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 GUIDELINES

Please refer to:

1) A. General Guidelines, B. Specific Guidelines, and C. Procedural Guidelines, IV. GUIDELINES, pages 2-10 of FDA Circular No. 2020-033 || Procedure for the Use of the Modified Electronic Registration System for Raw Materials and Prepackaged Processed Food Products Repealing FDA Circular No. 2016-014 "Procedure for the Use of Electronic Registration System for Prepackaged Processed Food Products"; and

2) III. General Guidelines, and IV. Specific Guidelines of FDA Circular No. 2020-033-A || Addendum to FDA Circular No. 2020-033, "Procedure for the Use of the Modified Electronic Registration System for Raw Materials and Prepackaged Processed Food Products Repealing FDA Circular No. 2016-014 "Procedure for the Use of Electronic Registration System for Prepackaged Processed Food Products" to include Guidelines for Pre-assessment and Reiteration of Pre-Assessment Procedures in Applying for Certificate of Product Registration for Food

CHECKLIST OF REQUIREMENTS FOR ALL TYPES OF FOOD PRODUCTS/FOOD CATEGORIZATION: RAW MATERIALS, LOW RISK, MEDIUM RISK AND HIGH RISK FOOD PRODUCTS

GENERAL REQUIREMENTS	BASIS/ISSUANCE	WHERE TO SECURE
☑ Accomplished Application Form as prescribed by FDA regulations e.g. E-Registration System	Administrative No. Order 2014-0029	FDA Website
☑ Proof of Payment of Fees as prescribed by current FDA regulations.	Administrative Order 50 s. 2001	Systems/Means prescribed by FDA

☑ Scanned Application Letter stating the intended changes (indicate ALL the changes/amendments to be made)	Administrative No. Order 2014-0029 FDA Circular No. 2020-033	Applicant Company
☑ Valid and appropriate FDA License to Operate (required for all types of CPR application)	Administrative No. Order 2014-0029 Republic Act 9711	FDA Philippines

ADDITIONAL Requirements per Amendment Type			
AMENDMENT TYPE	**☑ ADDITIONAL REQUIREMENTS**	**BASIS**	**WHERE TO SECURE**
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.	Administrative No. Order 2014-0029 FDA Circular No. 2020-033	Applicant Company Source/Supplier/Brand Owner IPO/Source/ Supplier
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	Administrative No. Order 2014-0029 FDA Circular No. 2020-033	Applicant Company/ Source/Supplier
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	Administrative No. Order 2014-0029 FDA Circular No. 2020-033	Applicant Company/ Source/Supplier
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 or Proforma Invoice or Memorandum of Agreement from the new supplier.	Administrative No. Order 2014-0029 FDA Circular No. 2020-033	Applicant Company/ Source/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.	Administrative No. Order 2014-0029 FDA Circular No. 2020-033	Applicant Company/ Source/Supplier
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	Administrative No. Order 2014-0029 FDA Circular No. 2020-033	Applicant Company/ Source/Supplier
2g. Change or Extension in Shelf-Life	☑ Stability study results with conclusion to support extension or change in shelf-life	Administrative No. Order 2014-0029 FDA Circular No. 2020-033	Applicant Company/ Source/Supplier
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	Administrative No. Order 2014-0029 FDA Circular No. 2020-033	Applicant Company/ Source/Supplier
***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.)	Administrative No. Order 2014-0029 FDA Circular No. 2020-033	Applicant Company/ Source/Supplier
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.	Administrative No. Order 2014-0029 FDA Circular No. 2020-033	Applicant Company/ Source/Supplier
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.	Administrative No. Order 2014-0029 FDA Circular No. 2020-033	Applicant Company/ Source/Supplier

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.	Administrative No. Order 2014-0029 FDA Circular No. 2020-033	Applicant Company/ Source/Supplier
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).	Administrative No. Order 2014-0029 FDA Circular No. 2020-033	Applicant Company/ Source/Supplier
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.	Administrative No. Order 2014-0029 FDA Circular No. 2020-033	Applicant Company/ Source/Supplier
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.	Administrative No. Order 2014-0029 FDA Circular No. 2020-033	Applicant Company/ Source/Supplier
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	Administrative No. Order 2014-0029 FDA Circular No. 2020-033	Applicant Company/ Source/Supplier
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	Administrative No. Order 2014-0029 FDA Circular No. 2020-033	Applicant Company/ Source/Supplier

	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.	Administrative No. Order 2014-0029 FDA Circular No. 2020-033	Applicant Company/ Source/Supplier
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.	Administrative No. Order 2014-0029 FDA Circular No. 2020-033	Applicant Company/ Source/Supplier
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.	Administrative No. Order 2014-0029 FDA Circular No. 2020-033	Applicant Company/ Source/Supplier
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	Administrative No. Order 2014-0029 FDA Circular No. 2020-033	Applicant Company/ Source/Supplier

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	Administrative No. Order 2014-0029 FDA Circular No. 2020-033	Applicant Company/ Source/Supplier
2k. 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	Administrative No. Order 2014-0029 FDA Circular No. 2020-033	Applicant Company/ Source/Supplier
2l. 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	Administrative No. Order 2014-0029 FDA Circular No. 2020-033	Applicant Company/ Source/Supplier
2m. Change in LTO Number and/or LTO Validity	☑ Copy of updated License to Operate	Administrative No. Order 2014-0029 FDA Circular No. 2020-033	Applicant Company/ Source/Supplier
2n. 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	Administrative No. Order 2014-0029 FDA Circular No. 2020-033	Applicant Company/ Source/Supplier

2o. 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	Administrative No. Order 2014-0029 FDA Circular No. 2020-033	Applicant Company/ Source/Supplier

CLIENT STEPS	AGENCY ACTION	PROCESSING TIME	PERSON RESPONSIBLE
1)The authorized representative of the applicant company double clicks on the specific product/CASE NUMBER in the INBOX folder, accomplishes (including uploading of the COMPLETE documentary requirements) the E-Registration System through the E-Portal https://eportal.fda.gov.ph based on the desired type of application in accordance to current FDA regulation/s on the use of the E-Registration Portal/E-Services. The client shall forward the application to **PRE-ASSESSMENT**. A system generated E-mail notification from FDA will be received by the client upon submission of application for Pre-Assessment.	1) **PRE-ASSESSMENT** FDA Personnel will pre-assess ONLY the completeness of the submitted documents through E-Registration System/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 E-Registration System INBOX. The client may refile by proceeding as stated on **CLIENT STEPS: 1)**.	Day 0	Center for Food Regulation and Research (CFRR) PRE-ASSESSOR (e.g. Food-Drug Regulation Officer (FDRO))

(PRE-ASSESSMENT: COMPLETE) 2) The applicant company receives the Order of Payment		Day 0	
3) The applicant company pays the assessed fee through Systems/Means prescribed by FDA	2) **POSTING** of payment FDA Cashier receives the payment/Official Receipt (OR)/ proof of payment through Systems/Means prescribed by FDA, and then post the payment. The application will then be forwarded to CFRR, **once payment is posted**.	Day 0 ***Refer to FDA Cashier 's Citizen Charter***	Administrative and Finance Services (AFS) STAFF
4) The applicant company receives Acknowledgement Receipt with the application and pre-assessment details.		Day 0	
	3) **EVALUATION** The CFRR-Licensing and Registration Division (LRD) Technical Personnel will evaluate the application and ALL the submitted documentary requirements in accordance to existing FDA regulation/s and Quality Work/Standard Procedures. The CFRR-LRD Technical Personnel will then draft recommendation if the application is for Approval or Disapproval, then will forward the same to the CHECKER.	8 Working Days (Days 1-8)	LRD EVALUATOR (e.g. FDRO)
	4) **CHECKING or Quality Assurance (QA)** The CFRR-LRD Technical Personnel will review the evaluated application, ALL the submitted documentary requirements, and the drafted recommendation of the EVALUATOR, in accordance to existing FDA regulation/s and Quality Work/Standard Procedures.	7 Working Days (Days 9-15)	LRD CHECKER (e.g. SENIOR FDRO or SUPERVISOR or DIVISION CHIEF)

	The CFRR-LRD Technical Personnel will then draft recommendation if the application is for Approval or Disapproval, then will forward the same to the APPROVING AUTHORITY.		
	5) **FINAL DECISION** The CFRR Approving Authority will review the checked application, ALL the submitted documentary requirements, and the drafted recommendation of the CHECKER, in accordance to existing FDA regulation/s and Quality Work/Standard Procedures. The CFRR Approving Authority will then finalizes the application by issuing **Certificate of Product Registration (CPR) (for APPROVED application)** or **Letter of Denial (LOD) (for DISAPPROVED application)**, through the E-Registration System.	5 Working Days (Days 16-20)	CFRR APPROVING AUTHORITY (e.g. DIRECTOR IV)
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) **GENERATION OF RESULT OF APPLICATION** The E-Registration System generates electronically signed CPR or LOD.		Information and Communication Technology Management Division (ICTMD) STAFF
		TOTAL: 20 Working Days	
Always refer to the current FDA regulation/s on the use of the E-Registration System/E-Services: FDA Website			
Please be advised that as per RA No.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.***			