Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA CIRCULAR
No. 2020-033-A

11 MAR 2021

SUBJECT: **Addendum to FDA Circular 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**

I. Background/Rationale

FDA Circular No. 2020-033, or the 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" was issued on 26 February 2021 to enhance specific features of the E-Registration system and improve the process of application and issuance of Certificate of Product Registration (CPR) for Food to comply with the provisions of Republic Act No. 11032 otherwise known as the "Ease of Doing Business and Efficient Government Service Delivery Act of 2018

Moreover, Rule VII, Section 2 B of the implementing Rules and Regulations of RA 11032 Acceptance of Application states, "The government office of agency shall not process deficient or incomplete applications or request, and shall only process an application or request if it is complete. In case the application or request is deficient, the processing time as provided in this Act and these Rules shall only commence once the application or requesting party has rectified the deficiency, all applications for processed food product registration shall undergo pre-assessment. Thus, the following guidelines in the pre-assessment stage of processed food product applications for registration are issued to serve as reference to all stakeholders.

II. Objectives

This Circular aims to provide detailed guidelines and reiterates pre-assessment procedures in applying for Certificate of Product Registration (CPR) for Food in line with FDA Circular 2020-033.

III. General Guidelines

1. The pre-assessment of an application shall only cover the determination of the completeness of the uploaded documentary requirements based on the new Center for Food Regulation and Research (CFRR) Citizen's Charter posted on the FDA website (www.fda.gov.ph).

2. An application that has been pre-assessed and furnished with a system-generated email notification of complete requirements for registration does not preclude disapproval nor guaranties approval or issuance of Certificate of Product Registration. The quality, correctness and substance of the documentary requirements shall be assessed during the actual evaluation after posting of payment based on the new FDA Citizen's Charter.

3. The processing time of twenty (20) working days shall commence after receipt of the complete application, following a successful pre-assessment.

IV. Specific Guidelines

A. Procedure for the submission of an application

1. Client shall fill out all required information completely and accurately in the E-Registration Portal Version 2 [https://eportal.fda.gov.ph], while diligently ensuring the correct/appropriate type of application (Initial, Amendment, Automatic Renewal, Reapplication, For Export Market Only) based on 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".

2. Client shall upload the complete documentary requirements after providing all necessary information on the e-Registration System Version 2 using the filename Name of Document Case Number (eg. Label_123456 or Certificate of Free Sale_123456).The size of total attachments is 25mb only with a limit of 2mb per document in .pdf or .png file format (200dpi and 150 dpi setting for labels and scanned documents, respectively).

3. Client shall forward the application to pre-assessment once all information and documentary requirements are provided to the e-Registration portal Version 2. A system-generated notification acknowledging its receipt shall be sent to the Applicant Company's registered official email address upon submission of the application for pre-assessment.

B. Criteria to determine if an application has complete requirements

An approved pre-assessment does not automatically mean that the product will be issued a CPR. A pre-assessed food product application for registration could be approved only if it conforms to all of following requirements:

1. Correct e-portal account consistent with the applicant company
2. Valid License to Operate (LTO). A valid LTO and approved product line is a pre-requisite to food product registration. For locally manufactured products, the product being applied should be included in the list of products and/or product line in the LTO. If there is an existing application for LTO variation to include product line, the applicant company should wait for its approval before proceeding to submit application for pre-assessment. Otherwise, this will be a ground for denial of the application.
3. Clear, valid and readable uploaded documents with integrity
4. Accurate and complete data entry declaration consistent with uploaded documents

5. Compliance of the product being applied with requirements as stipulated in the new CFRR Citizen's Charter based on existing rules and regulation (FDA Circular 2020-033; AO 2014-0029, FDA Circular 2013-010, AO 2014-0030, AO 88-a s. 1984, BC 2006-016, BC 2007-002), standards of identity based on FDA regulations, and all other applicable existing regulations. Refer to Annex D FDA Circular 2020-033 to determine if a particular documentary requirement conforms to FDA regulations.

C. Pre-assessment Stage

1. Successful pre-assessed application with complete documents

a. If the pre-assessed application is satisfactory based on completeness of uploaded documentary requirements, the official applicant company representative shall receive system-generated approved pre-assessment with Order of Payment thru its registered official email address. The applicant shall pay the corresponding assessed fee either through the BancNet online payment gateway or Link.Biz portal payment channel following the procedure per FDA Circular No. 2017-010, FDA Advisory 2021-046 or any applicable payment system prescribed by the FDA.

b. FDA Cashier will receive the payment/Official receipt/proof of payment of the transaction, and then post the payment accordingly. The official applicant company representative will also receive an Acknowledgement receipt with the application and pre-assessment details.

c. The e-registration system will forward the application to CFRR once payment is posted by the FDA Cashier. The next process of the application is evaluation, checking, final decision/issuance and generation of the electronically signed Certificate of Product Registration (CPR) or Letter of Denial (LOD).

2. Pre-assessed application with incomplete documents

a. If the pre-assessed application has incomplete uploaded documentary requirements, the official applicant company representative shall receive a downloadable system-generated result of pre-assessment indicating deficient requirements for registration thru its registered official email address.

b. No pre-assessed application with incomplete requirements will proceed to "payment" and "evaluation".

c. The case number of a pre-assessed application with incomplete requirements is considered "closed" prompting the applicant company representative to create a new case for the application. Note that previously submitted documentary requirements together with lacking documents during the pre-assessment shall be re-uploaded in the new application.

d. For Food Supplement, the proof of submission of a product sample in commercial presentation can be re-uploaded to the new application. The new application is subject for final pre-assessment.

e. It is important that the official applicant company representative will upload complete requirements to save time and ensure that the

application will proceed to payment once pre-assessed.

V. Separability Clause

If any provision of this Circular be declared as invalid or unenforceable, the validity and enforceability of the remaining portions or provisions shall remain in full force and in effect.

VI. Repealing Clause

Any issuance inconsistent with this Circular are hereby repealed and/or modified accordingly.

VII. Transitory Provisions

Starting 08 March 2021, the new E-Registration System shall be accessible for applications for registration of all pre-packaged processed food products and the old electronic registration portal can no longer be used to apply for food product registration.

VIII. Effectivity

The electronic registration of all prepackaged processed food products using the new and improved E-Registration System using e-portal Version 2 shall be fully implemented starting 08 March 2021.

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