



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

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

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

GENERAL 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
<input checked="" type="checkbox"/> Accomplished Application Form as prescribed by FDA regulations. e.g. E-Registration System.	FDA Circular No.2020-033 FDA Circular No. 2020-033-A	FDA Website
<input checked="" type="checkbox"/> Proof of payment of fees as prescribed by current FDA regulations	Administrative Order 50 s. 2001	Systems/Mean prescribed by FDA
<input checked="" type="checkbox"/> Valid and appropriate FDA License to Operate (required for all types of CPR application)	Administrative No. Order 2014-0029 Republic Act No. 9711	FDA
<input checked="" type="checkbox"/> A sworn statement indicating no change in or variation whatsoever in the product is attached to the application.	Implementing Rules and Regulations of Republic Act No. 9711	Applicant Company
<input checked="" type="checkbox"/> Upload ALL INITIAL requirements.	Administrative No. Order 2014-0029 FDA Circular No. 2020-033	Applicant Company/ In reference to the previously filed and approved INITIAL application (The validity of the documents to be submitted must be in accordance to current FDA regulation/s).

CLIENT STEPS	AGENCY ACTION	PROCESSING TIME	PERSON RESPONSIBLE
<p>1)The authorized representative of the applicant company 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.</p> <p>The client shall forward the application to PRE-ASSESSMENT.</p>	<p>1) PRE-ASSESSMENT</p> <p>FDA Personnel will pre-assess ONLY the completeness of the submitted documents through E-Registration System/E-Portal https://eportal.fda.gov.ph.</p> <p>Result of Pre-assessment will be received by the account holder.</p> <p>If found COMPLETE, an Order of Payment will be automatically generated and will be sent to the email of the account holder/client.</p>	Day 0	Center for Food Regulation and Research (CFRR) PRE-ASSESSOR (e.g. Food-Drug Regulation Officer (FDRO))



<p>A system generated E-mail notification from FDA will be received by the client upon submission of application for Pre-Assessment.</p>	<p>If found INCOMPLETE, a notification with result of Pre-Assessment from FDA will be received. To refile, the applicant must start a NEW CASE and upload initially submitted documentary requirements together with the documents for compliance to the deficiencies mentioned. <i>For Food Supplement application, the proof of submission of sample can be re-uploaded to the new application.</i></p>		
<p>(PRE-ASSESSMENT: COMPLETE) 2) The applicant company receives the Order of Payment</p>		<p>Day 0</p>	
<p>3) The applicant company pays the assessed fee through Systems/Mean prescribed by FDA</p>	<p>2) POSTING of payment</p> <p>FDA Cashier receives the payment/Official Receipt (OR)/ proof of payment through Systems/Mean prescribed by FDA, and then post the payment.</p> <p>The application will then be forwarded to CFRR, once payment is posted.</p>	<p>Day 0 Refer to FDA Cashier's Citizen Charter</p>	<p>Administrative and Finance Services (AFS) STAFF</p>
<p>4) The applicant company receives Acknowledgement Receipt with the application and pre-assessment details.</p>		<p>Day 0</p>	
	<p>3) EVALUATION</p> <p>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.</p> <p>The CFRR-LRD Technical Personnel will then draft</p>	<p>3 Working Days (Days 1-3)</p>	<p>LRD EVALUATOR (e.g. FDRO)</p>



	<p>recommendation if the application is for Approval or Disapproval, then will forward the same to the CHECKER.</p>		
	<p>4) CHECKING or Quality Assurance (QA)</p> <p>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.</p> <p>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.</p>	<p>2 Working Days (Days 4-5)</p>	<p>LRD CHECKER (e.g. SENIOR FDRO or SUPERVISOR or DIVISION CHIEF)</p>
	<p>5) FINAL DECISION</p> <p>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.</p> <p>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.</p>	<p>2 Working Days (Days 6-7)</p>	<p>CFRR APPROVING AUTHORITY (e.g. DIRECTOR IV)</p>
<p>5) If the application is APPROVED, an e-mail notification from FDA regarding the issuance of Certificate of Product Registration (CPR) will be received.</p> <p>If DISAPPROVED, an e-mail notification from</p>	<p>6) GENERATION OF RESULT OF APPLICATION</p> <p>The E-Registration System generates electronically signed CPR or LOD.</p>		<p>Information and Communication Technology Management Division (ICTMD) STAFF</p>



<p>FDA regarding the issuance of Letter of Denial/Disapproval (LOD) will be received.</p> <p>For Amendment:</p> <p>If the application is approved, the applicant company will receive an e-mail notification from FDA indicating that the application is approved (this includes those amendments with multiple applications with approved and disapproved results) and another e-mail notification containing the Amendment Decision Summary Table.</p> <p>If disapproved, a Letter of Denial/Disapproval (LOD) and another e-mail notification containing the Amendment Decision Summary Table will be received.</p>			
		<p>TOTAL: 7 Working Days</p>	
<p>Always refer to the current FDA regulation/s on the use of the E-Registration System/E-Services: FDA Website</p> <p>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.</p>			