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

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

GENERAL 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 current regulations. Through the E-Registration System, upload/attach the compliance to the deficiencies stated in the previously issued Letter of Denial	FDA Circular No.2020-033 FDA Circular No.2020-033-A Administrative No. Order 2014-0029	FDA Website 1) For the Certificate of Analysis: a) Applicant Company/ Manufacturer/Source/Supplier; or b) Laboratory analysis issued/conducted by FDA accredited laboratories.

(LOD) within 6 months upon receipt of LOD, using the same case number.		2) For other technical document(s): a) Applicant Company/ Manufacturer/Source/Supplier
☑ Proof of payment of fees as prescribed by current FDA regulations.	Administrative Order 50 s. 2001	Systems/Means prescribed by FDA
☑ Valid and appropriate FDA License to Operate (required for all types of CPR application)	Administrative No. Order 2014-0029 Republic Act No. 9711	FDA Philippines

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. The CFRR-LRD Technical Personnel will then draft	7 Working Days (Days 9-15)	LRD CHECKER (e.g. SENIOR FDRO or SUPERVISOR or DIVISION CHIEF)

	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.***			