carbohydrates per 100g, 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 1561987. • Certificate of Analysis for Microbiological parameters for FOLLOW-UP FORMULA/MILK SUPPLEMENTS: Salmonella/25g, SPC/APC		

	cfu/g & Enterobacteriaceae/10g based on FDA Circular 2013-010. • Clear and complete loose labels or artworks compliant with Department Circular 2008-0006.	
	HRJ2. CEREAL-BASED FOODS FOR INFANTS & YOUNG CHILDREN • Certificate of Analysis for Energy, Protein, Carbohydrates, Lipids, Minerals and Vitamins per 100 kcal or 100 kJ based on Codex Stan 074-1981, Rev 1-2006. • Certificate of Analysis for Microbiological parameters for CEREAL-BASED FOODS FOR INFANTS: Bacillus cereus cfu/g, Clostridium perfringes cfu/g, SPC/APC cfu/g, Salmonella/25g & Coliforms MPN/g based on FDA Circular 2013-010. • Clear and complete loose labels or artworks declaring the statement “Infants six months onwards should be given fresh, indigenous and natural food in combination with continued breastfeeding based on Department Circular 2008-0006.	
	HRJ2. CANNED BABY FOODS • Certificate of Analysis to support Nutrition Information based on Codex Stan 73-1981 amended 1989. • Certificate of Analysis for Microbiological parameters for BABY FOODS IN HERMETICALLY SEALED CONTAINERS: commercial sterility based on FDA Circular 2013-010. • Clear and complete loose labels or artworks declaring the statement “Infants six months onwards should be given fresh, indigenous and natural food in combination with continued breastfeeding based on Department Circular 2008-0006.	
	HRJ3. FOODS FOR SPECIAL MEDICAL PURPOSES • Scientific Studies indicating safety and benefits of the product for intended medical condition based Codex Stan 180-1991 and Administrative Order 2014-0029.	

	• Certificate of Analysis to support Nutrition Information based on Codex Stan 180-1991. • Clear and complete loose labels or artworks compliant with Codex Stan 180-1991.		
	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. • Certificate of Analysis to support Nutrition Information based on Codex Stan146-1985. • Clear and complete loose labels or artworks compliant with Codex Stan146-1985.		
	HRJ4. FORMULA FOODS FOR WEIGHT CONTROL DIETS • Certificate of Analysis to support Nutrition Information based on Codex Stan 181-1991. • Clear and complete loose labels or artworks compliant with Codex Stan 181-1991.		
	HRJ. BOTTLED WATER • Certificate of Analysis 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. • Clear and complete loose labels or artworks compliant with Administrative Order No. 39 s. 1996 and Administrative Order No. 18-A s. 1993.		
	HRK1. HERBS AND BOTANICALS AND/OR PRODUCTS WITH OTHER NUTRITIONAL		

	SUBSTANCES AND/OR COMBINATION AS FOOD SUPPLEMENTS • Shelf life study with stability data based on Administrative Order 2014-0029. • Certificate of Analysis of the physico-chemical and microbiological parameters of the finished product based on Administrative Order 2014-0029. • 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. • Safety data (include but not limited to acute toxicity test, safe history of use; research studies on safety of the product) based on Administrative Order 2014-0029. • For Dried Plants: Certificate of Analysis for Heavy Metals in the finished product based on Administrative Order 184 s. 2004. • Additional requirements in the registration of Virgin Coconut Oil Food Supplement with Flavor: 1) That the raw material (virgin coconut oil) used conforms with the Philippine National Standards for Virgin Coconut Oil; 2) That the flavoring added should be generally recognized as safe and suitable for human consumption as evidenced by a certification from the supplier. The nature of flavor used (natural, nature-identical, artificial) shall be indicated in the list of ingredients; 3) No other food additive shall be allowed except the flavor; 4) The label shall conform with BC 2 s. 1999; 5) The term “Food Supplement” shall be part of the product name. Based on Bureau Circular 2006-018 • Sample in actual commercial presentation based on Administrative Order 2014-0029. For **FOOD SUPPLEMENTS**, 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: • Personal Delivery to FDAC, Starmall, Alabang, Muntinlupa City or • 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.* Note: ***Please refer to current FDA regulation (e.g. FDA Circular 2020-026: Food and Drug Action Center (FDAC) New Normal Operational Guidelines of the Food and Drug Administration). Updates on FDAC Operational Guidelines will be announced/published accordingly.***	
		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. • Certificate of Analysis for Microbiological parameters for POWDERED	

BEVERAGES: SPC/APC cfu/g & Coliforms cfu/g.	
FOOD PRODUCTS CONTAINING TRANS-FATTY ACIDS (TFA) • Technical specifications of raw materials indicating specific oil(s) and/or fat(s) used and the processing it underwent; and • Recent (within 12 months) certificate of analysis of the finished product from an accredited laboratory of the FDA and/or Philippine Accreditation Board/Office (PAB/PAO), reflecting the TFA content per 100g or 100ml of total fat, reference methods of analysis, and the limit of detection for the method used in the analysis of TFA. Based on FDA Circular 2021-028.	

FOR AMENDMENT DATA CAPTURE	**WHERE TO SECURE**
1. General Requirements based on Administrative Order No. 2014-0029 • Accomplished Application Form as prescribed by FDA regulations (e-Registration e-Portal, refer to FDA Circular No.2020-033, FDA Circular No.2020-033-A or current FDA regulation).	FDA Website (www.fda.gov.ph)
• Proof of Payment of Fees as prescribed by current FDA regulations (A.O. 50 s. 2001).	FDA Cashier/Other FDA Authorized Payment Portals or Banks
• Scanned Application Letter stating the intended changes (indicate changes/amendments to be made)	Applicant Company
2. Upload **ALL INITIAL** requirements.	Applicant Company/ In reference to the previously filed and approved INITIAL application (The validity of the documents to be submitted must be in accordance to current FDA regulation/s).
3. Additional Requirements per Amendment Type based on Administrative Order No. 2014-0029 (Please refer to *II. TITLE OF CERTIFICATION/PERMIT:*	Applicant Company

CERTIFICATE OF PRODUCT REGISTRATION (CPR) – AMENDMENT (INITIAL APPLICATION APPROVED FROM MODIFIED E-REGISTRATION); 2) Additional Requirements per Amendment Type based on Administrative Order No. 2014-0029)	
FOR RE-APPLICATION DATA CAPTURE 1. Accomplished Application Form as prescribed by current regulations (e-Registration e-Portal, FDA Circular No.2020-033, FDA Circular No.2020-033-A or current FDA regulation). 2. Upload **ALL INITIAL** requirements and compliance to the deficiencies stated in the previously issued Letter of Denial (LOD) within 6 months upon receipt of LOD. 3. Proof of Payment of Fees as prescribed by current FDA regulations. (Administrative Order 50 s. 2001 current FDA regulation.)	**WHERE TO SECURE** FDA Website (www.fda.gov.ph) Applicant Company/ In reference to the previously filed and disapproved INITIAL application (The validity of the documents to be submitted must be in accordance to current FDA regulation/s). FDA Cashier/Other FDA Authorized Payment Portals or Banks
FOR RENEWAL DATA CAPTURE (REGULAR) 1) Accomplished Application Form as prescribed by FDA regulations. (e-Registration e-Portal, refer to FDA Circular No.2020-033, FDA Circular No.2020-033-A or current FDA regulation). 2) Upload **ALL INITIAL** requirements. 3) Proof of payment of fees as prescribed by current FDA regulations (AO 50 s. 2001 or current FDA regulation).	**WHERE TO SECURE** FDA Website (www.fda.gov.ph) Applicant Company/ In reference to the previously filed and approved INITIAL application (The validity of the documents to be submitted must be in accordance to current FDA regulation/s). FDA Cashier/Other FDA Authorized Payment Portals or Banks

CLIENT STEPS	AGENCY ACTION	PROCESSING TIME	PERSON RESPONSIBLE
1)The authorized representative of the applicant company accomplishes the on-	1) FDA Personnel will pre-assess the completeness of the submitted documents through e-Portal	Day 0	Center for Food Regulation and Research (CFRR) Technical Personnel

line form/e-Registration through the e-Portal https://eportal.fda.gov.ph based on the desired type of application in accordance to **current FDA regulation** on the use of the e-Registration Portal/e-Services. (E-mail notification from FDA will be received by the client upon submission of application for Pre-Assessment.)	https://eportal.fda.gov.ph. Result of Pre-assessment will be received by the account holder. If found complete, an Order of Payment will be automatically generated and will be sent to the email of the account holder/client. If found incomplete, a notification with result of Pre-Assessment from FDA will be received. To refile, the applicant must start a NEW CASE in filing an application for this product. Upload initially submitted documentary requirements together with documents for compliance to deficiencies mentioned. For Food Supplement application, the proof of submission of sample can be re-uploaded to the new application. ***(Please refer to current FDA regulation on the use of the e-Registration Portal/e-Services)***		(e.g. Food-Drug Regulation Officer (FDRO))
2) The applicant company receives the Order of Payment		Day 0	
3) The applicant company pays the assessed fee as per the system generated Order of Payment Form through FDAC Cashier or any other means prescribed by FDA (e.g. BANCNET).	2) FDA Cashier receives the payment/Official Receipt (OR)/ proof of payment transaction, and then post the payment. The application will then be forwarded to CFRR, once payment is posted.	Day 0	Administrative Staff, Cashier-Administrative and Finance Services (AFS)
4) The applicant company receives Acknowledgement Receipt with the application and pre-assessment details.		Day 0	
	3) Evaluation	8 Working Days (Days 1-8)	CFRR Technical Personnel (e.g. FDRO)

	4) Checking	7 Working Days (Days 9-15)	CFRR Technical Personnel (e.g. FDRO)
	5) Final Decision/Issuance	5 Working Days Days 16-20)	Director IV, CFRR
5) If the application is approved, e-mail notification from FDA containing how/where to download the Certificate of Product Registration will be received. If disapproved, e-mail notification from FDA containing how/where to download the Letter of Denial/Disapproval (LOD) will be received. For Amendment: If the application is approved, the applicant company will receive an e-mail notification from FDA indicating that the application is approved (this includes those amendments with multiple applications with approved and disapproved results) and another e-mail notification containing the Amendment Decision Summary Table. If disapproved, a Letter of Denial/Disapproval (LOD) and another e-mail notification containing the Amendment Decision Summary Table will be received.	6) The e-Portal generates electronically signed CPR or LOD.		N/A
	TOTAL:	20 Working Days	

Please be advised that as per RA 11032 IRR, page 22 of 48, Section 3, b) ***The maximum time prescribed in Section 9 (b) (1) of the Act may be extended only once for the same number of days, which shall be indicated in the Citizen's Charter.***

II. **TITLE OF CERTIFICATION/PERMIT: CERTIFICATE OF PRODUCT REGISTRATION (CPR)** – AMENDMENT (INITIAL APPLICATION APPROVED FROM MODIFIED E-REGISTRATION (VERSION 2))

Center/Office/Division	**:**	Center for Food Regulation and Research (CFRR)
Classification	**:**	Government to Business
Type of Transaction	**:**	Highly Technical
Who May Avail	**:**	All FOOD Manufacturers/Traders/Distributors (Importers/ Wholesalers/ Exporters)
Fees to be Paid	**:**	In accordance to Administrative Order 50 s. 2001 + Legal Research Fee (LRF). Change or Extension of Shelf-life: Php 1,000.00 + 1% LRF Other Types of Amendment: Php 200.00 + 1% LRF

GENERAL GUIDELINE/S *1. Submit **ONE (1)** scanned copy of the required document in the e-Registration Portal* *2. Product labels and pictures of the product in commercial presentation for upload should be scanned in 200-dpi setting* *3. Documents for upload should be scanned in 150-dpi setting* *4. Limit the total size of attachments to 25 MB with a limit of 2 MB per file using the format ".png" or ".pdf"* *5. Provide an appropriate file name for each scanned copy of documents to be uploaded in the E-registration system. For product labels, follow the format: "Label_(Case Number)"* *e.g. Label_12345.png or Label_12345.pdf* *6. The validity and contents of the Certificate of Analysis to be uploaded/attached must conform to FDA Circular 2020-033 and/or current FDA regulation (e.g. for Assessment of Microbiological Quality of Processed Food, the COA must indicate the methodology/ies used to verify test result/s for each parameter. The methodologies may be obtained from internationally recognized references as stated in FDA Circular 2013-010).* *7) Provide the required information completely and accurately.* *8) For amendment applications, select all amendment types for the desired changes except for any changes that is equivalent to an INITIAL application.* Note: ***(Please refer to current FDA regulation on the use of the e-Registration Portal/e-Services)***	
CHECKLIST OF REQUIREMENTS	**WHERE TO SECURE**

<table>
<tr><td><u>FOR ALL TYPES OF FOOD PRODUCTS/FOOD CATEGORIZATION:
RAW MATERIALS, LOW RISK, MEDIUM RISK AND HIGH RISK FOOD PRODUCTS</u>

I . General Requirements based on Administrative Order No. 2014-0029

• Accomplished Initial Application Form as prescribed by FDA regulations (e-Registration e-Portal, refer to FDA Circular No.2020-033, FDA Circular No.2020-033-A or current FDA regulation).
• Proof of Payment of Fees as prescribed by current FDA regulations (A.O. 50 s. 2001).
• Scanned Application Letter stating the intended changes (indicate changes/amendments to be made)</td><td>FDA Website (www.fda.gov.ph)

FDA Cashier/Other FDA Authorized Payment Portals or Banks
Applicant Company</td></tr>
<tr><td>II. Valid and appropriate FDA License to Operate (required for all types of CPR application)</td><td>FDA</td></tr>
<tr><td>III. ADDITIONAL Requirements per Amendment Type based on Administrative Order No. 2014-0029

<table>
<tr><td>2a. Change in Brand Name
• Clear and complete loose labels or artworks reflecting the change, as applicable, of all packaging sizes, or equivalents as defined by FDA regulations
• Authority from the source or the owner of the brand (imported & local)
• IPO registration, if available</td></tr>
<tr><td>2b. Change in Product Name/Additional Product Description
• Clear and complete loose labels or artworks reflecting the change, as applicable, of all packaging sizes, or equivalents as defined by FDA regulations</td></tr>
<tr><td>2c. Change in Company Name/Business Name
• Proof of change in business name (e.g. License to Operate)
• Clear and complete loose labels or artworks reflecting the change, as applicable, of all packaging sizes, or equivalents as defined by FDA regulations</td></tr>
<tr><td>2d. Change in/Additional Supplier
• Any of the following scanned copy of the original documents: Foreign Agency Agreement or Certificate of Distributorship or Appointment letter</td></tr>
</table></td><td>1) Applicant Company/ Manufacturer/Source/Supplier

2) For the Certificate of Analysis:
a) Applicant Company/ Manufacturer/Source/Supplier; OR
b) Laboratory analysis issued/conducted by FDA accredited laboratories.</td></tr>
</table>

	or Proforma Invoice or Memorandum of Agreement from the new supplier.	
	2e. Change in Packaging Material and/or Additional Packaging Type • Clear and complete proposed loose labels or artworks, as applicable, of all packaging sizes, or equivalents as defined by FDA regulations • 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. • Proof of suitability of packaging material for food, including stability of the product in the new packaging.	
	2f. Change of Packaging in Commercial Presentation (Change/Additional Packaging Size) • Clear and complete loose labels or artworks, as applicable, of all packaging sizes, or equivalents, reflecting the change/s, as defined by FDA Regulations	
	2g. Change or Extension in Shelf-Life • Stability study results with conclusion to support extension or change in shelf-life	
	2h. Change in/Additional Packaging design • Clear and complete loose labels or artworks, as applicable, of all packaging sizes, or equivalents, reflecting the change/s, as defined by FDA Regulations 2hi. Addition of Claims for Logos • Clear and complete loose labels or artworks, as applicable, of all packaging sizes, or equivalents, reflecting the change/s, as defined by FDA Regulations. • Valid Certificate (e.g. HALAL, Sangkap pinoy seal, Organic, Kosher, etc.) 2hii. Change in Label Color • Clear and complete loose labels or artworks, as applicable, of all packaging sizes, or equivalents, reflecting the change/s, as defined by FDA Regulations. 2hiii. Change in Font Size for Product Information • Clear and complete loose labels or artworks, as applicable, of all packaging sizes, or equivalents, reflecting the change/s, as defined by FDA Regulations.	

2hiv. Change/Additional Claims for Source of Vitamins/Minerals and Health and Nutrition Claims

- Clear and complete loose labels or artworks, as applicable, of all packaging sizes, or equivalents, reflecting the change/s, as defined by FDA Regulations.
- Certificate of Analysis (duly signed by competent technical staff including the complete name with appropriate parameters and result) or documents to substantiate claims.

2hv. Change /Update in Nutrition Information (Vitamin and Mineral)

- Clear and complete loose labels or artworks, as applicable, of all packaging sizes, or equivalents, reflecting the change/s, as defined by FDA Regulations.
- Certificate of Analysis (duly signed by competent technical staff including the complete name with appropriate parameters and result).

2hvi. Change/Additional Menu or Serving suggestion (Photograph)

- Clear and complete loose labels or artworks, as applicable, of all packaging sizes, or equivalents, reflecting the change/s, as defined by FDA Regulations.

2hvii. Compliance to CPR Remarks

- Clear and complete loose labels or artworks, as applicable, of all packaging sizes, or equivalents, reflecting the change/s, as defined by FDA Regulations.

2hviii. Declaration of Distributor

- Clear and complete loose labels or artworks, as applicable, of all packaging sizes, or equivalents, reflecting the change/s, as defined by FDA Regulations.
- Distributorship Agreement (Notarized, signed by the MAH/ Applicant Company and distributor reflecting the correct address

2hix. Change of Manufacturer's Name

- Clear and complete loose labels or artworks, as applicable, of all packaging sizes, or equivalents, reflecting the change/s, as defined by FDA Regulations.

	• 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). 2hx. Locally Produced with Additional Activity for Export • Clear and complete loose labels or artworks, as applicable, of all packaging sizes, or equivalents, reflecting the change/s, as defined by FDA Regulations. • LTO as food exporter if the company is not manufacturer. 2hxi. Declaration of "Exclusively Distributed by" • Clear and complete loose labels or artworks, as applicable, of all packaging sizes, or equivalents, reflecting the change/s, as defined by FDA Regulations. • Terms of Agreement/Exclusive Distributorship Agreement. 2hxii. Declaration of Manufacturer's Office Address on the Label • Clear and complete loose labels or artworks, as applicable, of all packaging sizes, or equivalents, reflecting the change/s, as defined by FDA Regulations.	
	2i. Transfer of Ownership of a Registered Product • Proof of Agreement between previous and current owners of the product transferring ownership • Clear and complete loose labels or artworks, as applicable, of all packaging sizes, or equivalents, reflecting the change/s, as defined by FDA Regulations	
	2j. Change in Importer/Distributor/Trader • Termination of agreement/Deed of assignment	

• Agreement of new manufacturer/importer/distributor or Appointment letter • Clear and complete loose labels or artworks, as applicable, of all packaging sizes, or equivalents, reflecting the change/s, as defined by FDA Regulations For Change in Importer/Distributor/Trader using a new user account: • Termination of agreement/Deed of assignment • Agreement of new manufacturer/importer/distributor or Appointment letter • Clear and complete loose labels or artworks, as applicable, of all packaging sizes, or equivalents, reflecting the change/s, as defined by FDA Regulations. • Upload ALL INITIAL requirements	
2k. Change in Company Address/Business Address (Not Applicable to Manufacturer and Repacker) • Proof of change in business name (e.g. License to Operate) • Clear and complete loose labels or artworks reflecting the change, as applicable, of all packaging sizes, or equivalents as defined by FDA regulations	
2l. Change in LTO Number and/or LTO Validity • Copy of updated License to Operate	
2m. Exportation of Previously Registered Product Initially for Local Distribution. • Clear and complete loose labels or artworks as applicable, of all packaging sizes, or equivalents as defined by FDA regulations or reflecting compliance to labelling requirements of importing country (if label is different from the approved one) • Copy of License to Operate as Food Exporter	
2n. Other Cases as Declared in Succeeding FDA Issuances (*Examples but not limited to the following; as long as there is no change in formulation and no change in manufacturer's address*) e.g. Change in Product Specification	

• Copy of updated Product Specification Sheet e.g. Change in Lot Code and Interpretation • Copy of updated Product Specification Sheet • Clear and complete loose labels or artworks reflecting the change, as applicable, of all packaging sizes, or equivalents as defined by FDA regulations	

CLIENT STEPS	AGENCY ACTION	PROCESSING TIME	PERSON RESPONSIBLE
1)The authorized representative of the applicant company accomplishes the on-line form/e-Registration through the e-Portal https://eportal.fda.gov.ph based on the desired type of application in accordance to **current FDA regulation** on the use of the e-Registration Portal/e-Services. (E-mail notification from FDA will be received by the client upon submission of application for Pre-Assessment.) To apply for amendment, 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.	1) FDA Personnel will pre-assess the completeness of the submitted documents through e-Portal https://eportal.fda.gov.ph. Result of Pre-assessment will be received by the account holder. If found complete, an Order of Payment will be automatically generated and will be sent to the email of the account holder/client. If found incomplete, a notification with result of Pre-Assessment from FDA will be received. The application will return to client's inbox. The client may refile by proceeding as stated on CLIENT STEPS: 1). ***(Please refer to current FDA regulation on the use of the e-Registration Portal/e-Services)***	Day 0	Center for Food Regulation and Research (CFRR) Technical Personnel (e.g. Food-Drug Regulation Officer (FDRO))
2) The applicant company receives the Order of Payment		Day 0	
3) The applicant company pays the assessed fee as per the system generated	2) FDA Cashier receives the payment/Official Receipt (OR)/ proof of payment	Day 0	Administrative Staff, Cashier-Administrative and

Order of Payment Form through FDAC Cashier or any other means prescribed by FDA (e.g. BANCNET).	transaction, and then post the payment. The application will then be forwarded to CFRR, once payment is posted.		Finance Services (AFS)
4) The applicant company receives Acknowledgement Receipt with the application and pre-assessment details.		Day 0	
	3) Evaluation	8 Working Days (Days 1-8)	CFRR Technical Personnel (e.g. FDRO)
	4) Checking	7 Working Days (Days 9-15)	CFRR Technical Personnel (e.g. FDRO)
	5) Final Decision/Issuance	5 Working Days (Days 16-20)	Director IV, CFRR
5) If the application is approved, the applicant company will receive an e-mail notification from FDA indicating that the application is approved (this includes amendment with multiple applications with approved and disapproved results) and another e-mail notification containing the Amendment Decision Summary Table. If disapproved, a Letter of Denial/Disapproval (LOD) and another e-mail notification containing the Amendment Decision Summary Table will be received.	6) The e-Portal generates electronically signed CPR or LOD.		N/A
	TOTAL:	20 Working Days	

Please be advised that as per RA 11032 IRR, page 22 of 48, Section 3, b) ***The maximum time prescribed in Section 9 (b) (1) of the Act may be extended only once for the same number of days, which shall be indicated in the Citizen's Charter.***

III. TITLE OF CERTIFICATION/PERMIT: CERTIFICATE OF PRODUCT REGISTRATION (CPR) – AUTOMATIC RENEWAL APPLICATION (INITIAL) APPLICATION APPROVED FROM MODIFIED E-REGISTRATION (VERSION 2))

Center/Office/Division	**:**	Center for Food Regulation and Research (CFRR)
Classification	**:**	Government to Business
Type of Transaction	**:**	Simple
Who May Avail	**:**	All FOOD Manufacturers/Traders/Distributors (Importers/ Wholesalers/ Exporters)
Fees to be Paid	**:**	In accordance to Administrative Order 50 s. 2001 + Legal Research Fee (LRF). Conventional Food (Category 1): Php 1,000.00/5 years of validity + 1% LRF Conventional Food (Category 2): Php 1,250.00/5 year of validity + 1% LRF Food Supplement: Php 5,000.00/5 years of validity + 1% LRF Bottled Water: Php 5,000.00/5 years of validity + 1% LRF

GENERAL GUIDELINE/S *1. The application shall be filed before expiration date of the CPR (within 90 days before the date of expiration)* *2. There is no condition stated at the back of the issued Certificate of Product Registration. Compliance to remarks on previously issued CPR processed under modified e-Registration Version 2 requires CPR amendment that automatically disqualifies the product for automatic renewal registration.* *3. There is no change and/or variation (no reformulation, no amendment or label changes or any changes in the data entry) in the product being applied.*	
CHECKLIST OF REQUIREMENTS **FOR ALL TYPES OF FOOD PRODUCTS/FOOD CATEGORIZATION:** **RAW MATERIALS, LOW RISK, MEDIUM RISK AND HIGH RISK FOOD PRODUCTS** I. Accomplished Application Form as prescribed by FDA regulations. (e-Registration e-Portal, refer to FDA Circular No.2020-033, FDA Circular No.2020-033-A or current FDA regulation). Select “RENEWAL” as type of application using the same case number used in initial application in the modified e-Registration System/Portal.	**WHERE TO SECURE** FDA Website (www.fda.gov.ph)
II. Proof of payment of fees as prescribed by current FDA regulations (AO 50 s. 2001).	FDA Cashier/Other FDA Authorized Payment Portals or Banks

III. Valid and appropriate FDA License to Operate (required for all types of CPR application)	FDA
IV. A sworn statement indicating no change in or variation whatsoever in the product is attached to the application.	Applicant Company

CLIENT STEPS	AGENCY ACTION	PROCESSING TIME	PERSON RESPONSIBLE
1)The authorized representative of the applicant company accomplishes the on-line form/e-Registration through the e-Portal https://eportal.fda.gov.ph based on the desired type of application in accordance to **current FDA regulation** on the use of the e-Registration Portal/e-Services. (E-mail notification from FDA will be received by the client upon submission of application for Pre-Assessment.) To apply for 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.	1) FDA Personnel will pre-assess the completeness of the submitted documents through e-Portal https://eportal.fda.gov.ph. Result of Pre-assessment will be received by the account holder. If found complete, an Order of Payment will be automatically generated and will be sent to the email of the account holder/client. If found incomplete, a notification with result of Pre-Assessment from FDA will be received. The application will return to client's inbox. The client may refile by proceeding as stated on CLIENT STEPS: 1). ***(Please refer to current FDA regulation on the use of the e-Registration Portal/e-Services)***	Day 0	Center for Food Regulation and Research (CFRR) Technical Personnel (e.g. Food-Drug Regulation Officer (FDRO))
2) The applicant company receives the Order of Payment		Day 0	
3) The applicant company pays the assessed fee as per the system generated Order of Payment Form through FDAC Cashier or any other means	2) FDA Cashier receives the payment/Official Receipt (OR)/ proof of payment transaction, and then post the payment.	Day 0	Administrative Staff, Cashier-Administrative and Finance Services (AFS)

prescribed by FDA (e.g. BANCNET).	The application will then be forwarded to CFRR, once payment is posted.		
4) The applicant company receives Acknowledgement Receipt with the application and pre-assessment details.		Day 0	
	3) Final Decision/Issuance	3 Working Days (Days 1-3)	Director IV, CFRR
5) If the application is approved, e-mail notification from FDA containing how/where to download the Certificate of Product Registration will be received. If disapproved, e-mail notification from FDA containing how/where to download the Letter of Denial/Disapproval will be received.	4) The e-Portal generates electronically signed CPR or LOD.		N/A
	TOTAL:	3 Working Days	

Please be advised that as per RA 11032 IRR, page 22 of 48, Section 3, b) ***The maximum time prescribed in Section 9 (b) (1) of the Act may be extended only once for the same number of days, which shall be indicated in the Citizen's Charter.***

IV. TITLE OF CERTIFICATION/PERMIT: CERTIFICATE OF PRODUCT REGISTRATION (CPR): AUTOMATIC RENEWAL (DATA CAPTURE)

(DATA CAPTURE in the modified e-Registration System/Portal (Version 2) refers to applications processed in the old e-Registration Portal (Version 1) or thru manual registration system)

Center/Office/Division	**:**	Center for Food Regulation and Research (CFRR)
Classification	**:**	Government to Business
Type of Transaction	**:**	Simple
Who May Avail	**:**	All FOOD Manufacturers/Traders/Distributors (Importers/ Wholesalers/ Exporters)
Fees to be Paid	**:**	In accordance to Administrative Order 50 s. 2001 + Legal Research Fee (LRF). Conventional Food (Category 1): Php 1,000.00/5 years of validity + 1% LRF Conventional Food (Category 2): Php 1,250.00/5 year of validity + 1% LRF

		Food Supplement: Php 5,000.00/5 years of validity + 1% LRF Bottled Water: Php 5,000.00/5 years of validity + 1% LRF

GENERAL GUIDELINE/S *1. The application shall be filed before expiration date of the CPR (within 90 days before the date of expiration)* *2. There is no condition stated at the back of the issued Certificate of Product Registration. Compliance to remarks on previously issued CPR processed under e-Registration Version 1 requires CPR amendment that automatically disqualifies the product for automatic renewal registration.* *3. There is no change and/or variation (no reformulation, no amendment or label changes or any changes in the data entry) in the product being applied.*	
CHECKLIST OF REQUIREMENTS **FOR ALL TYPES OF FOOD PRODUCTS/FOOD CATEGORIZATION:** **RAW MATERIALS, LOW RISK, MEDIUM RISK AND HIGH RISK FOOD PRODUCTS** I. Accomplished Application Form as prescribed by FDA regulations. (e-Registration e-Portal, refer to FDA Circular No.2020-033, FDA Circular No.2020-033-A or current FDA regulation).	**WHERE TO SECURE** FDA Website (www.fda.gov.ph)
II. Proof of payment of fees as prescribed by current FDA regulations (AO 50 s. 2001).	FDA Cashier/Other FDA Authorized Payment Portals or Banks
III. Valid and appropriate FDA License to Operate (required for all types of CPR application)	FDA
IV. A sworn statement indicating no change in or variation whatsoever in the product is attached to the application.	Applicant Company
V. Upload **ALL INITIAL** requirements.	Applicant Company/ In reference to the previously filed and approved INITIAL application (The validity of the documents to be submitted must be in accordance to current FDA regulation/s).

CLIENT STEPS	AGENCY ACTION	PROCESSING TIME	PERSON RESPONSIBLE
1)The authorized representative of the applicant company accomplishes the on-line form/e-Registration	1) FDA Personnel will pre-assess the completeness of the submitted documents through e-Portal https://eportal.fda.gov.ph.	Day 0	Center for Food Regulation and Research (CFRR) Technical Personnel (e.g. Food-Drug

through the e-Portal https://eportal.fda.gov.ph based on the desired type of application in accordance to **current FDA regulation** on the use of the e-Registration Portal/e-Services. (E-mail notification from FDA will be received by the client upon submission of application for Pre-Assessment.)	Result of Pre-assessment will be received by the account holder. If found complete, an Order of Payment will be automatically generated and will be sent to the email of the account holder/client. If found incomplete, a notification with result of Pre-Assessment from FDA will be received. To refile, the applicant must start a NEW CASE in filing an application for this product. Upload initially submitted documentary requirements together with documents for compliance to deficiencies mentioned. For Food Supplement application, the proof of submission of sample can be re-uploaded to the new application. ***(Please refer to current FDA regulation on the use of the e-Registration Portal/e-Services)***		Regulation Officer (FDRO))
2) The applicant company receives the Order of Payment		Day 0	
3) The applicant company pays the assessed fee as per the system generated Order of Payment Form through FDAC Cashier or any other means prescribed by FDA (e.g. BANCNET).	2) FDA Cashier receives the payment/Official Receipt (OR)/ proof of payment transaction, and then post the payment. The application will then be forwarded to CFRR, once payment is posted.	Day 0	Administrative Staff, Cashier-Administrative and Finance Services (AFS)
4) The applicant company receives Acknowledgement Receipt with the application and pre-assessment details.		Day 0	
	3) Evaluation	3 Working Days (Days 1-3)	CFRR Technical Personnel (e.g. FDRO)
	4) Checking	2 Working Days (Days 4-5)	CFRR Technical Personnel (e.g. FDRO)

	5) Final Decision/Issuance	2 Working Days Days 6-7)	Director IV, CFRR
5) If the application is approved, e-mail notification from FDA containing how/where to download the Certificate of Product Registration will be received. If disapproved, e-mail notification from FDA containing how/where to download the Letter of Denial/Disapproval (LOD) will be received.	6) The e-Portal generates electronically signed CPR or LOD.		N/A
	TOTAL:	7 Working Days	

Please be advised that as per RA 11032 IRR, page 22 of 48, Section 3, b) ***The maximum time prescribed in Section 9 (b) (1) of the Act may be extended only once for the same number of days, which shall be indicated in the Citizen's Charter.***

V. TITLE OF CERTIFICATION/PERMIT: CERTIFICATE OF PRODUCT REGISTRATION (CPR) – RE-APPLICATION (INITIAL APPLICATION DISAPPROVED FROM MODIFIED E-REGISTRATION)

Center/Office/Division	**:**	Center for Food Regulation and Research (CFRR)
Classification	**:**	Government to Business
Type of Transaction	**:**	Highly Technical
Who May Avail	**:**	All FOOD Manufacturers/Traders/Distributors (Importers/ Wholesalers/ Exporters)
Fees to be Paid	**:**	In accordance to Administrative Order 50 s. 2001 + Legal Research Fee (LRF). Re-application Fee PhP 200.00 + 1% LRF

GENERAL GUIDELINE/S *1. Submit **ONE (1)** scanned copy of the required document in the e-Registration Portal* *2. Product labels and pictures of the product in commercial presentation for upload should be scanned in 200-dpi setting* *3. Documents for upload should be scanned in 150-dpi setting* *4. Limit the total size of attachments to 25 MB with a limit of 2 MB per file using the format ".png" or ".pdf"* *5. Provide an appropriate file name for each scanned copy of documents to be uploaded in the E-registration system. For product labels, follow the format: "Label_(Case Number)"*	

e.g. Label_12345.png or Label_12345.pdf *6. The validity and contents of the Certificate of Analysis to be uploaded/attached must conform to FDA Circular 2020-033 and/or current FDA regulation (e.g. for Assessment of Microbiological Quality of Processed Food, the COA must indicate the methodology/ies used to verify test result/s for each parameter. The methodologies may be obtained from internationally recognized references as stated in FDA Circular 2013-010).* Note: ***(Please refer to current FDA regulation on the use of the e-Registration Portal/e-Services)***	
CHECKLIST OF REQUIREMENTS **FOR ALL TYPES OF FOOD PRODUCTS/FOOD CATEGORIZATION:** **RAW MATERIALS, LOW RISK, MEDIUM RISK AND HIGH RISK FOOD PRODUCTS**	**WHERE TO SECURE**
I. Accomplished Application Form as prescribed by current regulations (e-Registration e-Portal, FDA Circular No.2020-033, FDA Circular No.2020-033-A or current FDA regulation). Through the e-Registration Portal, upload/attach the compliance to the deficiencies stated in the previously issued Letter of Denial (LOD) within 6 months upon receipt of LOD, using the same case number. (Administrative Order 2014-0029 or current FDA regulation).	FDA Website (www.fda.gov.ph) 1) For the Certificate of Analysis: a) Applicant Company/ Manufacturer/Source/Supplier; **OR** b) Laboratory analysis issued/conducted by FDA accredited laboratories. 2) For other technical document(s): a) Applicant Company/ Manufacturer/Source/Supplier
II. Proof of Payment of Fees as prescribed by current FDA regulations. (Administrative Order 50 s. 2001 or current FDA regulation)	FDA Cashier/Other FDA Authorized Payment Portals or Banks
III. Valid and appropriate FDA License to Operate (required for all types of CPR application)	FDA

CLIENT STEPS	AGENCY ACTION	PROCESSING TIME	PERSON RESPONSIBLE
1)The authorized representative of the applicant company accomplishes the on-line form/e-Registration through the e-Portal https://eportal.fda.gov.ph based on the	1) FDA Personnel will pre-assess the completeness of the submitted documents through e-Portal https://eportal.fda.gov.ph. Result of Pre-assessment will be received by the account holder. If found	Day 0	Center for Food Regulation and Research (CFRR) Technical Personnel (e.g. Food-Drug Regulation Officer (FDRO))

desired type of application in accordance to **current FDA regulation** on the use of the e-Registration Portal/e-Services. (E-mail notification from FDA will be received by the client upon submission of application for Pre-Assessment.) 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.	complete, an Order of Payment will be automatically generated and will be sent to the email of the account holder/client. If found incomplete, a notification with result of Pre-Assessment from FDA will be received. The application will return to client's inbox. The client may refile by proceeding as stated on CLIENT STEPS: 1). ***(Please refer to current FDA regulation on the use of the e-Registration Portal/e-Services)***		
2) The applicant company receives the Order of Payment		Day 0	
3) The applicant company pays the assessed fee as per the system generated Order of Payment Form through FDAC Cashier or any other means prescribed by FDA (e.g. BANCNET).	2) FDA Cashier receives the payment/Official Receipt (OR)/ proof of payment transaction, and then post the payment. The application will then be forwarded to CFRR, once payment is posted.	Day 0	Administrative Staff, Cashier-Administrative and Finance Services (AFS)
4) The applicant company receives Acknowledgement Receipt with the application and pre-assessment details.		Day 0	
	3) Evaluation	8 Working Days (Day 1-8)	CFRR Technical Personnel (e.g. FDRO)
	4) Checking	7 Working Days (Day 9-15)	CFRR Technical Personnel (e.g. FDRO)
	5) Final Decision/Issuance	5 Working Days Day 16-20)	Director IV, CFRR

5) If the application is approved, e-mail notification from FDA containing how/where to download the Certificate of Product Registration will be received. If disapproved, e-mail notification from FDA containing how/where to download the Letter of Denial/Disapproval will be received.	6) The e-Portal generates electronically signed CPR or LOD.		N/A
	TOTAL:	20 Working Days	

Please be advised that as per RA 11032 IRR, page 22 of 48, Section 3, b) ***The maximum time prescribed in Section 9 (b) (1) of the Act may be extended only once for the same number of days, which shall be indicated in the Citizen's Charter.***

VI. TITLE OF CERTIFICATION/PERMIT: CERTIFICATE OF PRODUCT REGISTRATION (CPR) – FOR EXPORT MARKET ONLY

Center/Office/Division	**:**	Center for Food Regulation and Research (CFRR)
Classification	**:**	Government to Business
Type of Transaction	**:**	Highly Technical
Who May Avail	**:**	All FOOD Exporters
Fees to be Paid	**:**	In accordance to Administrative Order 50 s. 2001 + Legal Research Fee (LRF). Conventional Food (Category 1): Php 200.00/year of validity + 1% LRF Conventional Food (Category 2): Php 250.00/year of validity + 1% LRF Food Supplement: Php 1,000.00/year of validity + 1% LRF Bottled Water: Php 1,000.00/year of validity + 1% LRF

GENERAL GUIDELINE/S *1. Submit **ONE (1)** scanned copy of the required document in the e-Registration Portal* *2. Product labels and pictures of the product in commercial presentation for upload should be scanned in 200-dpi setting* *3. Documents for upload should be scanned in 150-dpi setting* *4. Limit the total size of attachments to 25 MB with a limit of 2 MB per file using the format ".png" or ".pdf"* *5. Provide an appropriate file name for each scanned copy of documents to be uploaded in the E-registration system. For product labels, follow the format: "Label_(Case Number)"*	

e.g. Label_12345.png or Label_12345.pdf *6. The validity and contents of the Certificate of Analysis to be uploaded/attached must conform to FDA Circular 2020-033 and/or current FDA regulation (e.g. for Assessment of Microbiological Quality of Processed Food, the COA must indicate the methodology/ies used to verify test result/s for each parameter. The methodologies may be obtained from internationally recognized references as stated in FDA Circular 2013-010).* Note: ***(Please refer to current FDA regulation on the use of the e-Registration Portal/e-Services)***	
CHECKLIST OF REQUIREMENTS **FOR ALL TYPES OF FOOD PRODUCTS/FOOD CATEGORIZATION:** **RAW MATERIALS, LOW RISK, MEDIUM RISK AND HIGH RISK FOOD PRODUCTS**	**WHERE TO SECURE**
I. General requirements based on Administrative Order 2014-0029:	
1. Accomplished Initial Application Form as prescribed by FDA regulations (e-Registration e-Portal, refer to FDA Circular No.2020-033, FDA Circular No.2020-033-A or current FDA regulation).	FDA Website (www.fda.gov.ph)
2. Proof of Payment of Fees as prescribed by current FDA regulations (A.O. 50 s. 2001 or current FDA regulation).	FDA Cashier/Other FDA Authorized Payment Portals or Banks
3. Loose label/artwork/picture of the product compliant with the existing regulations of the importing country.	Applicant Company/ Manufacturer/Source/Supplier
4. 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, as applicable.	Applicant Company/ Manufacturer/Source/Supplier
5. For FOOD SUPPLEMENT, a sample in actual commercial presentation shall be submitted.	Applicant Company/ Manufacturer/Source/Supplier
II. For Locally Manufactured Products: (in cases when the source is not directly from the manufacturer) Distributorship agreement or contract agreement, whichever is applicable, signed by the duly authorized representative of the establishment as reflected in the records of CFRR. (FDA Circular 2016-007).	Applicant Company/ Manufacturer/Source/Supplier

<table>
<tr><td></td><td></td></tr>
<tr><td>III. Scanned copy of ANY ONE of the following: Request for Quotation OR purchase order OR packing list OR valid notarized agreement signed by importing and exporting parties OR Proforma Invoice, whichever is applicable, as supporting document that the product is for export market.</td><td>Buyer/Recipient</td></tr>
<tr><td>IV. Valid and appropriate FDA License to Operate (required for all types of CPR application)</td><td>FDA</td></tr>
<tr><td>V. ADDITIONAL REQUIREMENTS PER FOOD CATEGORY

1. <u>MEDIUM-RISK FOOD PRODUCTS</u>

<table>
<tr><td>MRA1a. CONDENSED MILK
• Certificate of Analysis for Microbiological parameters for Sweetened Condensed Milk: Coliforms cfu/g, Yeast & Mold Count cfu/g & SPC/APC cfu/g based on FDA Circular 2013-010.</td></tr>
<tr><td>MRA2. MILK POWDER
• Certificate of Analysis 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, SPC/APC cfu/g & Enterobacteriaceae cfu/g based on FDA Circular 2013-010.</td></tr>
<tr><td>MRA3. MILK PRODUCTS FOR SPECIFIC TARGET AGE GROUP
• Certificate of Analysis 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, SPC/APC cfu/g & Enterobacteriaceae cfu/g based on FDA Circular 2013-010.</td></tr>
<tr><td>MRB2. EDIBLE ICES (POPSICLES)
• Certificate of Analysis for Microbiological parameters for Flavored Ice: SPC/APC cfu/g, Coliforms MPN/g, YMC cfu/g & Salmonella/25g based on FDA Circular 2013-010.</td></tr>
<tr><td>MRC2. FROZEN FRUITS
• Certificate of Analysis for Microbiological parameters for Frozen Fruits: E. coli MPN/g based on FDA Circular 2013-010.</td></tr>
<tr><td>MRC3. CANNED OR BOTTLED FRUITS & VEGETABLE PRESERVE IN JUICE, SYRUP & BRINE</td></tr>
</table>
</td><td>For the Certificate of Analysis:
1) Applicant Company/ Manufacturer/Source/Supplier; OR
2) Laboratory analysis issued/conducted by FDA accredited laboratories.

For other technical document(s):
1) Applicant Company/ Manufacturer/Source/Supplier</td></tr>
</table>

	• Certificate of Analysis for Microbiological parameters for Fruits and Vegetable Products in Hermetically Sealed Containers: Commercial Sterility based on FDA Circular 2013-010.		
	MRC7. FERMENTED VEGETABLES • Certificate of Analysis for Microbiological parameters for Fermented Vegetable (Ready to Eat): YMC cfu/g, Coliforms MPN/g, E. coli MPN/g, Salmonella/25g & S. aureus cfu/g based on FDA Circular 2013-010.		
	MRD. COCOA POWDER • Certificate of Analysis for Microbiological parameters for Cocoa Powder: Molds cfu/g, Salmonella/25g, Coliforms MPN/g & SPC/APC cfu/g based on FDA Circular 2013-010.		
	MRD. CHOCOLATE PRODUCTS • Certificate of Analysis for Microbiological parameters for Chocolate Products: Molds cfu/g, Salmonella/25g, Coliforms MPN/g & SPC/APC cfu/g based on FDA Circular 2013-010.		
	MRF1Ai. CURED (INCLUDING SALTED) NON-HEAT TREATED PROCESSED MEAT, POULTRY AND GAME PRODUCTS • Certificate of Analysis for Microbiological parameters for Packaged Cooked, Cured/Salted Meat: S. aureus (coagulase +) cfu/g, Salmonella/25g & Listeria monocytogenes/25g based on FDA Circular 2013-010. • Certificate of Analysis for Microbiological parameters for Cured/Smoked Poultry: S. aureus (coagulase +) cfu/g & Salmonella/25g based on FDA Circular 2013-010.		
	MRF1Aii. CURED (INCLUDING SALTED) DRIED NON-HEAT TREATED PROCESSED MEAT, POULTRY AND GAME PRODUCTS • Certificate of Analysis for Microbiological parameters for Packaged Cooked, Cured/Salted Meat: S. aureus (coagulase +) cfu/g, Salmonella/25g & Listeria monocytogenes/25g based on FDA Circular 2013-010.		
	MRF2Ai. FERMENTED NON-HEAT TREATED PROCESSED MEAT, POULTRY AND GAME PRODUCTS • Certificate of Analysis for Microbiological parameters for Fermented, Comminuted Meat, not cooked (dry & semi-dry fermented sausages): E. coli MPN/g, S. aureus (coagulase +) cfu/g & Salmonella/25g based on FDA Circular 2013-010.		

	MRJa. CAKES, COOKIES, PIES, PASTRIES, DOUGHNUTS, SWEET ROLLS, CONES, MUFFINES, WAFFLES-PLAIN /WITHOUT FILLING • Certificate of Analysis for Microbiological parameters for Baked Goods: S. aureus (coagulase +) cfu/g, MYC cfu/g, SPC/APC cfu/g & Coliforms cfu/g) based on FDA Circular 2013-010.	
	MRJa. FROZEN BAKERY PRODUCTS • Certificate of Analysis for Microbiological parameters for Frozen Bakery Products: S. aureus (coagulase +) cfu/g & Salmonella/25g based on FDA Circular 2013-010.	
	MRjb. FROZEN DOUGH • Certificate of Analysis for Microbiological parameters for Frozen and Refrigerated Doughs: Molds cfu/g, Yeast & Yeastlike Fungi cfu/g, Coliforms cfu/g, Psychrotrophic bacteria cfu/g & SPC/APC cfu/g based on FDA Circular 2013-010.	
	MRK2a. EMULSIFIED SAUCES AND DIPS (SALAD DRESSING- i.e. MAYONNAISE, THOUSAND ISLAND, RANCH, FRENCH) • Certificate of Analysis for Microbiological parameters for Salad Dressing: SPC/APC cfu/g, YMC cfu/g, Salmonella/25g & Listeria monocytogenes/25g based on FDA Circular 2013-010.	
	MRL1a. FRUIT AND VEGETABLE JUICES • 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.	
	MRL1c. SPORTS, ENERGY DRINK & ELECTROLYTE DRINKS • 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.	
	MRL1ci. CARBONATED WATER-BASED FLAVORED DRINKS • 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.	
	MRL1cii. NON-CARBONATED WATER-BASED FLAVORED DRINKS • 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.	

	MRL1ciii. FROZEN CONCENTRATE • Certificate of Analysis for Microbiological parameters for Frozen Juice Concentrates: SPC/APC cfu/mL & YMC cfu/mL based on FDA Circular 2013-010.	
	MRL1d. POWDERED COCOA DRINK MIXES • Certificate of Analysis for Microbiological parameters for Powdered Beverage: SPC/APC cfu/g & YMC cfu/g based on FDA Circular 2013-010.	
	MRM1. VITAMINS, MINERALS & AMINO ACIDS AS FOOD SUPPLEMENTS • Shelf life study with stability data based on Administrative Order 2014-0029. • Certificate of Analysis of the physico-chemical (Vitamins, Minerals & Amino Acids Assays) and microbiological parameters of the finished product based on Administrative Order 2014-0029. • Safety data (include but not limited to acute toxicity test, safe history of use; research studies on safety of the product) based on Administrative Order 2014-0029. • Sample in actual commercial presentation based on Administrative Order 2014-0029. For **FOOD SUPPLEMENTS**, 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.* NOTE: ***Please refer to current FDA regulation (e.g. FDA Circular 2020-026: Food and Drug Action Center (FDAC) New Normal Operational Guidelines of the Food and Drug Administration). Updates on FDAC Operational Guidelines will be announced/published accordingly.***	

2. **HIGH-RISK FOOD PRODUCTS**

	HRA1a. MILK (PLAIN) AND BUTTERMILK PLAIN • Certificate of Analysis for Microbiological parameters for Liquid Milk (evaporated & ready to drink)-UHT/Sterilized: Commercial Sterility based on FDA Circular 2013-010. • Certificate of Analysis for Microbiological parameters for Pasteurized Milk: Coliforms cfu/mL, Salmonella/25mL, Listeria monocytogenes/25mL, Psychrotrophic bacteria cfu/mL & SPC/APC cfu/mL based on FDA Circular 2013-010.	
	HRA1b. DAIRY-BASED DRINKS, FLAVORED AND/OR FERMENTED • Certificate of Analysis for Microbiological parameters for Liquid Milk (evaporated & ready to drink)-UHT/Sterilized: Commercial Sterility based on FDA Circular 2013-010. • Certificate of Analysis for Microbiological parameters for Pasteurized Milk: Coliforms cfu/mL, Salmonella/25mL, Listeria monocytogenes/25mL, Psychrotrophic bacteria cfu/mL & SPC/APC cfu/mL based on FDA Circular 2013-010. • Certificate of Analysis for Microbiological parameters for Yogurt and Fermented Milk: S. aureus (coagulase +) cfu/mL, Coliforms cfu/mL, Salmonella/25mL & Lactic acid cfu/mL based on FDA Circular 2013-010.	
	HRA3a. PASTEURIZED CREAM • Certificate of Analysis for Microbiological parameters for Pasteurized Cream: Coliforms cfu/g, Salmonella/25g, Listeria	

	monocytogenes/25g, Psychrotrophic bacteria cfu/g & SPC/APC cfu/g based on FDA Circular 2013-010.		
	HRA3b. STERILIZED AND UHT CREAMS, WHIPPING AND WHIPPED CREAMS, AND REDUCED FAT CREAMS (PLAIN) • Certificate of Analysis for Microbiological parameters for Cream (UHT/Sterilized): Commercial Sterility based on FDA Circular 2013-010.		
	HRA4a. UNRIPENED CHEESE • Certificate of Analysis for Microbiological parameters for Cheese and Cheese (moisture ≥ 39% & pH): S. aureus (coagulase +) cfu/g, E. coli MPN/g, Coliforms MPN/g, Psychrotrophic bacteria cfu/g, Salmonella/25g & Listeria monocytogenes/25g based on FDA Circular 2013-010. • Certificate of Analysis for Microbiological parameters for All Raw Milk Cheese: Campylobacter/25g, Salmonella/25g, Listeria monocytogenes/25g and S. aureus (coagulase +) cfu/g based on FDA Circular 2013-010.		
	HRA4di. PLAIN PROCESSED CHEESE • Certificate of Analysis for Microbiological parameters for Processed Cheese Spread: S. aureus (coagulase +) cfu/g, Coliforms cfu/g & SPC /APC cfu/g based on FDA Circular 2013-010.		
	HRA4di. FLAVORED PROCESSED CHEESE • Certificate of Analysis for Microbiological parameters for Processed Cheese Spread: S. aureus (coagulase +) cfu/g, Coliforms cfu/g & SPC /APC cfu/g based on FDA Circular 2013-010.		
	HRA5. DAIRY BASED DESSERT (e.g. Yogurt) • Certificate of Analysis for Microbiological parameters for Yogurt and Fermented Milk: S. aureus (coagulase +) cfu/mL, Coliforms cfu/mL, Salmonella/25mL & Lactic acid cfu/mL based on FDA Circular 2013-010.		
	HRA8. DAIRY BASED FROZEN DESSERT • Certificate of Analysis for Microbiological parameters for Ice Cream & Sherbet (plain and flavored): Coliforms cfu/g, Listeria monocytogenes/25g, Salmonella/25g, SPC/APC cfu/g & S. aureus (coagulase +) cfu/g based on FDA Circular 2013-010. • Certificate of Analysis for Microbiological parameters for Ice Cream with added ingredients (nuts, fruits, cocoa etc.): Coliforms		

	cfu/g, Listeria monocytogenes/25g, Salmonella/25g, SPC/APC cfu/g & S. aureus (coagulase +) cfu/g based on FDA Circular 2013-010.	
	HRB1. DRIED FRUIT • Certificate of Analysis for Microbiological parameters for Sun Dried Fruits: Mold cfu/g, OsmophilicYeasts cfu/g & E. coli MPN/g based on FDA Circular 2013-010.	
	HRB1. DRIED VEGETABLE • Certificate of Analysis for Microbiological parameters for Dried Vegetable: E. coli MPN/g based on FDA Circular 2013-010.	
	HRD. CHOCOLATE WITH NUTS • Certificate of Analysis for Microbiological parameters for Chocolate Products: Molds cfu/g, Salmonella/25g, Coliforms MPN/g & SPC/APC cfu/g based on FDA Circular 2013-010.	
	HRF1. FINE BAKERY PRODUCTS WITH FILLINGS • Certificate of Analysis for Microbiological parameters for 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) based on FDA Circular 2013-010. • Certificate of Analysis for Microbiological parameters for Coated or Filled, Dried Shelf-Stable Biscuits: Coliforms MPN/g & Salmonella/25g based on FDA Circular 2013-010.	
	HRG1a./HRG2a. HEAT-TREATED PROCESSED MEAT, POULTRY AND GAME PRODUCTS (CANNED) • Certificate of Analysis for Microbiological parameters for Meat Products in Hermetically Sealed Containers: Commercial Sterility based on FDA Circular 2013-010.	
	HRG2b. FROZEN PROCESSED MEAT, POULTRY AND GAME PRODUCTS (NUGGETS, PATTIES, DUMPLINGS, SALAMI, MEAT LOAF, HOTDOG) • Certificate of Analysis for Microbiological parameters for Cold Cuts, Frozen & Chilled Hotdogs: E. coli MPN/g, Salmonella/25g, S. aureus (coagulase +) cfu/g & SPC/APC cfu/g based on FDA Circular 2013-010.	
	HRH1A. FROZEN FISH, FISH FILLETS AND FISH PRODUCTS • Certificate of Analysis for Microbiological parameters for Fresh Frozen Fish: E. coli	

	MPN/g, S. aureus (coagulase +) cfu/g, V. parahaemolyticus cfu/g, Salmonella/25g & SPC/APC cfu/g based on FDA Circular 2013-010.	
	HRH1B. FROZEN BATTERED FISH, FISH FILLETS AND FISH PRODUCTS, INCLUDING MOLLUSCS, CRUSTACEANS AND ECHINODERMS • Certificate of Analysis for Microbiological parameters for Pre-Cooked Breaded Fish: E. coli MPN/g, S. aureus (coagulase +) cfu/g & SPC/APC cfu/g based on FDA Circular 2013-010.	
	HRH1DII. COOKED MOLLUSCS, CRUSTACEANS AND ECHINODERMS • Certificate of Analysis for Microbiological parameters for Frozen Cooked Crustaceans: E. coli MPN/g, S. aureus (coagulase +) cfu/g, V. parahaemolyticus cfu/g, Salmonella/25g & SPC/APC cfu/g based on FDA Circular 2013-010.	
	HRH2. FULLY PRESERVED, INCLUDING CANNED OR FERMENTED FISH AND FISH PRODUCTS • Certificate of Analysis for Microbiological parameters for Fish & Shellfish Products in Hermetically Sealed Containers (thermally processed): commercial sterility based on FDA Circular 2013-010.	
	HRH2. FULLY PRESERVED, INCLUDING CANNED OR FERMENTED FISH AND FISH PRODUCTS (BAGOONG (COOKED)) • Certificate of Analysis for Microbiological parameters for Fish & Shellfish Products in Hermetically Sealed Containers (thermally processed): commercial sterility based on FDA Circular 2013-010.	
	HRIA. LIQUID EGG PRODUCTS • Certificate of Analysis for Microbiological parameters for Pasteurized Egg Products (Liquid, Frozen, Dried): Coliforms cfu/g, Salmonella/25g, YMC cfu/g (for dried products) & SPC/APC cfu/g based on FDA Circular 2013-010.	
	HRJ1. INFANT FORMULA & FORMULAS FOR SPECIAL MEDICAL PURPOSED INTENDED FOR INFANTS (POWDER) • Certificate of Analysis for Microbiological parameters for Powdered Infant Formula with or without added Lactic acid producing cultures: Cronobacter spp./10g, Salmonella/25g, SPC/APC cfu/g &	

	Enterobacteriaceae/10g based on FDA Circular 2013-010.		
	HRJ1. INFANT FORMULA & FORMULAS FOR SPECIAL MEDICAL PURPOSED INTENDED FOR INFANTS (LIQUID) • Certificate of Analysis for Microbiological parameters for Infant Formula- Liquid (UHT/Sterilized) cultures: commercial sterility based on FDA Circular 2013-010.		
	HRJ1. FOLLOW-UP FORMULA/MILK SUPPLEMENT • Certificate of Analysis for Microbiological parameters for Follow-up Formula/Milk Supplements: Salmonella/25g, SPC/APC cfu/g & Enterobacteriaceae/10g based on FDA Circular 2013-010.		
	HRJ2. CEREAL-BASED FOODS FOR INFANTS & YOUNG CHILDREN • Certificate of Analysis for Microbiological parameters for Cereal-based Foods for Infants: Bacillus cereus cfu/g, Clostridium perfringes cfu/g, SPC/APC cfu/g, Salmonella/25g & Coliforms MPN/g based on FDA Circular 2013-010.		
	HRJ2. CANNED BABY FOODS • Certificate of Analysis for Microbiological parameters for Baby Foods in Hermetically Sealed Containers: commercial sterility based on FDA Circular 2013-010.		
	HRK1. HERBS AND BOTANICALS AND/OR PRODUCTS WITH OTHER NUTRITIONAL SUBSTANCES AND/OR COMBINATION AS FOOD SUPPLEMENTS • Shelf life study with stability data based on Administrative Order 2014-0029. • Certificate of Analysis of the physico-chemical and microbiological parameters of the finished product based on Administrative Order 2014-0029. • Safety data (include but not limited to acute toxicity test, safe history of use; research studies on safety of the product) based on Administrative Order 2014-0029. • For Dried Plants: Certificate of Analysis for Heavy Metals in the finished product based on Administrative Order 184 s. 2004. • Additional requirements in the registration of Virgin Coconut Oil Food Supplement with Flavor: 1) That the raw material (virgin coconut oil) used conforms with the Philippine National Standards for Virgin		

Coconut Oil; 2) That the flavoring added should be generally recognized as safe and suitable for human consumption as evidenced by a certification from the supplier. The nature of flavor used (natural, nature-identical, artificial) shall be indicated in the list of ingredients; 3) No other food additive shall be allowed except the flavor; 4) The label shall conform with BC 2 s. 1999; 5) The term "Food Supplement" shall be part of the product name. Based on Bureau Circular 2006-018

- Sample in actual commercial presentation based on Administrative Order 2014-0029.

For **FOOD SUPPLEMENTS**, 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.

NOTE: ***Please refer to current FDA regulation (e.g. FDA Circular 2020-026: Food and Drug Action Center (FDAC) New Normal Operational Guidelines of***

	the Food and Drug Administration). Updates on FDAC Operational Guidelines will be announced/published accordingly.	
	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. • Certificate of Analysis for Microbiological parameters for Powdered Beverages: SPC/APC cfu/g & Coliforms cfu/g.	

CLIENT STEPS	AGENCY ACTION	PROCESSING TIME	PERSON RESPONSIBLE
1)The authorized representative of the applicant company accomplishes the on-line form/e-Registration through the e-Portal https://eportal.fda.gov.ph based on the desired type of application in accordance to **current FDA regulation** on the use of the e-Registration Portal/e-Services. (E-mail notification from FDA will be received by the client upon submission of application for Pre-Assessment.)	1) FDA Personnel will pre-assess the completeness of the submitted documents through e-Portal https://eportal.fda.gov.ph. Result of Pre-assessment will be received by the account holder. If found complete, an Order of Payment will be automatically generated and will be sent to the email of the account holder/client. If found incomplete, a notification with result of Pre-Assessment from FDA will be received. To refile, the applicant must start a NEW CASE in filing an application for this product. Upload initially submitted documentary requirements together with documents for compliance to deficiencies mentioned. For Food Supplement application, the proof of submission of sample can be re-uploaded to the new application. ***(Please refer to current FDA regulation on the use***	Day 0	Center for Food Regulation and Research (CFRR) Technical Personnel (e.g. Food-Drug Regulation Officer (FDRO))

	of the e-Registration Portal/e-Services)		
2) The applicant company receives the Order of Payment		Day 0	
3) The applicant company pays the assessed fee as per the system generated Order of Payment Form through FDAC Cashier or any other means prescribed by FDA (e.g. BANCNET).	2) FDA Cashier receives the payment/Official Receipt (OR)/ proof of payment transaction, and then post the payment. The application will then be forwarded to CFRR, once payment is posted.	Day 0	Administrative Staff, Cashier-Administrative and Finance Services (AFS)
4) The applicant company receives Acknowledgement Receipt with the application and pre-assessment details.		Day 0	
	3) Evaluation	8 Working Day (Day 1-8)	CFRR Technical Personnel (e.g. FDRO)
	4) Checking	7 Working Days (Day 9-15)	CFRR Technical Personnel (e.g. FDRO)
	5) Final Decision/Issuance	5 Working Days (Day 16-20)	Director IV, CFRR
5) If the application is approved, e-mail notification from FDA containing how/where to download the Certificate of Product Registration will be received. If disapproved, e-mail notification from FDA containing how/where to download the Letter of Denial/Disapproval will be received.	6) The e-Portal generates electronically signed CPR or LOD.		N/A
	TOTAL:	20 Working Days	

Please be advised that as per RA 11032 IRR, page 22 of 48, Section 3, b) ***The maximum time prescribed in Section 9 (b) (1) of the Act may be extended only once for the same number of days, which shall be indicated in the Citizen's Charter.***

C. OTHER CFRR AUTHORIZATIONS

I. TITLE OF CERTIFICATION/PERMIT: SANGKAP PINOY SEAL/DIAMOND SANGKAP PINOY SEAL

Center/Office/Division	**:**	Center for Food Regulation and Research (CFRR)
Classification	**:**	Government to Business
Type of Transaction	**:**	Highly Technical Transaction
Who May Avail	**:**	All Food Manufacturers of Fortified Products
Fees to be Paid	**:**	P8,000.00 non-refundable fee for the use of the seal (Regular Seal) P500.00 processing fee for every application (Regular Seal or Diamond Seal) + 1% LRF

CHECKLIST OF REQUIREMENTS	**WHERE TO SECURE**
GENERAL GUIDELINE/S *1. Submit **ONE (1)** scanned copy of the required document.*	
Basic Requirements based on RA 8976 (Food Fortification Law of 2000), RA 8172 (ASIN Law), the Sangkap Pinoy Seal Program Manual of Operations (December 2000) and Administrative Order No. 82 s. 2003 (Guidelines on the Granting of Diamond Sangkap Pinoy Seal to Manufacturers of Fortified Products): • Duly accomplished application forms • Copy of LTO issued by the FDA • Results of product analysis for vitamin A, Iron and Iodine from an FDA recognized laboratory. • Sample label with Sangkap Pinoy Seal/Diamond Sangkap Pinoy Seal • Proof of payment • Inspection report with Certificate of Compliance	FDA FDA For the Certificate of Analysis: Laboratory analysis issued/conducted by FDA accredited laboratories. Applicant Company/ Manufacturer/Source/Supplier FDA Cashier/Other FDA Authorized Payment Portals or Banks (where payment was made) FDA Regional Field Office

CLIENT STEPS	AGENCY ACTION	PROCESSING TIME	PERSON RESPONSIBLE
	1) Receives document requirements from FDA	1 Working Day (Day 1)	Center for Food Regulation and

	Regional Field Office and decks the same to CFRR technical evaluators.		Research (CFRR) Technical Personnel (e.g. Food-Drug Regulation Officer (FDRO))
	2) Evaluation	8 Working Days (Day 2-9)	CFRR Technical Personnel (e.g. FDRO)
	3) Checking	5 Working Days (Day 10-14)	CFRR Technical Personnel (e.g. FDRO)
	4) Printing	1 Working Day (Day 15)	Administrative Staff, CFRR
	5) Signing of Certificate/Authorization	4 Working Days (Day 16-19)	Director IV, CFRR
	6) The CFRR personnel will forward the Certificate/Authorization to the Office of Director General, for signature.	1 Working Day (Day 20)	Administrative Staff, CFRR
	TOTAL:	20 Working Days	

Please be advised that as per RA 11032 IRR, page 22 of 48, Section 3, b) ***The maximum time prescribed in Section 9 (b) (1) of the Act may be extended only once for the same number of days, which shall be indicated in the Citizen's Charter.***

II. TITLE OF CERTIFICATION/PERMIT: GMP/HACCP CERTIFICATE

Center/Office/Division	**:**	Center for Food Regulation and Research (CFRR)
Classification	**:**	Government to Business
Type of Transaction	**:**	Highly Technical Transaction
Who May Avail	**:**	All FOOD Manufacturers (Importer of raw material for own use/Exporters)
Fees to be Paid	**:**	GMP – Php 500.00 + LRF per year; HACCP – Php1,000.00 + LRF per year

CHECKLIST OF REQUIREMENTS	**WHERE TO SECURE**
GENERAL GUIDELINE/S *1. Submit **ONE (1)** scanned copy of the required document.*	
• Inspection report with certificate of Compliance/ Recommendation Letter from RFO • Valid LTO • Proof of payment	FDA Regional Field Office FDA FDA Cashier/Other FDA Authorized Payment Portals or

	Banks (where payment was made)

CLIENT STEPS	AGENCY ACTION	PROCESSING TIME	PERSON RESPONSIBLE
	1) Receives document requirements from FDA Regional Field Office and decks the same to CFRR technical evaluators.	1 Working Day (Day 1)	Center for Food Regulation and Research (CFRR) Technical Personnel (e.g. Food-Drug Regulation Officer (FDRO))
	2) Evaluation	8 Working Days (Days 2-9)	CFRR Technical Personnel (e.g. FDRO)
	3) Checking	5 Working Days (Days 10-14)	CFRR Technical Personnel (e.g. FDRO)
	4) Printing	1 Working Day (Day 15)	Administrative Staff, CFRR
	5) Approval	4 Working Days (Days 16-19)	Director IV, CFRR
1) The applicant company receives the Certificate/Authorization Note: ***Please refer to current FDA regulation (e.g. FDA Circular 2020-026: Food and Drug Action Center (FDAC) New Normal Operational Guidelines of the Food and Drug Administration). Updates on FDAC Operational Guidelines will be announced/published accordingly.***	6) The FDA personnel will forward the Certificate/Authorization to Food and Drug Action Center (FDAC) for release. Note: ***Please refer to current FDA regulation (e.g. FDA Circular 2020-026: Food and Drug Action Center (FDAC) New Normal Operational Guidelines of the Food and Drug Administration). Updates on FDAC Operational Guidelines will be announced/published accordingly.***	1 Working Day (Day 20)	FDA Personnel, FDAC
	TOTAL:	20 Working Days	

Please be advised that as per RA 11032 IRR, page 22 of 48, Section 3, b) ***The maximum time prescribed in Section 9 (b) (1) of the Act may be extended only once for the same number of days, which shall be indicated in the Citizen's Charter.***

III. TITLE OF CERTIFICATION/PERMIT: BOC CLEARANCE/ IMPORT PERMIT

Center/Office/Division	**:**	Center for Food Regulation and Research (CFRR)
Classification	**:**	Government to Business
Type of Transaction	**:**	Simple Transaction
Who May Avail	**:**	All FOOD Manufacturers/Traders/Distributors (Importers/ Wholesalers/ Exporters) and Donee/Consignee
Fees to be Paid	**:**	In accordance to A.O. 50 s. 2001 BOC Clearance/ Import Permit: Php 500.00/invoice + 1% LRF

CHECKLIST OF REQUIREMENTS	**WHERE TO SECURE**
GENERAL GUIDELINE/S *1. Submit **ONE (1)** scanned copy of the required document.*	
For Release of Samples: • Application Letter	- No specific format, this document is initiated by applicant company
• Notarized Affidavit of Undertaking	- See sample template (Annex A)
• Certificate of Analysis/ Certificate of Free Sale	- Country of Origin or Source of Product to be imported
• Pro Forma Invoice	- Product source/company
• Packing List	- Product source/company
• Bill of Lading/Airway Bill (if available)	- Courier or Shipping Company
• Valid License to Operate	- FDA Issued
• Payment	- FDA Cashier/Other FDA Authorized Payment Portals or Banks
For release of donated food: • BIHC Endorsement Letter	- BIHC of DOH (The Director)
• Letter request from Donee	- From Donee
• Certificate of Quality (should reflect the expiration or last recommended date of consumption) / Certificate of Free Sale	- Product Source/Company
• Certificate of Donation	- From Donor
• Deed of Acceptance	- From Donee - From product source/company

• Invoice Packing List • Bill of Lading/Airway Bill (if available) • Payment (Php 510.00/inclusive of 1% LRF)	- Courier or shipping company - FDA Cashier/Other FDA Authorized Payment Portals or Banks

CLIENT STEPS	AGENCY ACTION	PROCESSING TIME	PERSON RESPONSIBLE
1) The authorized representative submits documents to the Food and Drug Action Center (FDAC) in Alabang for pre-assessment or as prescribed by current FDA regulation. ***Please refer to current FDA regulation (e.g. FDA Circular 2020-026: Food and Drug Action Center (FDAC) New Normal Operational Guidelines of the Food and Drug Administration). Updates on FDAC Operational Guidelines will be announced/published accordingly.***	1) FDA Personnel will pre-assess the completeness of the submitted documents. If complete, Order of Payment will be generated and will be given to the client. Otherwise, all the documents will not be received and will be returned to the client for compliance. The client may refile by proceeding as stated on CLIENT STEPS: 1). ***Please refer to current FDA regulation (e.g. FDA Circular 2020-026: Food and Drug Action Center (FDAC) New Normal Operational Guidelines of the Food and Drug Administration). Updates on FDAC Operational Guidelines will be announced/published accordingly.***	Day 0	Authorized FDA Personnel, Food Drug Action Center (FDAC) or Center for Food Regulation and Research (CFRR)
2) The applicant company receives the Order of Payment		Day 0	
3) The applicant company pays the assessed fee as per the system generated Order of Payment Form through FDAC Cashier or as prescribed by current FDA regulation. ***Please refer to current FDA regulation (e.g. FDA Circular 2020-026: Food and Drug Action Center (FDAC) New Normal Operational Guidelines of the Food and Drug Administration). Updates on FDAC Operational Guidelines will be announced/published accordingly.***	2) FDA Personnel receives the complete documents and Official Receipt (OR)/ proof of payment transaction. ***Please refer to current FDA regulation (e.g. FDA Circular 2020-026: Food and Drug Action Center (FDAC) New Normal Operational Guidelines of the Food and Drug Administration). Updates on FDAC Operational Guidelines will be***	Day 0	FDA Personnel, (e.g. FDAC or CFRR Staff)

	announced/published accordingly.		
4) The applicant company receives Acknowledgement stating the completeness of the submitted documents & Official Receipt of payment.		Day 0	
	3) FDA Cashier posts the payment and forwards the application to CFRR.	Day 0	Administrative Staff, Cashier-Administrative and Finance Services (AFS)
	4) Receives applications and forwards the same to CFRR receiving.	4 Hours (Day 1)	FDA Personnel, (e.g. FDAC Staff)
	5) Receives applications and forwards the same to assigned CFRR evaluators.	4 Hours (Day 1)	CFRR Personnel (e.g. Administrative Staff)
	6) Evaluation	4 Hours (Day 2)	CFRR Technical Personnel (e.g. FDRO)
	7) Checking	4 Hours (Day 2)	CFRR Technical Personnel (e.g. FDRO)
	8) Final Recommendation	4 Hours (Day 3)	Director IV, CFRR
5) The applicant company shall claim the IMPORT PERMIT /BOC CLEARANCE Note: ***Please refer to current FDA regulation (e.g. FDA Circular 2020-026: Food and Drug Action Center (FDAC) New Normal Operational Guidelines of the Food and Drug Administration). Updates on FDAC Operational Guidelines will be announced/published accordingly.***	9) The FDA personnel will forward the Certificate/Authorization to Food and Drug Action Center (FDAC) for release. Note: ***Please refer to current FDA regulation (e.g. FDA Circular 2020-026: Food and Drug Action Center (FDAC) New Normal Operational Guidelines of the Food and Drug Administration). Updates on FDAC Operational Guidelines will be announced/published accordingly.***	4 Hours (Day 3)	FDA Personnel, (e.g. FDAC or CFRR Staff)
	TOTAL:	3 Working Days	

Please be advised that as per RA 11032 IRR, page 22 of 48, Section 3, b) ***The maximum time prescribed in Section 9 (b) (1) of the Act may be extended only once for the same number of days, which shall be indicated in the Citizen's Charter.***

ANNEX A

Affidavit of Undertaking

(Name of Applicant) of legal age, (Position in the Company) and/or duly authorized representative of (Name of Company and Address), after having been sworn in accordance with law, hereby declare that:

1. The aforementioned company has imported from (Country of Origin) the food products: see attached product list.

2. The said importation is covered by Proforma Invoice No. ____ dated _____ of (Source/Principal of the Importer), copy of which is cross-checked with the original.

3. The applicant company has a valid License to Operate as an importer, with LTO No. _____ covering the said shipment.

4. The products are not adulterated nor misbranded, and contain ingredients and additives that are permitted for use in human and in accordance with relevant regulations issued by FDA.

5. The said product is for use by (Company Name) for sampling purposes and product development only. Moreover, it will not find its way in the market for sale or for distribution.

6. The company understands and agrees that the products may be subjected to FDA Laboratory examination at any time to verify the food product safety and quality and that the cost of laboratory examination shall be charged to the importing company.

7. This Affidavit is executed to confirm the truth of the foregoing.

(Date) at (Place of Execution)

(Affiant)

Subscribed and sworn to before me this (date) day of (month), (year) at _____.

Notary Public

IV. TITLE OF CERTIFICATION/PERMIT: SALES PROMO PERMIT (INITIAL AND AMENDMENT APPLICATION)

Center/Office/Division	**:**	Center for Food Regulation and Research (CFRR)
Classification	**:**	Government to Business
Type of Transaction	**:**	Complex Transaction
Who May Avail	**:**	Food Manufacturers, Importers, Exporters, Wholesalers/Distributors and Third Party Marketing Agencies
Fees to be Paid	**:**	In accordance to DTI-DOH JAO NO. 1 s. 2000 **Amount of Prizes: (Fees)** Php 150,000.00- below Php 300,000.00: Php 1,000.00.00 + 1% LRF Php 300, 001.00-Php 500,000.00: Php 2,000.00 + 1% LRF Php 500,001.00- Php 1,000,000.00: Php 3,000.00 + 1% LRF Above Php 1,000.000.00: Php 5,000.00 + 1% LRF **Coverage: (Fees)** NCR only or in several regions in NCR and Nationwide: Php 1,000.00.00 + 1% LRF More than one (1) region in NCR and Nationwide: Php 750.00 + 1% LRF Several provinces/cities/municipalities within a single region: Php 500.00 + 1% LRF Single province/city/municipality: Php 250.00 + 1% LRF **Amendment/Extension:** Php 300.00 + 1% LRF

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
I. Initial Application: • Integrated Application Form • Completely and accurately filled-up Information Sheet and Mechanics of Sales Promotion	FDA Website (www.fda.gov.ph)
• Photocopy of valid Certificate of Product Registration (CPR) and Cosmetic Notification (NN)of the company • Advertising/Collateral Materials to be used in the promotion, if any • Proof of Payment of Fees	FDA
II. Amendment Application: • Integrated Application Form • Letter of Intent stating the desired changes • Photocopy of Approved Permit • Additional Advertising/Collateral Materials to be used in Promotion if any	FDA Website (www.fda.gov.ph)
• Proof of Payment of Fees	FDA Cashier/Other FDA Authorized Payment Portals or Banks (where payment was made)

SALES PROMO PERMIT (INITIAL AND AMENDMENT APPLICATION) PROCESS FLOW based on FDA Circular No.2021-013: Interim Guidelines of the Center for Food Regulation and Research (CFRR) for the Application and Receiving of Sales Promo Permit Applications in Compliance to the Republic Act No. 11032 otherwise known as The Ease of Doing Business and Efficient Government Service Delivery Act Of 2018

CLIENT STEPS	AGENCY ACTION	PROCESSING TIME	PERSON RESPONSIBLE
1) The applicant company requests for DTN and schedule of submission for pre-assessment to Food and Drug Action Center (FDAC) through email.	1) FDAC personnel will send the DTN and schedule of submission for pre-assessment thru email to the client	Day 0	FDAC personnel
2) Applicant company submits documents for pre-assessment through email to Center for Food Regulation and Research (CFRR) on their assigned schedule.	1) FDRO will pre-assess the completeness and correctness of the submitted documents. If complete and correct, an email stating that the company can proceed with the payment will be sent to the email address of the authorized representative. A CFRR pre-assessment slip will also be attached on the email. Otherwise, an email stating the deficiency/ies noted on the documents for the client to comply and they will be advice to secure another DTN and schedule.	Day 0	Center for Food Regulation and Research (CFRR) Technical Personnel (e.g. Food-Drug Regulation Officer (FDRO))
2) Applicant company receives email to proceed with the payment and must pay through any applicable payment system prescribed by FDA		Day 0	
3) The applicant company pays the indicated fee as per Integrated Application Form through any applicable payment system prescribed by FDA	2) FDA Cashier will verify and post the payment through FDA FIS.	Day 0	Administrative Staff, Cashier-Administrative and Finance Services (AFS)

4) The applicant company submits the complete and correct documents to FDAC through email.	3) FDAC Personnel forwards the application to CFRR.	1 Working Day (Day 1)	FDA Personnel, Food and Drug Action Center (FDAC)
	4) CFRR Database controller receives the Sales Promo Permit Application and decks the application to the assigned evaluator.	1 Working Day (Day 2)	Administrative Staff, CFRR
	5) Evaluation	1 Working Day (Day 3)	CFRR Personnel (e.g. FDRO)
	6) Checking	1 Working Day (Day 4)	CFRR Personnel (e.g. FDRO)
	7) Approval	1 Working Day (Day 5)	Director IV, CFRR
	8) CFRR Database controller forwards the Sales Promotion Permit to FDAC and updates the FIS indicating that the Sales Promotion Permit will be forwarded to Records section for release.	1 Working Day (Day 6)	Administrative Staff, CFRR
6) The applicant company receives the Certificate/Authorization through courier or pick-up.	9) The FDA personnel will release the said Certificate/Authorization from the Releasing Unit of Food and Drug Action Center (FDAC), through courier or pick up.	1 Working Day (Day 7)	FDA Personnel, Records Section/FDAC
	TOTAL:	7 working days	

Please be advised that as per RA 11032 IRR, page 22 of 48, Section 3, b) ***The maximum time prescribed in Section 9 (b) (1) of the Act may be extended only once for the same number of days, which shall be indicated in the Citizen's Charter.***

Field Regulatory Operations Office Inspection Agenda

A.SIMPLE

Bureau of Customs – For Donation

Certification	Classification[1]	Type of Transaction[2]	Processing Time[3]	List of Requirements
Inspection Report with recommendation for release (Upon validation/inspection of the products)	Simple	Government-to-Business (G2B)	3 days upon receipt of request for inspection from the consignee	FDA Clearance issued by Centers

Legend:
[1] Classify if Simple, Complex, or Highly Technical Transaction
[2] Classify if Government-to- Citizens (G2C), Government-to-Business (G2B), and Government-to-Government (G2G)
[3] Based on Current Citizen's Charter Timeline

Bureau of Customs – For Personal Use

Certification	Classification[1]	Type of Transaction[1]	Processing Time[2]	List of Requirements
E-mail Reply (citing Joint Circular No.1)	Simple	Government-to-Business (G2B)	1 day upon receipt of request from the consignee	E-mail Request

Legend:
[1] Classify if Simple, Complex, or Highly Technical Transaction
[2] Classify if Government-to- Citizens (G2C), Government-to-Business (G2B), and Government-to-Government (G2G)
[3] Based on Current Citizen's Charter Timeline

FOOD AND DRUG ADMINISTRATION ACTION CENTER (FDAC)

1. Issuance of Electronic Portal (E-Portal) User Account

Center/Office/Division	:	**FDAC** Account Section
Classification	:	Simple
Type of Transaction	:	G2B - Government to Business
Who may Avail	:	Manufacturer, Traders, Distributors, Importers, Exporters, Wholesalers, Drug Outlets, and other Establishment and Facilities of health products, as determined by Food and Drug Administration
Fees to be paid	:	No required payment

CHECKLIST OF REQUIREMENTS	**WHERE TO SECURE**
1. Signed and notarized Authorization Letter (Annex B - FDA Circular No. 2016-004) (pdf format)	**Food and Drug Administration Philippines Website** **FDA Circular No. 2016-004** **"**Procedure on the Use of the New Application Form for License to Operate (LTO) thru the Food and Drug Administration (FDA) Electronic Portal**"**

CLIENT STEPS	**AGENCY ACTION**	**Fees to be Paid**	**PROCESSING TIME**	**PERSON RESPONSIBLE**
1. Sends an email request to fdac@fda.gov.ph	1.Checks the received e-mail as to completeness and appropriateness of the request	None	15 Minutes	FDAC Staff Information Officer II
2. Receives username and password	2. Issues user account (username and password) to client	None	Next Working Day	FDAC Staff Information Officer II
	TOTAL:	**None**	**1 Working Day, 15 Minutes**	

2. Issuance of Appointment Schedule and Document Tracking Number

Center/Office/Division	:	FDAC Account Section
Classification	:	Simple
Type of Transaction	:	G2B - Government to Business
Who may Avail	:	Manufacturer, Traders, Distributors, Importers, Exporters, Wholesalers, Drug Outlets, and other Establishment and Facilities of health products, as determined by Food and Drug Administration
Fees to be paid	:	No required payment

CHECKLIST OF REQUIREMENTS	**WHERE TO SECURE**
1. Accomplished Integrated Application Form (IAF) (pdf format) 2. Signed and Notarized Petition (pdf format)	**Food and Drug Administration Philippines Website** **FDA Circular No. 2014-003**

		"Filling and Receiving of Registration, Licensing and Other Application using the Integrated Application Form"		
CLIENT STEPS	**AGENCY ACTION**	**Fees to be Paid**	**PROCESSING TIME**	**PERSON RESPONSIBLE**
1. Send application e-mail to fdac@fda.gov.ph	1.Checks the received e-mail as to completeness and appropriateness of the request	None	15 Minutes	FDAC Staff Information Officer II
2. Receives Document Tracking Log and Appointment Schedule	2.Issues appointment schedule and Document Tracking Log (DTL) to the client's e-mail	None	Next Working Day	FDAC Staff Information Officer II
	TOTAL:	**None**	**1 Working Day, 15 Minutes**	

3. Filing of Complaint (Walk-in)

Filing of complaint through personal appearance at the Food and Drug Action Center (FDAC)

Center/Office/Division	:	FDAC CSAT/E-Report Section
Classification	:	Simple
Type of Transaction	:	G2G - Government to Business, G2C - Citizen, or G2G – Government
Who may Avail	:	All
Fees to be paid	:	None

CHECKLIST OF REQUIREMENTS	**WHERE TO SECURE**
Written letter addressed to Director General of Food and Drug Administration (FDA) ▪ Full name ▪ Address ▪ Contact details ▪ Details of the acts complained of ▪ Name of center/office of person(s) charged, if applicable ▪ Evidence of such violation, if applicable	Food and Drug Action Center

CLIENT STEPS	**AGENCY ACTION**	**Fees to be paid**	**PROCESSING TIME**	**PERSON RESPONSIBLE**

FOOD AND DRUG ADMINISTRATION ACTION CENTER (FDAC)

1. Submits a written letter addressed to the Director General of the Food and Drug Administration (FDA) to E-Report Section of the Food and Drug Action Center (FDAC) Address: 3rd Flr. Starmall Alabang, Muntinlupa	1. Receives the written letter and encodes the details in the FDA Inventory System and generates Document Tracking Number (DTN)	None	5 Minutes	FDAC E-Report Staff (Administrative Assistant III)
2. Receives an acknowledgement receipt.	2. Encodes the DTN and details of the E-Report Database for tracking and monitoring. 3. Prints the acknowledgement receipt	None	5 Minutes	
	4. Endorses the received document/s to the concerned center/office	None	Day 1	
	TOTAL:	**None**	**1 Working Day, 10 Minutes**	

4. Filing of Complaint (Online)

Filling of complaint through e-mail, **e-report@fda.gov.ph**

Center/Office/Division	:	FDAC CSAT/E-Report Section
Classification	:	Simple
Type of Transaction	:	G2B - Government to Business, G2C - Citizen, or G2G – Government
Who may Avail	:	All
Fees to be paid	:	None

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
For complaint or feedback via e-mail, kindly include the following information if applicable: ▪ Full name: ▪ Address: ▪ Contact details: ▪ Details of the complaint/feedback ▪ Person(s) in-charged ▪ Evidence of such violation	Food and Drug Action Center

FOOD AND DRUG ADMINISTRATION ACTION CENTER (FDAC)

CLIENT STEPS	AGENCY ACTION	Fees to be paid	PROCESSING TIME	PERSON RESPONSIBLE
1. Send complaint via e-mail with the detailed information to the Food and Drug Action Center (FDAC) E-mail: e-report@fda.gov.ph customersatisfactionteam@fda.gov.ph	1. Checks the received document along with other attached documents if available.	None	5 Minutes	FDAC E-Report Staff (Administrative Assistant III)
	2. Encodes the complaint details and generates Document Tracking Number (DTN) in the FDA Inventory System	None		
	3. Encodes the DTN and compliant details in the E-Report Database for tracking and monitoring.	None		
2. Receives acknowledgement receipt and DTN	4. Send an acknowledgement receipt including DTN	None	5 Minutes	
	5. Endorse the received document/s to the concerned center/office through e-mail	None	Day 1	
TOTAL:		**None**	**1 Working Day, 10 Minutes**	

5. Receiving of Application(s) and Other Documents of FDAC - Public Assistance and Complaint Desk (PACD) and Letter Section

Center/Office/Division	:	FDAC PACD and Letter Section
Classification	:	Simple
Type of Transaction	:	G2B - Government to Business
Who may Avail	:	Manufacturer, Traders, Distributors, Importers, Exporters, Wholesalers, Drug Outlets, and other Establishment and Facilities of health products, as determined by Food and Drug Administration
Fees to be paid	:	Administrative Order No. 50 s. 2001 "Revised 2001 Schedule of Fees and Charges for the Corresponding Services Rendered by the Bureau of Food and Drugs"

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
1. Issued Document Tracking Log (Scheduled Client) 2. Soft copies (PDF File format) of the documents based on the application requirements	**Applicant**

CLIENT STEPS	AGENCY ACTION	Fees to be paid	PROCESSING TIME	PERSON RESPONSIBLE

1. Submits application and other documents to PACD or Letter Section	1. Checks the application and other documents if the payment has been made	AO No. 50 s. 2001	5 Minutes	FDAC Information Officer II
2. Receives acknowledgement receipt	2. Checks the received application/s and other documents. 3. Stamp the client's Document Tracking Log as an acknowledgement receipt of the document/s	None	3 minutes	FDAC Information Officer II
	4. Routes the received application and/or other document to the concerned center/office	None	Next Working Day (Before 12nn)	FDAC Courier Information Officer II
	TOTAL:	**None**	**1 Working Day, 8 minutes**	

6. Assistance to Phone Callers

Center/Office/Division	:	FDAC Phone Operator Section
Classification	:	Simple
Type of Transaction	:	G2B - Government to Business, G2C - Citizen, or G2G – Government
Who may Avail	:	All
Fees to be paid	:	None

CHECKLIST OF REQUIREMENTS	**WHERE TO SECURE**
None	None

CLIENT STEPS	**AGENCY ACTION**	**Fees to be paid**	**PROCESSING TIME**	**PERSON RESPONSIBLE**
Calls the FDAC designated landline numbers 8-8211177 8-8211176 8-8211159 8-8211220 8-8211162	1. Answer phone calls and identify the client's concern 2. Acts on client's concern 3. Highly technical concerns are advise to send an e-mail to the	None	10 Minutes Depending on the complexity of the issue	FDAC Phone Operators Information Officer II

	designated center/office e-mail address			
TOTAL:		**None**	**10 Minutes**	

7. Customer Satisfaction Survey (CSS) Form

Center/Office/Division	:	FDAC CSAT/E-Report Section
Classification	:	Simple
Type of Transaction	:	G2B - Government to Business, G2C - Citizen, or G2G – Government
Who may Avail	:	All
Fees to be paid	:	None

CHECKLIST OF REQUIREMENTS	**WHERE TO SECURE**
CSS Form	Food and Drug Action Center (FDAC)

CLIENT STEPS	**AGENCY ACTION**	**Fees to be paid**	**PROCESSING TIME**	**PERSON RESPONSIBLE**
1. Fill-out the CSS form and drops it at the designated suggestion box	1. Consolidates all filled-out CSS forms at the end of the month	None	3 Minutes	FDAC E-Report Staff (Administrative Assistant III)
	2. Routes the consolidated forms to the concerned center/office	None	Day 1	
TOTAL:		**None**	**1 Working day, 3 Minutes**	

FOOD AND DRUG ADMINISTRATION ACTION CENTER (FDAC)

FEEDBACK AND COMPLAINT MECHANISM	
How to send feedback	Answer the Customer Satisfaction Survey form in the receiving area and drop it in the suggestion box Food and Drug Action Center (FDAC) Contact info: (8)821-1177, (8)8211176, (8)8211159, (8)8211220, (8)8211162
How feedback are processed	The admin verifies the nature of feedback after a month. The same will be referred to the office concerned. Upon receiving the response of the concerned center/office, the client will be informed via e-mail. For follow-up, the contact information are as follows: 8)821-1177, (8)8211176, (8)8211159, (8)8211220, (8)8211162 For queries, the contact information are as follows: 8)821-1177, (8)8211176, (8)8211159, (8)8211220, (8)8211162 info@fda.gov.ph
How to file a complaint	To file a complaint against the Food and Drug Administration (FDA) or product under jurisdiction of FDA, provide the following details via e-mail or walk-in ▪ Full name and contact information of the complainant ▪ Narrative of the complaint ▪ Evidence, if applicable ▪ Name of the person being complained, if applicable Send all complaints against the FDA or product to e-report@fda.gov.ph or through walk-in at Food and Drug Action Center (FDAC)
How complaints are processed	All complaints received will be monitored by the E-Report Section at the Food and Drug Action Center (FDAC) The FDAC shall coordinate with the concerned Center or Office to answer the complaint and shall investigate, if necessary. The E-Report Section or concerned Center or Office shall give the feedback to the client/complainant via e-mail or letter.