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

**FDA ADVISORY No.** 2020-1655

14 SEP 2020

**TO** : **FDA-REGULATED FOOD ESTABLISHMENTS WITHIN NCR AND THE GENERAL PUBLIC**

**SUBJECT** : **Pilot Implementation of the Food and Drug Administration (FDA) Food Product Registration Portal V. 2 for Certificate of Product Registration (CPR) Application of Food Products**

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The FDA, with its aim to streamline submissions of all market authorization applications and to provide efficient public service, is currently enhancing the Electronic Portal for FDA food product registration. This revised online platform shall be used in securing Certificate of Product Registration (CPR) and amended thereof. The Food Product Registration Portal v.2 for CPR application is accessible to stakeholders for pilot testing (dry run) on **15 September 2020**. Pilot testing or dry run is important to address glitches, loopholes, technical concerns or problems that may be encountered.

In this regard, all stakeholders within the National Capital Region (NCR) who intend to apply for CPR of food products are encouraged to use the new FDA Food Product Registration Portal v. 2 through this link https://eportal.fda.gov.ph/.

| **FDA Food Product Registration Portal v. 2** | |
|---|---|
| Establishment Activities | Manufacturer, Distributor (Importer, Exporter, and Wholesaler), and Trader of Food Products |
| Type of CPR Application | Initial, Amendment, Renewal, and Re-Application |
| Fees to be Paid | Based on Current Issuance on Fees and Charges (DOH Administrative Order No.50 s. 2001) |
| Validity of CPR | Based on Current Issuance on Fees and Charges (DOH Administrative Order No.50 s. 2001) |

Please follow Annex A & B of this Advisory for the Step-by-Step Guide in applying in the FDA Food Product Registration Portal V.2. and Checklist of Requirements.

The regulatory requirements for CPR application of food products shall still follow the provisions of DOH Administrative Order No. 2014-0029 entitled "Rules and Regulations on the Licensing of Food Establishments and Registration of Processed Food, and other Food Products, and for Other Purposes" and FDA Circular 2016-014.

For compliance.

**ROLANDO ENRIQUE D. DOMINGO, MD**
Director General

DTN 20200611161946

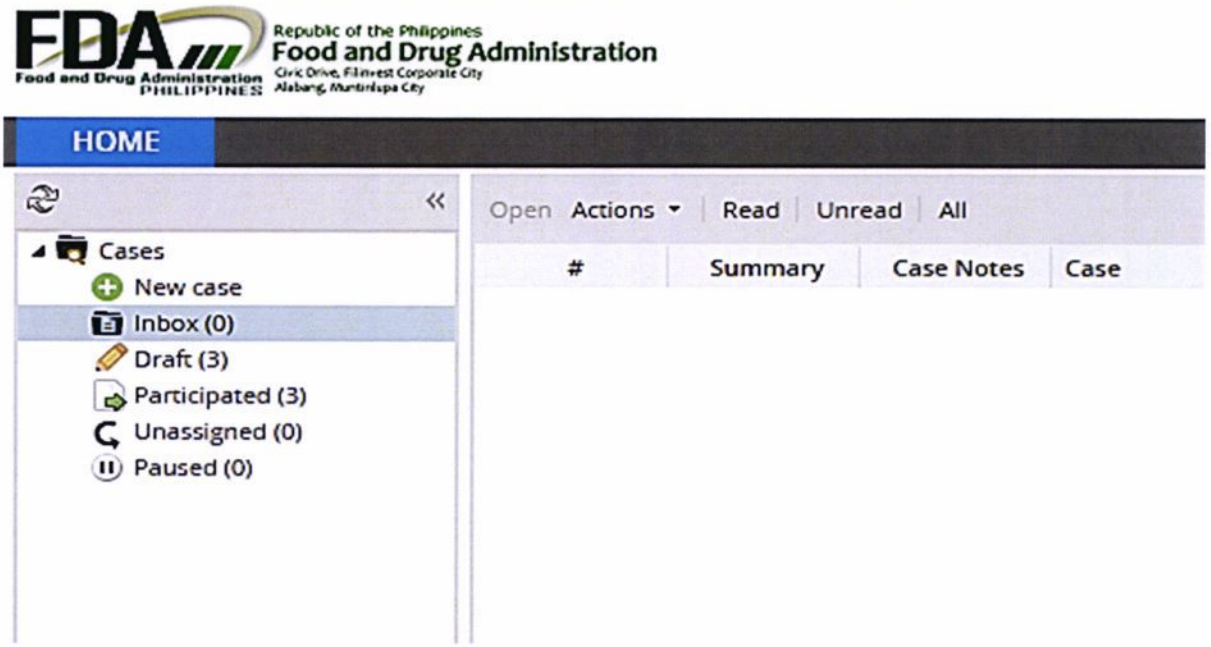
*Annex A*

**Procedure for the Use of Food Product Registration Portal v. 2**
**for Certificate of Product Registration Application**

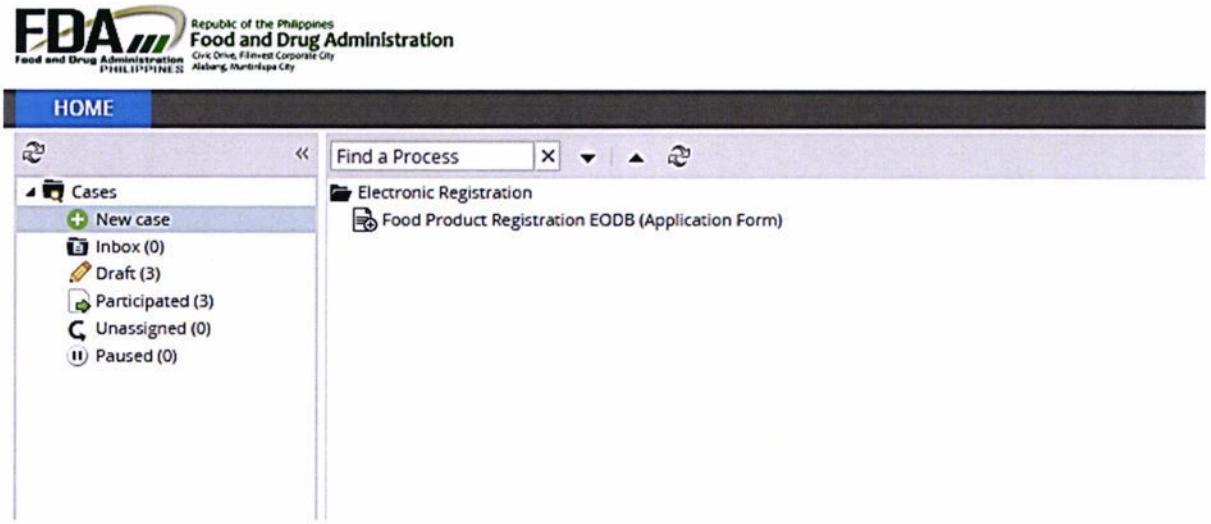
## A. Application for Initial CPR

1. To start the application, access the online portal through https://eportal.fda.gov.ph/ with the CFRR issued User Account e-mailed to the applicant's registered email address.

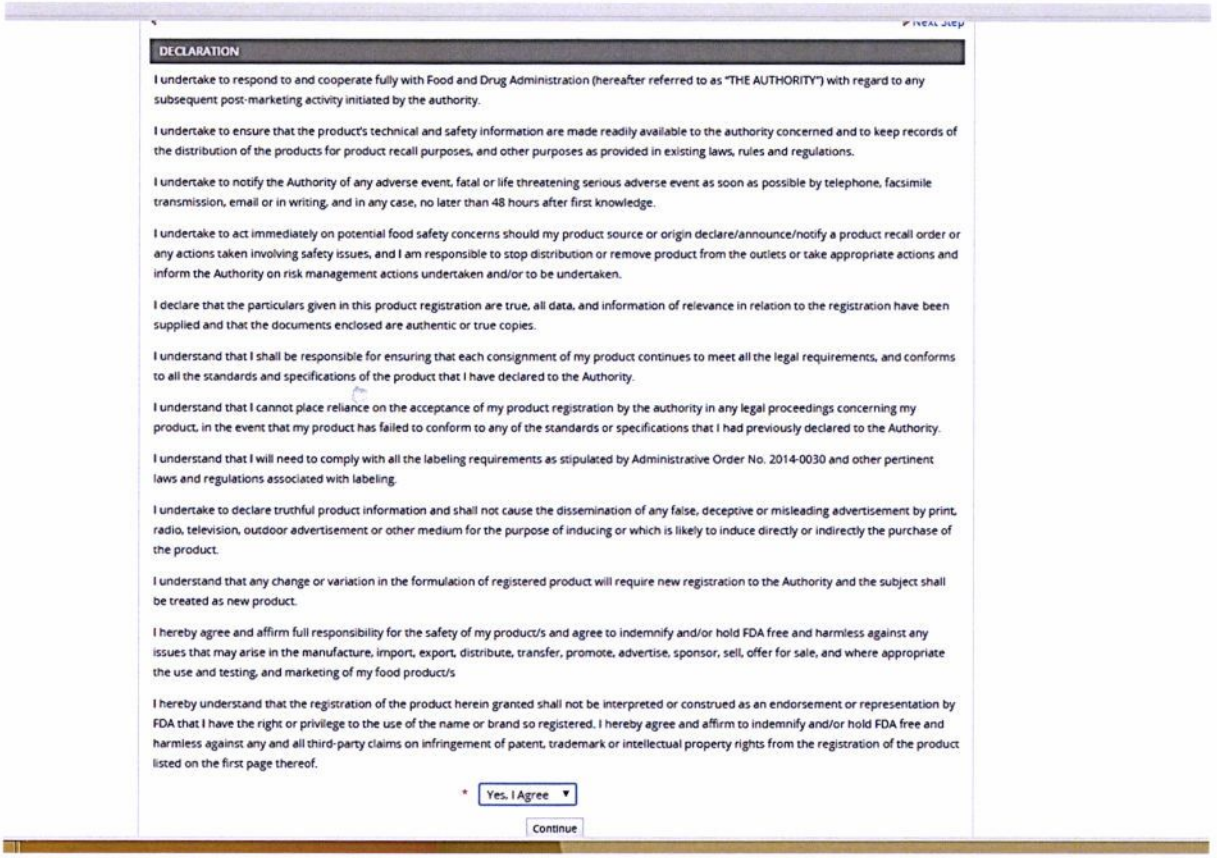
2. Click on the "New Case" located on the upper left corner of the system.




3. Select the "Food Product Registration EODB (Application Form).



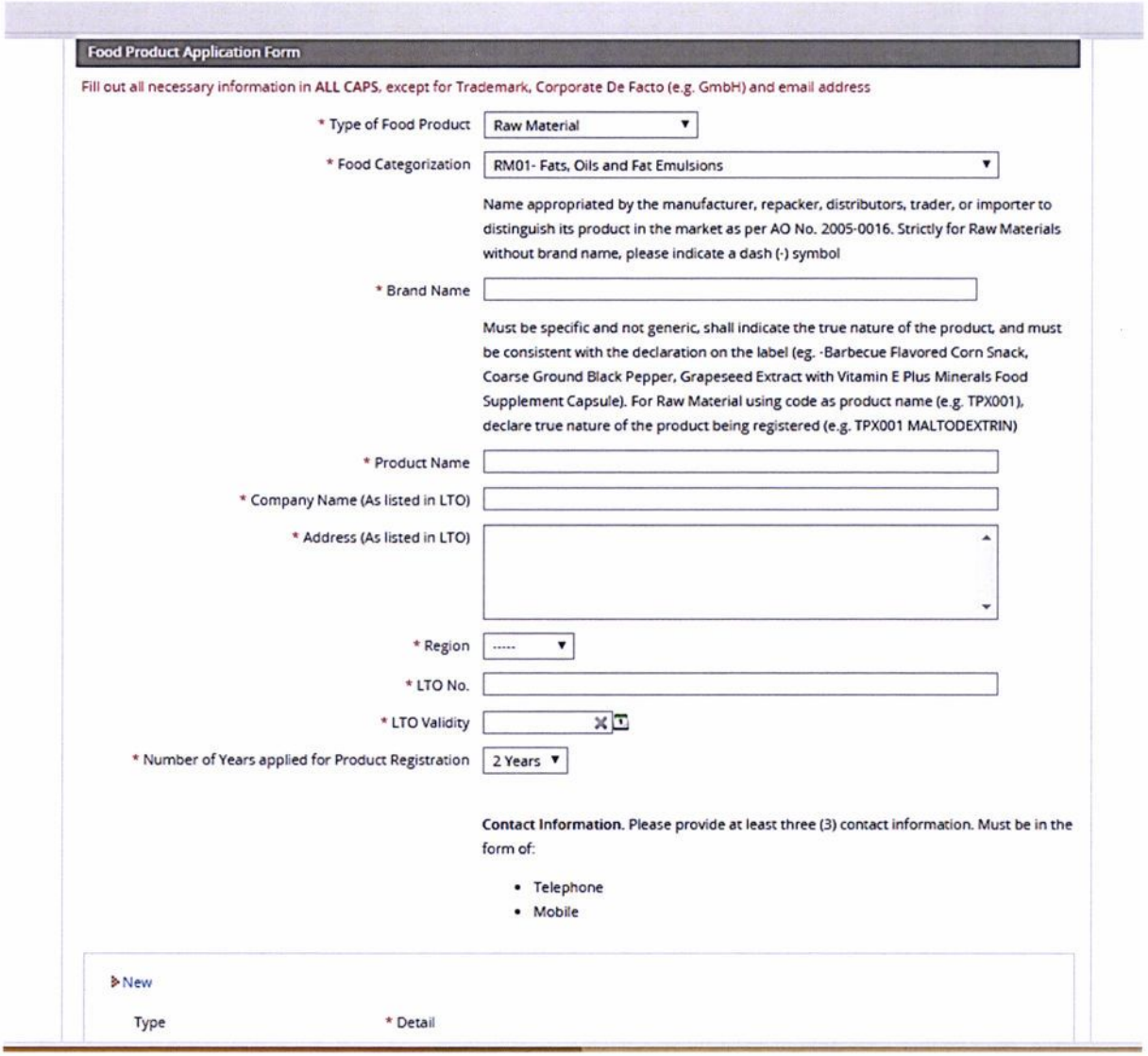
4. Read carefully the **"DECLARATION"** before proceeding with the application process. The **"DECLARATION"** conveys the binding agreement between the applicant and the FDA to provide complete and accurate information, assuming full responsibility for the safety of the product being registered; with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




5. Select the type of application (Initial) under the General Information and click on "Next".

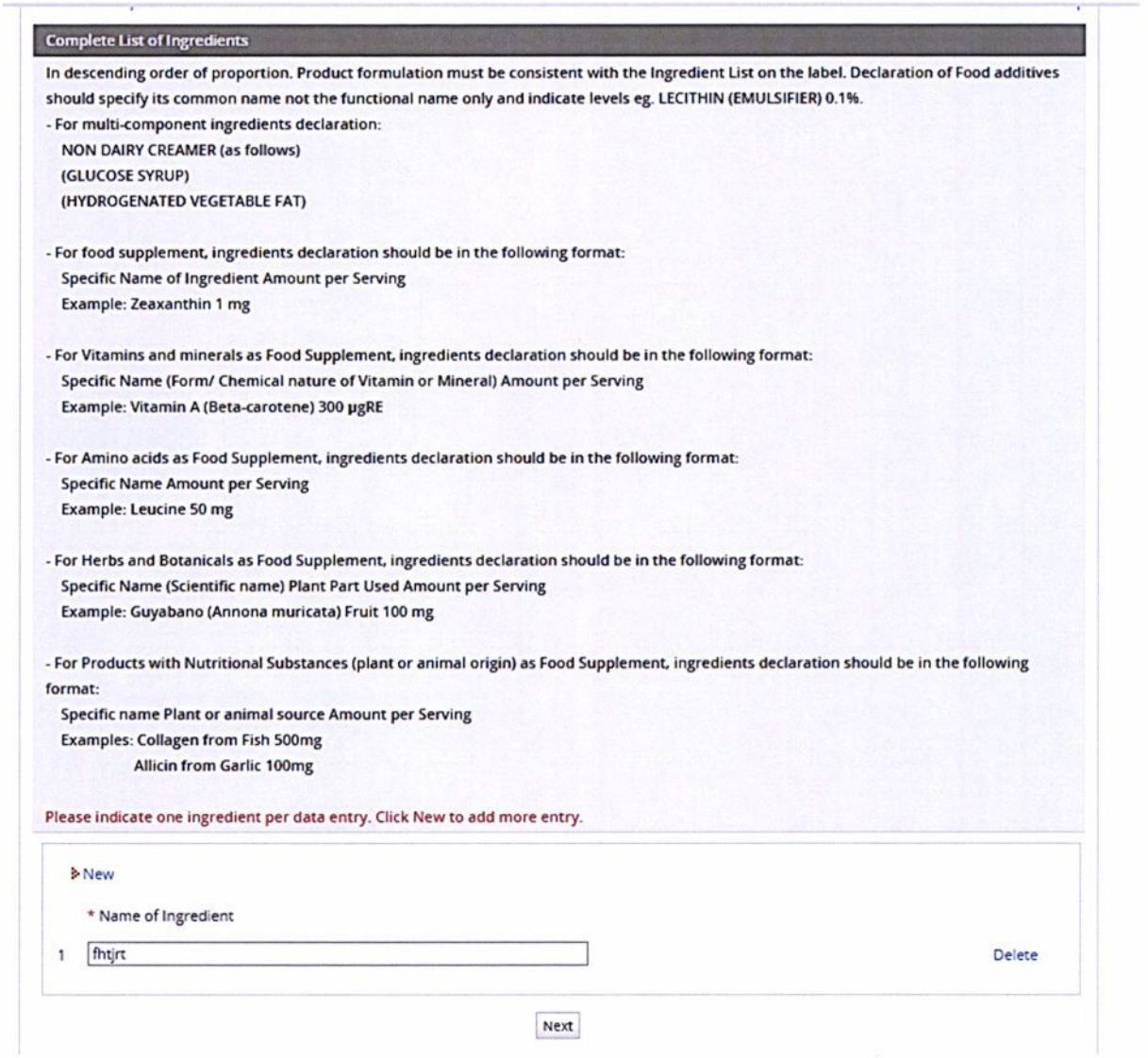
6. Fill-out the Food Product Application Form in **ALL CAPS**, except for Trademark, Corporate De Facto (e.g. GmbH) and e-mail address. The applicant shall make sure that the LTO Number is valid before proceeding to the next step. A **minimum** of three (3) contact information in the form of e-mail, telephone and mobile number must be declared.

   All items mark with asterisk (*) are required fields.




7. Select the corresponding company activity/ies in the drop-down button.

8. Declare all ingredients in DESCENDING order of proportion. For multi-component ingredients (e.g. non-dairy creamer), indicate the phrase as "follows" in parenthesis after the ingredient and declare each specific component also in parenthesis.

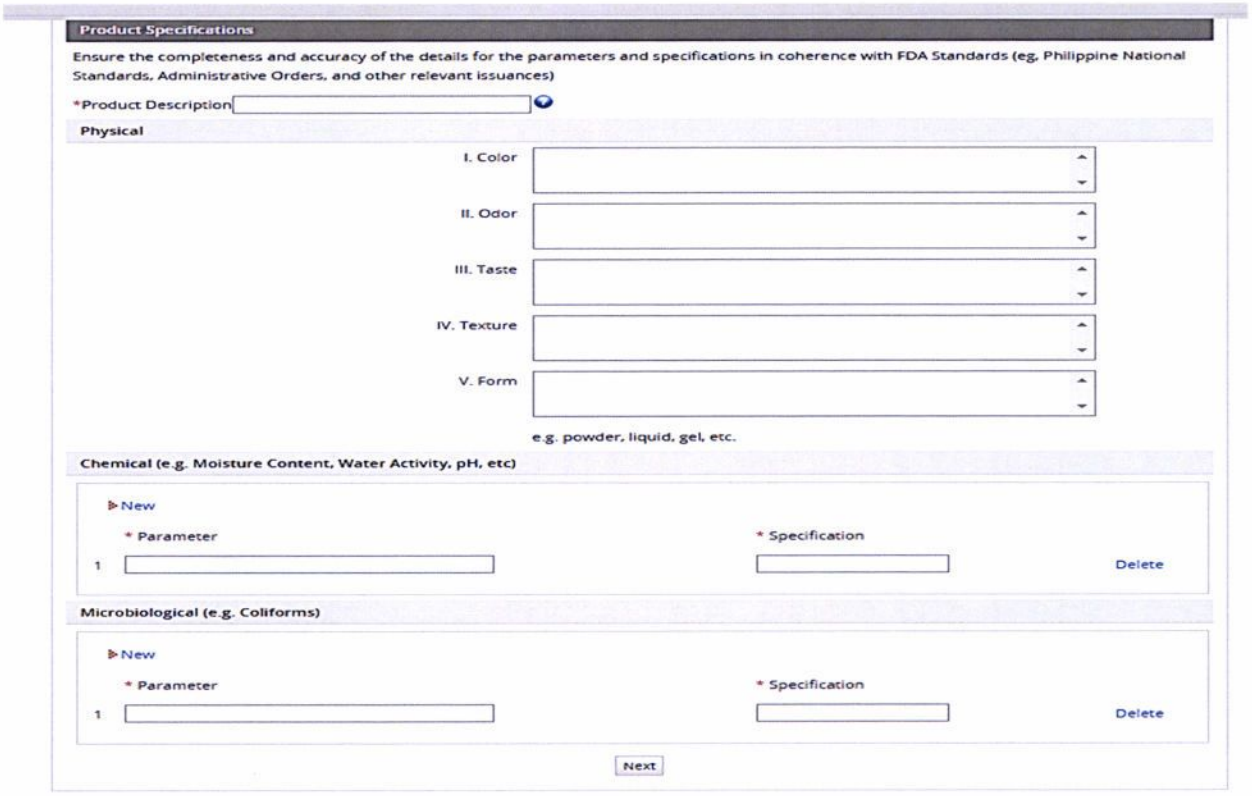



9. In declaring the product specification for physical, chemical, and microbiological parameters, ensure the completeness and accuracy of the details since these shall be verified later during the Post-Market Surveillance (PMS).

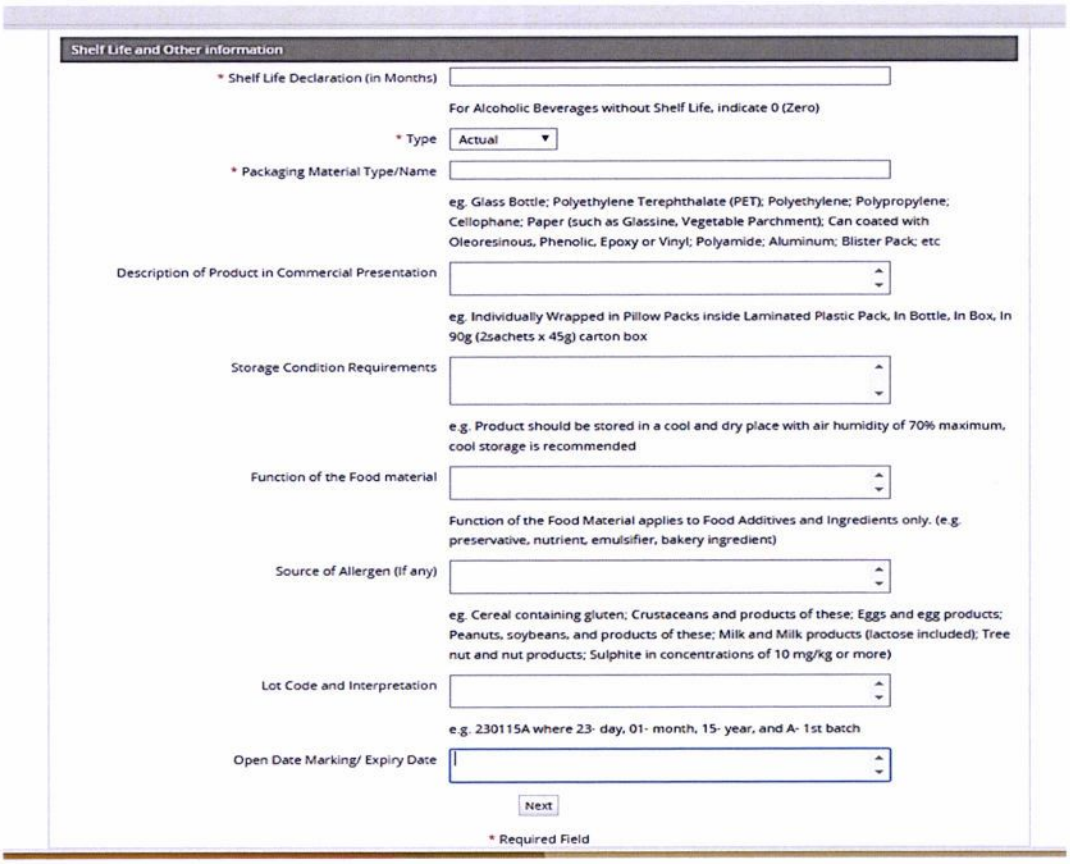
   Declare the appropriate product description of the food including type of packing medium, form or style, and the condition or type of treatment it has undergone (e.g. Canned Spanish Style Tuna Chunks, Pickled Cucumber in Brine, Dried Fish, Frozen Corn Kernel, Milk powder, etc.).

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

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

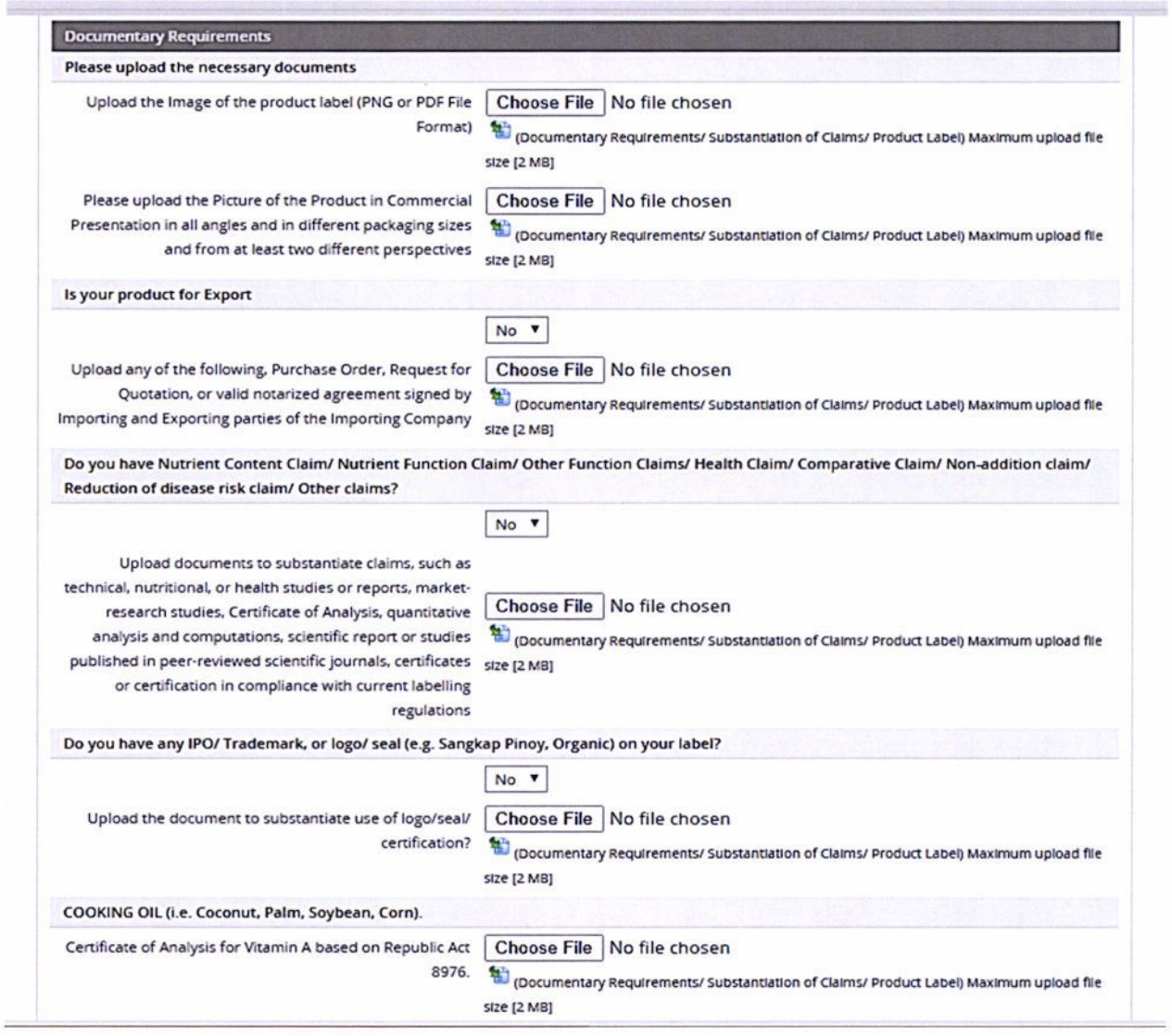



10. Fill-out the Shelf Life and other product information accurately and clearly.



11. In attaching Product Labels and other documentary requirements, make sure that ALL information is reflected **CLEARLY** and **ACCURATELY**. Limit the total size of attachments to 20 MB with a limit of 2 MB per file using the format ".png" or ".pdf".

    Product Labels in commercial presentation should be scanned clearly reflecting all sides with complete information and shall be named following the format "Label_ (Case Number)".



| Documentary Requirements | |
|---|---|
| **Please upload the necessary documents** | |
| Upload the Image of the product label (PNG or PDF File Format) | Choose File No file chosen<br>(Documentary Requirements/ Substantiation of Claims/ Product Label) Maximum upload file size [2 MB] |
| Please upload the Picture of the Product in Commercial Presentation in all angles and in different packaging sizes and from at least two different perspectives | Choose File No file chosen<br>(Documentary Requirements/ Substantiation of Claims/ Product Label) Maximum upload file size [2 MB] |
| **Is your product for Export** | |
| | No |
| Upload any of the following, Purchase Order, Request for Quotation, or valid notarized agreement signed by Importing and Exporting parties of the Importing Company | Choose File No file chosen<br>(Documentary Requirements/ Substantiation of Claims/ Product Label) Maximum upload file size [2 MB] |
| **Do you have Nutrient Content Claim/ Nutrient Function Claim/ Other Function Claims/ Health Claim/ Comparative Claim/ Non-addition claim/ Reduction of disease risk claim/ Other claims?** | |
| | No |
| Upload documents to substantiate claims, such as technical, nutritional, or health studies or reports, market-research studies, Certificate of Analysis, quantitative analysis and computations, scientific report or studies published in peer-reviewed scientific journals, certificates or certification in compliance with current labelling regulations | Choose File No file chosen<br>(Documentary Requirements/ Substantiation of Claims/ Product Label) Maximum upload file size [2 MB] |
| **Do you have any IPO/ Trademark, or logo/ seal (e.g. Sangkap Pinoy, Organic) on your label?** | |
| | No |
| Upload the document to substantiate use of logo/seal/ certification? | Choose File No file chosen<br>(Documentary Requirements/ Substantiation of Claims/ Product Label) Maximum upload file size [2 MB] |
| **COOKING OIL (i.e. Coconut, Palm, Soybean, Corn).** | |
| Certificate of Analysis for Vitamin A based on Republic Act 8976. | Choose File No file chosen<br>(Documentary Requirements/ Substantiation of Claims/ Product Label) Maximum upload file size [2 MB] |

12. 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:

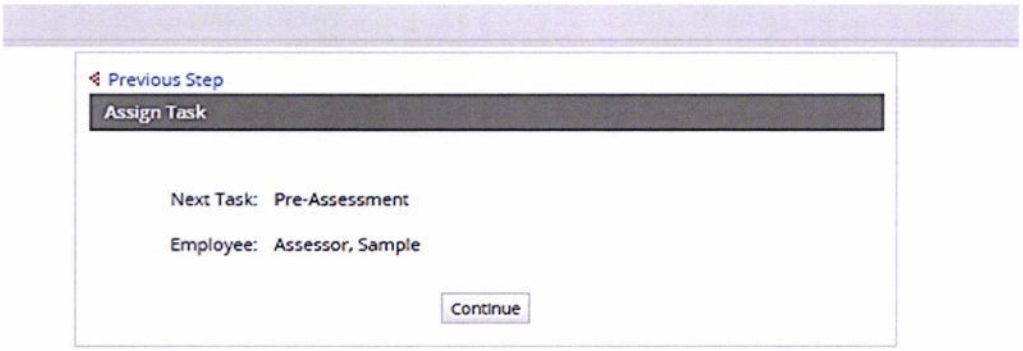
        TO: FOOD AND DRUG ACTION CENTER (FDAC)
        3rd Floor Starmall, Alabang, Muntinlupa City

        FROM: Company's complete name & address

        SUBJECT: Food Product E-Registration
        Application (Case No.)

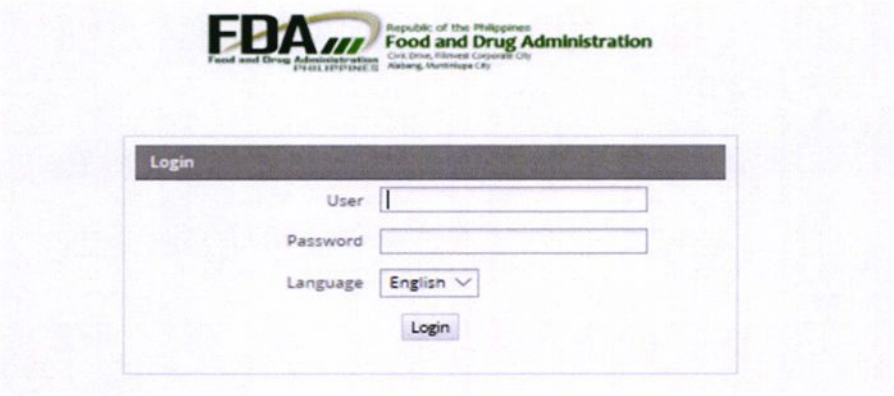
The proof of submission of sample (Acknowledgement Receipt from FDAC or Receipt from Registered Courier) shall be uploaded together with the other documentary requirements.


13. Click on "Continue" to proceed with Pre-Assessment.

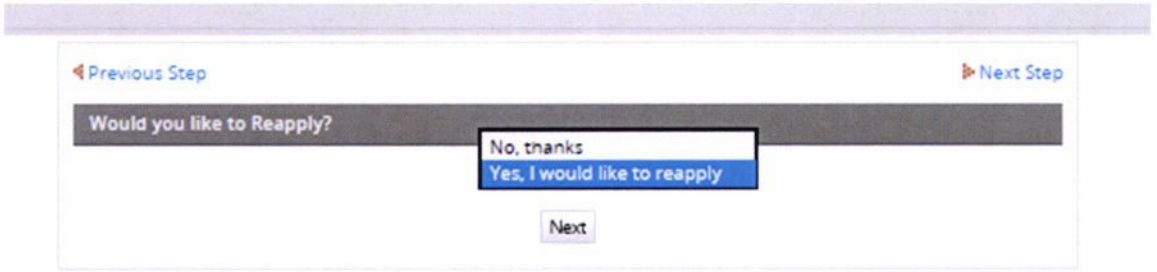


## B. Re-application

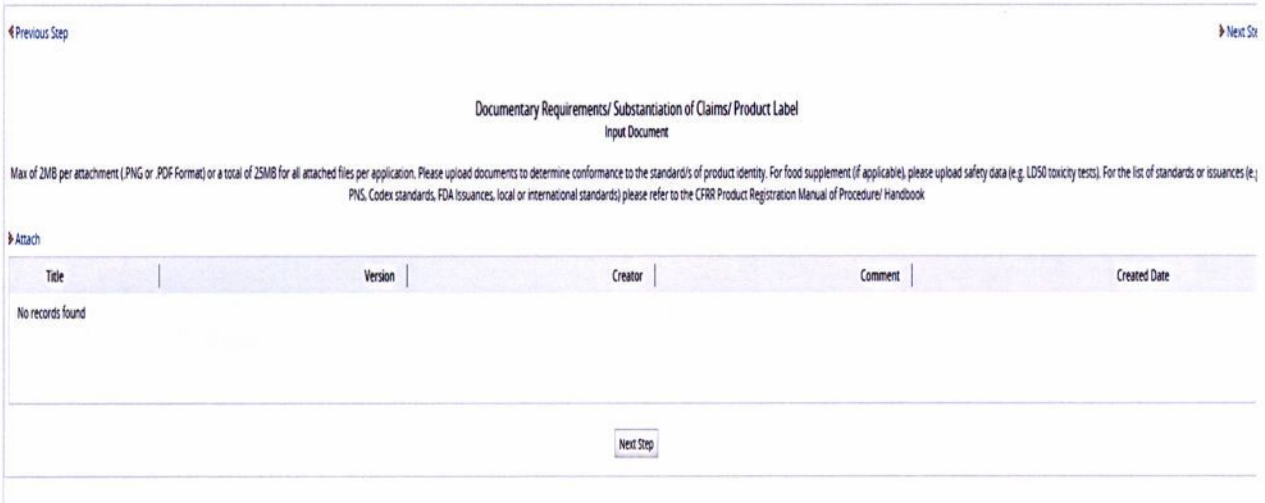
1. To apply for re-application, access the online portal through https://eportal.fda.gov.ph/. Provide the company-specific Username and Password, and double click on the specific product in the Inbox folder.



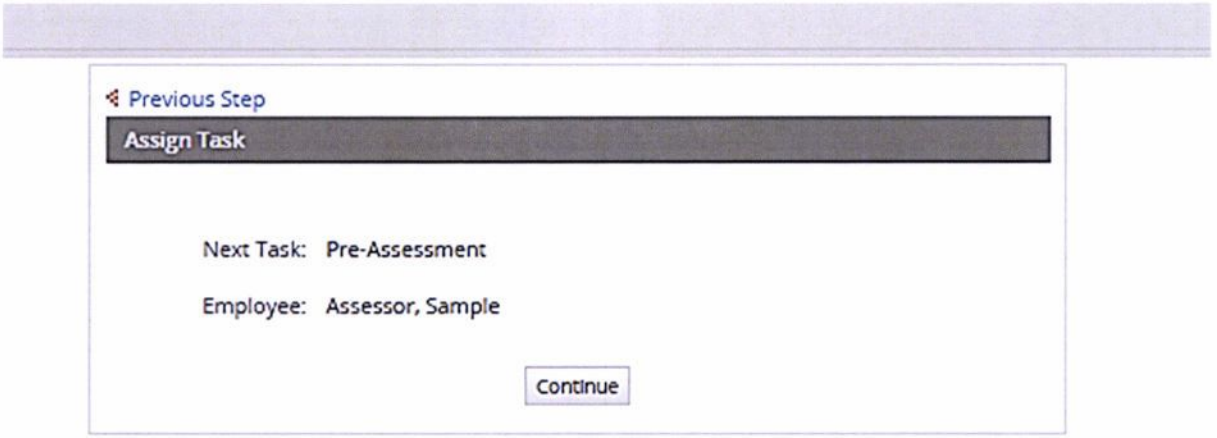

2. Select "Yes, I would like to reapply".




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



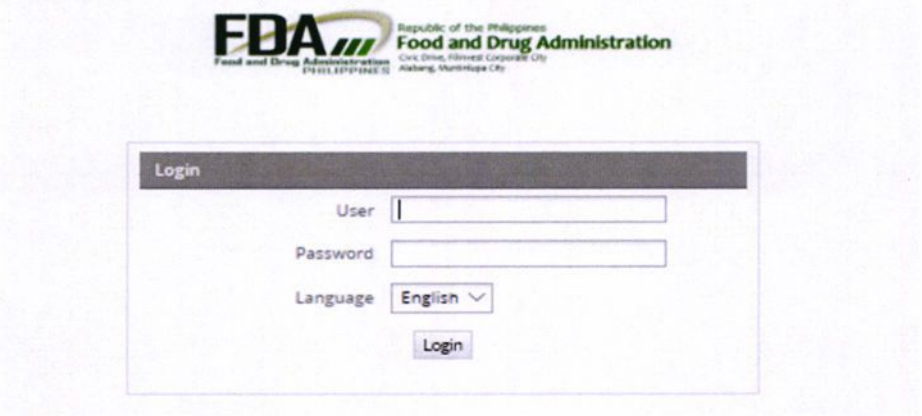
4. Click on "Continue" to proceed with Pre-Assessment



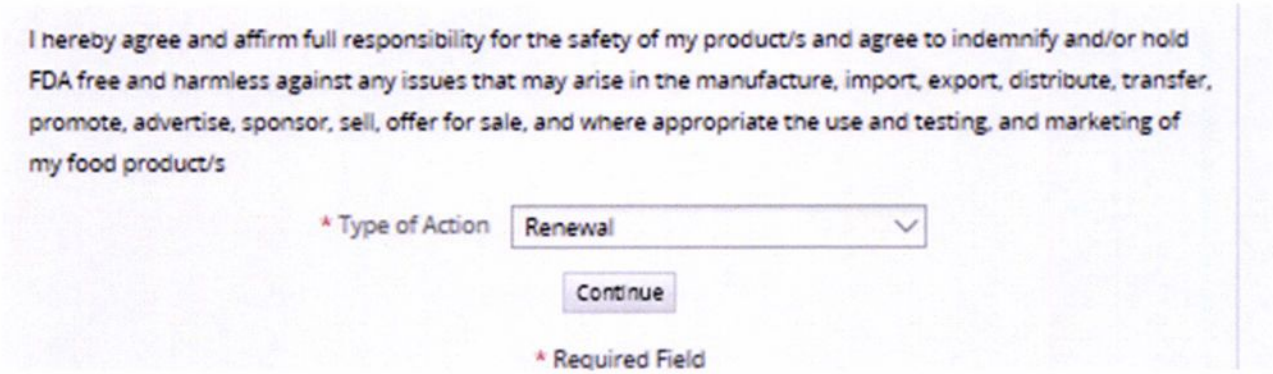

5. Upon receipt of system-generated result of pre-assessment indicating complete re-application requirements, pay the corresponding assessed fee through the FDA Cashier at FDAC, Starmall, Alabang or BancNet online payment gateway following the procedure per FDA Circular No. 2017-010 or any applicable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

## C. Amendment/Renewal Application

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




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




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

*Annex B*

**Checklist of Requirements based on Citizen's Charter**

**CERTIFICATE OF PRODUCT REGISTRATION (CPR)**

I. **TITLE OF CERTIFICATION/PERMIT: CERTIFICATE OF PRODUCT REGISTRATION (CPR)** – INITIAL/ RENEWAL DATA CAPTURE/ AMENDMENT DATA CAPTURE/ REAPPLICATION DATA CAPTURE

| | | |
|---|---|---|
| **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).<br><br>Conventional Food (Category 1): Php 200.00/year of validity + 1% LRF<br>Conventional Food (Category 2): Php 250.00/year of validity + 1% LRF<br>Food Supplement: Php 1,000.00/year of validity + 1% LRF<br>Bottled Water: Php 1,000.00/year of validity + 1% LRF |

| CHECKLIST OF REQUIREMENTS | WHERE TO SECURE |
|---|---|
| *1. Submit one (1) scanned copy of the required document in the e-Registration Portal*<br>*2. Product labels and pictures of the product in commercial presentation for upload should be scanned in 200-dpi setting*<br>*3. Documents for upload should be scanned in 150-dpi setting*<br>*4. 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* | |
| 1. General Requirements based on Administrative Order 2014-0029 | |
| ✓ Accomplished Initial Application Form as prescribed by FDA regulations (e-Registration e-Portal, refer to FDA Circular 2016-014). | 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 |
| ✓ 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). | Applicant Company/ Manufacturer/Source/Supplier |
| ✓ 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. | Applicant Company/ Manufacturer/Source/Supplier |

| | |
|---|---|
| ✓ As applicable, documents to substantiate claims, such as technical, nutritional or health studies or reports, market-research studies, Certificate of Analysis, quantitative analysis and computations, scientific report or studies published in peer-reviewed scientific journals, certificates or certification to support use of logo/seal on Sangkap Pinoy, Halal, Organic, or Kosher food and in compliance with current labeling regulations. | Applicant Company/ Manufacturer/Source/Supplier<br>For the Certificate of Analysis:<br>a) Manufacturer/Supplier/Source<br>b) Laboratory analysis issued/conducted by FDA accredited laboratories. |
| 2) General Requirements based on FDA Circular 2016-007<br>• 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).<br><br>• For Imported Products:<br>a. Any scanned copy of the original copy of Distributorship agreement or contract agreement Sales Invoice or Proforma Invoice, or whichever is applicable, signed by the duly authorized representative of the establishment as reflected in the records of CFRR (FDA Circular 2016-007).<br>b. 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:<br>✓ Valid manufacturer's certificate of registration with GMP compliance or its equivalent;<br>✓ Valid Phytosanitary Certificate/ Health Certificate;<br>✓ Valid ISO 22000 Certification;<br>✓ Valid HACCP Certificate; or<br>✓ 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 |
| 3) ADDITIONAL REQUIREMENTS PER FOOD CATEGORY<br><br>1. **LOW-RISK FOOD PRODUCTS**<br><br>A.1. COOKING OIL (i.e. Coconut, Palm, Soybean, Corn).<br>• Certificate of Analysis for Vitamin A | 1) For the Certificate of Analysis:<br>a) Applicant Company/ Manufacturer/Source/Supplier; or<br>b) Laboratory analysis issued/conducted by FDA accredited laboratories.<br><br>2) For other technical document(s):<br>a) Applicant Company/ |

| | |
|---|---|
| based on Republic Act 8976. | Manufacturer/Source/Supplier |
| D.1. WHEAT FLOUR<br>• Certificate of Analysis for Vitamin A and Iron based on Republic Act 8976. | |
| G.1. REFINED SUGAR<br>• Certificate of Analysis for Vitamin A based on Republic Act 8976. | |
| I.1. IODIZED SALT & SALT SUBSTITUTES<br>• Certificate of Analysis for Iodine Content based on Republic Act 8172. | |
| I.8. SOY SAUCE<br>• Certificate of Analysis for 3-MCPD based on FDA Memorandum 2011-028. | |
| D.6. PRE-PACKED RICE<br>• Certificate of Analysis for Iron based on Republic Act 8976. | |

2. **MEDIUM-RISK FOOD PRODUCTS**

| | |
|---|---|
| MRA1a. CONDENSED MILK<br>• 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.<br>• Certificate of Analysis for Total Milk Solids and Milk Fat based on Administrative Order No. 132 s. 1970. | |
| MRA2. MILK POWDER<br>• 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.<br>• 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<br>• 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.<br>• Certificate of Analysis for pH, Protein, Fat, Milk Solids, Milk Fat and Moisture (whichever is applicable) based on Administrative Order No. 132 s. 1970.<br>• Certificate of Analysis to support Nutrition Information declaration. | |
| | MRB2. EDIBLE ICES (POPSICLES)<br>• 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<br>• Certificate of Analysis for Total Soluble Solids and Titratable Acidity based on Administrative Order No. 233 s. 1974. | |
| | MRC2. FROZEN FRUITS<br>• 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<br>• 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<br>• 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<br>• Certificate of Analysis for Microbiological parameters for Cocoa Powder: Molds cfu/g, Salmonella/25g, Coliforms cfu/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 cfu/g & SPC/APC cfu/g based on FDA Circular 2013-010. | |
| | MRF1Ai. CURED (INCLUDING SALTED) NON-HEAT TREATED PROCESSED MEAT, POULTRY AND GAME PRODUCTS<br>• 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.<br>• Certificate of Analysis for Microbiological parameters for Cured/Smoked Poultry: S. aureus (coagulase +) cfu/g & Salmonella/25g based on FDA Circular 2013-010.<br>• 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<br>• 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.<br>• 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<br>• 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.<br>• 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<br>• 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<br>• 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<br>• 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)<br>• 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.<br>• For Mayonnaise: Certificate of Analysis for Fat Content based on Administrative Order No. 235 s. 1975. | |
| | MRL1a. FRUIT AND VEGETABLE JUICES<br>• 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<br>• 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.<br>• Certificate of Analysis for Caffeine and Vitamin Assays based on Administrative Order 2014-0029. | |
| | MRL1ci. CARBONATED WATER-BASED FLAVORED DRINKS<br>• 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.<br>• For Cola-type Beverage: Certificate of Analyis for Caffeine Content based on Administrative Order 88-A s. 1984. | |
| | MRL1cii. NON-CARBONATED WATER-BASED FLAVORED DRINKS<br>• 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<br>• 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<br>• 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<br>• Shelf life study with stability data based on Administrative Order 2014-0029.<br>• 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.<br>• 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.<br>• 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.

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.*

3. **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

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| | cfu/mL & SPC/APC cfu/mL based on FDA Circular 2013-010. | |
| | HRA1b. DAIRY-BASED DRINKS, FLAVORED AND/OR FERMENTED<br>• Certificate of Analysis for Microbiological parameters for Liquid Milk (evaporated & ready to drink)-UHT/Sterilized: Commercial Sterility based on FDA Circular 2013-010.<br>• 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.<br>• 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<br>• 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)<br>• Certificate of Analysis for Microbiological parameters for Cream (UHT/Sterilized): Commercial Sterility based on FDA Circular 2013-010. | |
| | HRA4a. UNRIPENED CHEESE<br>• Certificate of Analysis for Microbiological parameters for Cheese and Cheese (moisture $\geq$ 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.<br>• 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.<br>• Certificate of Analysis for Fat in Dry Matter and Moisture Content based on Administrative Order No. 200-A s. 1973 | |

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| | HRA4di. PLAIN PROCESSED CHEESE<br>• 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<br>• 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)<br>• 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<br>• 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.<br>• 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<br>• 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<br>• 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<br>• Certificate of Analysis for Microbiological parameters for Peanut Butter & Other Nut Spreads: Salmonella/25g based on FDA Circular 2013-010. | | |
| | HRD. CHOCOLATE WITH NUTS | | |

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| | • Certificate of Analysis for Microbiological parameters for Chocolate Products: Molds cfu/g, Salmonella/25g, Coliforms cfu/g & SPC/APC cfu/g based on FDA Circular 2013-010. | |
| | HRF1. FINE BAKERY PRODUCTS WITH FILLINGS<br>• 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.<br>• 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)<br>• Certificate of Analysis for Microbiological parameters for Meat Products in Hermetically Sealed Containers: Commercial Sterility based on FDA Circular 2013-010.<br>• 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)<br>• 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<br>• 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 | |

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| | AND ECHINODERMS<br>• 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<br>• 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<br>• 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))<br>• 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))<br>• 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<br>• 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)<br>• Certificate of Analysis for Energy, Protein, Total Fat, Linolenic Acid, Total Carbohydrates per 100g, Vitamins and Minerals, Trace Minerals and Other Substances, | |

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| | Lauric/Mystiric/Trans Fatty Acids, Optional Ingredients- Taurine, DHA and Contaminants based on Codex Stan 72-1981 Rev. 2007.<br>• 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.<br>• Clear and complete loose labels or artworks compliant with Department Circular 2008-0006.<br>• 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)<br>• 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.<br>• Certificate of Analysis for Microbiological parameters for Infant Formula- Liquid (UHT/Sterilized) cultures: commercial sterility based on FDA Circular 2013-010.<br>• Clear and complete loose labels or artworks compliant with Department Circular 2008-0006.<br>• 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<br>• 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.<br>• Certificate of Analysis for Microbiological parameters for Follow-up Formula/Milk Supplements: Salmonella/25g, SPC/APC cfu/g | |

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| | & Enterobacteriaceae/10g based on FDA Circular 2013-010.<br>• Clear and complete loose labels or artworks compliant with Department Circular 2008-0006. | |
| | HRJ2. CEREAL-BASED FOODS FOR INFANTS & YOUNG CHILDREN<br>• Certificate of Analysis for Energy, Protein, Carbohydrates, Lipids, Minerals and Vitamins based on Codex Stan 074-1981, Rev 1-2006.<br>• 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.<br>• 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<br>• Certificate of Analysis to support Nutrition Information based on Codex Stan 73-1981 amended 1989.<br>• Certificate of Analysis for Microbiological parameters for Baby Foods in Hermetically Sealed Containers: commercial sterility based on FDA Circular 2013-010.<br>• 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<br>• Scientific Studies indicating safety and benefits of the product for intended medical condition based Codex Stan 180-1991 and Administrative Order 2014-0029.<br>• Certificate of Analysis to support Nutrition Information based on Codex Stan 180-1991.<br>• Clear and complete loose labels or artworks compliant with Codex Stan 180-1991. | |
| | HRJ5. FOODS FOR SPECIAL DIETARY USE<br>• Scientific Studies indicating safety and | |

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| | suitability of the product to specific disease and disorder to which it is intended based on Codex Stan146-1985 and Administrative Order 2014-0029.<br>• Certificate of Analysis to support Nutrition Information based on Codex Stan146-1985.<br>• Clear and complete loose labels or artworks compliant with Codex Stan146-1985. | |
| | HRJ4. FORMULA FOODS FOR WEIGHT CONTROL DIETS<br>• Certificate of Analysis to support Nutrition Information based on Codex Stan 181-1991.<br>• Clear and complete loose labels or artworks compliant with Codex Stan 181-1991. | |
| | HRJ. BOTTLED WATER<br>• 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.<br>• 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<br>• Shelf life study with stability data based on Administrative Order 2014-0029.<br>• Certificate of Analysis of the physico-chemical and microbiological parameters of the finished product based on Administrative Order 2014-0029.<br>• 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.
- 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.*

HRK2. HERBS AND BOTANICALS AND/OR PRODUCTS WITH OTHER NUTRITIONAL SUBSTANCES AS

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| CONVENTIONAL FOOD PRODUCT<br>• 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.<br>● Certificate of Analysis for Microbiological parameters for Powdered Beverages: SPC/APC cfu/g & Coliforms cfu/g. | |

## II. TITLE OF CERTIFICATION/PERMIT: CERTIFICATE OF PRODUCT REGISTRATION (CPR) – AMENDMENT (INITIAL APPLICATION APPROVED VIA E-REGISTRATION)

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| **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).<br><br>Change or Extension of Shelf-life: Php 1,000.00 + 1% LRF<br>Other Types of Amendment: Php 200.00 + 1% LRF |

| CHECKLIST OF REQUIREMENTS | WHERE TO SECURE |
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| *1. Submit one (1) scanned copy of the required document in the e-Registration Portal*<br>*2. Product labels and pictures of the product in commercial presentation for upload should be scanned in 200-dpi setting*<br>*3. Documents for upload should be scanned in 150-dpi setting*<br>*4. 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* | |
| 1) . General Requirements based on Administrative Order No. 2014-0029<br><br>● Accomplished Initial Application Form as prescribed by FDA regulations (e-Registration e-Portal, refer to FDA Circular 2016-014).<br>● Proof of Payment of Fees as prescribed by current FDA regulations (A.O. 50 s. 2001).<br><br>● Scanned Application Letter stating the intended changes (indicate changes/amendments to be made) | FDA Website (www.fda.gov.ph)<br><br>FDA Cashier/Other FDA Authorized Payment Portals or Banks<br><br>Applicant Company |
| 2) Additional Requirements per Amendment Type based on Administrative Order No. 2014-0029 | 1) Applicant Company/ Manufacturer/Source/Supplier |

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| 2a. Change in Brand Name<br>• Clear and complete loose labels or artworks reflecting the change, as applicable, of all packaging sizes, or equivalents as defined by FDA regulations<br>• Authority from the source or the owner of the brand (if imported)<br>• IPO registration, if available | 2) For the Certificate of Analysis:<br>a) Applicant Company/ Manufacturer/Source/Supplier; or<br>b) Laboratory analysis issued/conducted by FDA accredited laboratories. |
| 2b. Change in Product Name<br>• Clear and complete loose labels or artworks reflecting the change, as applicable, of all packaging sizes, or equivalents as defined by FDA regulations | |
| 2c. Change in Company Name/Business Name<br>• Proof of change in business name (e.g. License to Operate)<br>• Clear and complete loose labels or artworks reflecting the change, as applicable, of all packaging sizes, or equivalents as defined by FDA regulations | |
| 2d. Change in Supplier Details<br>• Any of the following scanned copy of the original documents: Foreign Agency Agreement or Certificate of Distributorship or Appointment letter or Proforma Invoice or Memorandum of Agreement from the new supplier. | |
| 2e. Change in Packaging Material and/or Additional Packaging Type<br>• Clear and complete proposed loose labels or artworks, as applicable, of all packaging sizes, or equivalents as defined by FDA regulations<br>• 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.<br>• 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)<br>• 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 | |

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| • Stability study results with conclusion to support extension or change in shelf-life | |
| 2h. Change in/Additional Packaging design<br>• 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<br>• Proof of Agreement between previous and current owners of the product transferring ownership<br>• Clear and complete loose labels or artworks, as applicable, of all packaging sizes, or equivalents, reflecting the change/s, as defined by FDA Regulations<br>• Proof of cancellation of the previously issued FR No. under the E-portal account of previous owner. | |
| 2j. Change in Importer/Distributor<br>• Termination of agreement/Deed of assignment<br>• Agreement of new manufacturer/importer/distributor or Appointment letter<br>• Clear and complete loose labels or artworks, as applicable, of all packaging sizes, or equivalents, reflecting the change/s, as defined by FDA Regulations<br>• Proof of cancellation of the previously issued FR No. under the E-portal account of previous owner. | |
| 2k. Change in Company Address/Business Address (Not Applicable to Manufacturer and Repacker)<br>• Proof of change in business name (e.g. License to Operate)<br>• 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<br>• Copy of updated License to Operate | |
| 2m. Change in Product Specification<br>• Copy of updated Product Specification Sheet | |
| 2n. Change in Lot Code and Interpretation<br>• Copy of updated Product Specification Sheet<br>• Clear and complete loose labels or artworks reflecting the change, as applicable, of all | |

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| packaging sizes, or equivalents as defined by FDA regulations | |
| 2o. Exportation of Previously Registered Product Initially for Local Distribution.<br>• Clear and complete loose labels or artworks as applicable, of all packaging sizes, or equivalents as defined by FDA regulations (if the label is different from the approved one). | |

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

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| **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 with Administrative Order 50 s. 2001 + Legal Research Fee (LRF).<br><br>Conventional Food (Category 1): Php 1,000.00/5 years of validity + 1% LRF<br>Conventional Food (Category 2): Php 1,250.00/5 year of validity + 1% LRF<br>Food Supplement: Php 5,000.00/5 years of validity + 1% LRF<br>Bottled Water: Php 5,000.00/5 years of validity + 1% LRF |

| CHECKLIST OF REQUIREMENTS | WHERE TO SECURE |
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| 1) Accomplished Application Form as prescribed by FDA regulations. Select "RENEWAL" as type of application using the same case number used in initial application in the e-Registration Portal. | FDA Website (www.fda.gov.ph) |
| 2) Proof of payment of fees as prescribed by current FDA regulations (AO 50 s. 2001). | FDA Cashier/Other FDA Authorized Payment Portals or Banks |

IV. **TITLE OF CERTIFICATION/PERMIT: CERTIFICATE OF PRODUCT REGISTRATION (CPR)** – RE-APPLICATION (INITIAL APPLICATION DISAPPROVED VIA E-REGISTRATION)

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| **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 with Administrative Order 50 s. 2001 + Legal Research Fee (LRF).<br><br>Re-application Fee PhP 200.00 + 1% LRF |

| CHECKLIST OF REQUIREMENTS | WHERE TO SECURE |
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| *1. Submit one (1) scanned copy of the required document in the e-Registration Portal*<br>*2. Product labels and pictures of the product in commercial presentation for upload should be scanned in 200-dpi setting*<br>*3. Documents for upload should be scanned in 150-dpi setting*<br>*4. 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* | |
| 1. Accomplished Application Form as prescribed by FDA regulations.<br><br>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 & FDA Circular 2016-014). | FDA Website (www.fda.gov.ph)<br><br>1) For the Certificate of Analysis:<br>a) Applicant Company/ Manufacturer/Source/Supplier; or<br>b) Laboratory analysis issued/conducted by FDA accredited laboratories.<br><br>2) For other technical document(s):<br>a) Applicant Company/ Manufacturer/Source/Supplier |
| 2. Proof of Payment of Fees as prescribed by current FDA regulations. (Administrative Order 50 s. 2001) | FDA Cashier/Other FDA Authorized Payment Portals or Banks |

## V. 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 with Administrative Order 50 s. 2001 + Legal Research Fee (LRF).<br><br>Conventional Food (Category 1): Php 200.00/year of validity + 1% LRF<br>Conventional Food (Category 2): Php 250.00/year of validity + 1% LRF<br>Food Supplement: Php 1,000.00/year of validity + 1% LRF<br>Bottled Water: Php 1,000.00/year of validity + 1% LRF |

| CHECKLIST OF REQUIREMENTS | WHERE TO SECURE |
|---|---|
| 1) I. Basic Requirements based on Administrative Order 2014-0029:<br><br>• Accomplished Initial Application Form as prescribed by FDA regulations (e-Registration e-Portal, refer to FDA Circular 2016-014). | FDA Website (www.fda.gov.ph) |

<table>
<tr><td>

• Proof of Payment of Fees as prescribed by current FDA regulations (A.O. 50 s. 2001).

• Loose label/artwork/picture of the product complaint with the existing regulations of the importing country.
• For food supplement, a sample in actual commercial presentation shall be submitted.

</td><td>FDA Cashier/Other FDA Authorized Payment Portals or Banks<br><br>Applicant Company/ Manufacturer/Source/Supplier</td></tr>
<tr><td>2) 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).</td><td>Applicant Company/ Manufacturer/Source/Supplier</td></tr>
<tr><td>3) Scanned copy of any of the following: Request for Quotation or valid notarized agreement signed by importing and exporting parties whichever is applicable, as supporting documents that the product is for the export market.</td><td>Buyer/Recipient</td></tr>
<tr><td>4) ADDITIONAL REQUIREMENTS PER FOOD CATEGORY<br><br>1. <u>MEDIUM-RISK FOOD PRODUCTS</u><br><br>
<table>
<tr><td>MRA1a. CONDENSED MILK<br>• 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<br>• 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<br>• 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</td></tr>
</table>
</td><td>For the Certificate of Analysis:<br>1) Applicant Company/ Manufacturer/Source/Supplier; or<br>2) Laboratory analysis issued/conducted by FDA accredited laboratories.<br><br>For other technical document(s):<br>1) Applicant Company/ Manufacturer/Source/Supplier</td></tr>
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| | than 36 months of age and adults): Salmonella/25g, SPC/APC cfu/g & Enterobacteriaceae cfu/g based on FDA Circular 2013-010. | |
| | MRB2. EDIBLE ICES (POPSICLES)<br>• 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. | |
| | MRC2. FROZEN FRUITS<br>• 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<br>• 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<br>• 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<br>• Certificate of Analysis for Microbiological parameters for Cocoa Powder: Molds cfu/g, Salmonella/25g, Coliforms cfu/g & SPC/APC cfu/g based on FDA Circular 2013-010. | |
| | MRD. CHOCOLATE PRODUCTS<br>• Certificate of Analysis for Microbiological parameters for Chocolate Products: Molds cfu/g, Salmonella/25g, Coliforms cfu/g & SPC/APC cfu/g based on FDA Circular 2013-010. | |
| | MRF1Ai. CURED (INCLUDING SALTED) NON-HEAT TREATED PROCESSED MEAT, POULTRY AND GAME PRODUCTS<br>• 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.<br>• Certificate of Analysis for | |

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| | 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<br>• 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<br>• 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<br>• 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<br>• 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<br>• 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)<br>• Certificate of Analysis for Microbiological parameters for Salad Dressing: SPC/APC cfu/g, YMC cfu/g, Salmonella/25g & Listeria | |

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| | monocytogenes/25g based on FDA Circular 2013-010. | |
| | MRL1a. FRUIT AND VEGETABLE JUICES<br>• 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<br>• 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<br>• 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<br>• 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<br>• 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<br>• 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<br>• Shelf life study with stability data based on Administrative Order 2014-0029.<br>• 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.<br>• 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 **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.*

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.

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| | HRA1b. DAIRY-BASED DRINKS, FLAVORED AND/OR FERMENTED<br>• Certificate of Analysis for Microbiological parameters for Liquid Milk (evaporated & ready to drink)-UHT/Sterilized: Commercial Sterility based on FDA Circular 2013-010.<br>• 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.<br>• 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<br>• 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)<br>• Certificate of Analysis for Microbiological parameters for Cream (UHT/Sterilized): Commercial Sterility based on FDA Circular 2013-010. | |
| | HRA4a. UNRIPENED CHEESE<br>• 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.<br>• 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<br>• 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. | |

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| | HRA4di. FLAVORED PROCESSED CHEESE<br>• 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)<br>• 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<br>• 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.<br>• 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<br>• 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<br>• Certificate of Analysis for Microbiological parameters for Dried Vegetable: E. coli MPN/g based on FDA Circular 2013-010. | |
| | HRD. CHOCOLATE WITH NUTS<br>• Certificate of Analysis for Microbiological parameters for Chocolate Products: Molds cfu/g, Salmonella/25g, Coliforms cfu/g & SPC/APC cfu/g based on FDA Circular 2013-010. | |
| | HRF1. FINE BAKERY PRODUCTS WITH FILLINGS<br>• 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 | |

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| | cfu/g & Coliforms cfu/g) based on FDA Circular 2013-010.<br>• 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)<br>• 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)<br>• 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<br>• 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<br>• 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<br>• 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 | |

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| | FISH PRODUCTS<br>• 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))<br>• 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<br>• 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)<br>• 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 PURPOSES INTENDED FOR INFANTS (LIQUID)<br>• 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<br>• 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<br>• Certificate of Analysis for Microbiological parameters for Cereal-based Foods for Infants: Bacillus cereus cfu/g, Clostridium perfringes | |

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| | cfu/g, SPC/APC cfu/g, Salmonella/25g & Coliforms MPN/g based on FDA Circular 2013-010. | |
| | HRJ2. CANNED BABY FOODS<br>• 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<br>• Shelf life study with stability data based on Administrative Order 2014-0029.<br>• Certificate of Analysis of the physico-chemical and microbiological parameters of the finished product based on Administrative Order 2014-0029.<br>• For Dried Plants: Certificate of Analysis for Heavy Metals in the finished product based on Administrative Order 184 s. 2004.<br>• 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.<br>• Sample in actual commercial presentation based on Administrative Order 2014-0029.<br><br>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:<br><br>i. Personal Delivery to FDAC, Starmall, Alabang, Muntinlupa City or<br><br>ii. Delivery via registered courier that must contain the following information:<br><br>**TO:**<br>FOOD AND DRUG ACTION CENTER (FDAC)<br>3rd Floor Starmall, Alabang, Muntinlupa City | |

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| | | **FROM:** Company's complete name & address<br><br>**SUBJECT:** Food Product E-Registration Application (Case No.)<br><br>*The proof of submission of sample (Acknowledgement Receipt from FDAC or Receipt from Registered Courier) shall be uploaded together with the other documentary requirements.* | |
| | | HRK2. HERBS AND BOTANICALS AND/OR PRODUCTS WITH OTHER NUTRITIONAL SUBSTANCES AS CONVENTIONAL FOOD PRODUCT<br>• 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.<br>• Certificate of Analysis for Microbiological parameters for Powdered Beverages: SPC/APC cfu/g & Coliforms cfu/g. | |