Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA CIRCULAR
No. 2020-033-B

31 MAR 2023

SUBJECT : **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 Process Steps for the Correction of Certificate of Product Registration, Additional Guidelines in Accomplishing Online Application Form, To include the requirements stipulated in FC No. 2021-028, and Express Repeal of Relevant FDA Issuances for this Purpose."**

I. RATIONALE

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", there is a need to amend 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", to include process steps for the correction of Certificate of Product Registration (CPR), additional guidelines in accomplishing online application form, to include the requirements stipulated in FC No. 2021-028, and express repeal of relevant FDA issuances for this purpose.

II. OBJECTIVES

This Circular aims to:

A. Include information for sweetened beverages, HALAL or Organic products, with front of pack labeling, and with Sangkap Pinoy Seal (SPS), Diamond Sangkap Pinoy Seal (DSPS) or Saktong Iodine sa Asin (SISA) Seal in accomplishing the electronic registration application;

B. Include certain provisions stipulated in FC No. 2021-028 relative to food products containing Trans Fatty Acids (TFA); and

C. Include procedural guidelines for the correction and cancellation of CPR.

III. SCOPE

This Circular shall cover all initial application, renewal, reapplication, and amendment registration of prepackaged processed food products (raw materials or ingredients, low risk, medium risk, and high risk).

IV. DEFINITION OF TERMS

A. **Diamond Sangkap Pinoy Seal (DSPS)** refers to the seal of good nutrition quality that will be awarded as an incentive to FDA registered staple manufacturers who will fortify their products according to standards.

B. **Sangkap Pinoy Seal Program (SPSP)** refers to a strategy to encourage food manufacturers to fortify processed foods or food products with essential nutrients at levels approved by the DOH. The fundamental concept of the program is to authorize food manufacturers to use the DOH seal of acceptance for processed foods or food products, after these products passed a set of defined criteria. The seal is a guide used by consumers in selecting nutritious foods.

C. **Saktong Iodine Sa Asin Seal (SISA)** is developed to strengthen and revitalize the existing DSPS used in the labels of iodized salt.

D. **Sweetened Beverage (SB)** refers to non-alcoholic beverages of any constitution (liquid, powder, or concentrates), containing caloric and/or non-caloric sweetener added by the manufacturer that shall include but not limited to the following, as described in the Food Category Descriptors (Codex Stan 192-1995 Rev 2017 or the latest) as adopted by the FDA:

1) Sweetened juice drinks;
2) Sweetened tea;
3) All carbonated beverages;
4) Flavored water;
5) Energy and sports drinks;
6) Other powdered drinks not classified as milk, juice, tea and coffee;
7) Cereal and grain beverages; and
8) Other non-alcoholic beverages that contain added sugar

E. **Trans-Fatty Acids (TFA)** refers to the fatty acids with at least a double bond in the trans configuration, regardless of whether they are produced industrially or come from ruminant sources, including linoleic acid.

V. GENERAL GUIDELINES

Under Section IV.C.2. Accomplishing E-Registration Applications is hereby amended to include the following provisions:

m. The applicant company shall declare the establishment's name and address, License to Operate (LTO) number and its validity, and the company activity as stated in the valid LTO certificate. Likewise, the complete name and address of the supplier (if not directly sourced from the manufacturer), manufacturer, toll manufacturer or repacker, and trader or wholesaler shall also be stated.

n. It shall be indicated if a sweetened beverage product is a reformulated version of an existing product which shall also reflect the Food Registration number of the previous formulation.

o. For Food Products with label claims on Halal or Organic, the name of the Certifying Body and its Certificate number shall be indicated and a scanned copy of the original issued certificate shall be uploaded.

p. Select "Yes" or "No" for products with declared "front of pack labeling (energy or calorie content)".

q. For products with SPS, DSPS or SISA on the label, a scanned copy of the issued original certificate shall be uploaded.

r. For Food Products with TFA-containing ingredients such as oils, fats and dairy products, the nutrition information (protein, carbohydrates including dietary fiber and sugar), fat including saturated fat, trans fat and cholesterol, sodium and energy value or calories shall be indicated to committedly update the monitoring and database of such products. Additional documentary requirements as specified in FC No. 2021-028 shall also be uploaded.

s. The trans-fat content of raw materials or ingredients such as for oils and fats shall be indicated. Documentary requirements as specified in FC No. 2021-028 shall also be uploaded.

Under Section IV.C.6. Procedural Guidelines is hereby amended to include the following provision:

g. Applications for CPR renewal shall be fully compliant to pertinent rules and regulation. All CPR remarks shall be complied through amendment prior to filing renewal applications.

Under Section IV.C. Procedural Guidelines is hereby amended to include the following provisions:

7. Correction of Certificate of Product Registration (CPR)

a. Correction of CPR shall only be applicable to products approved through E-Portal Version 2 with wrong CPR details caused after evaluation and/or with indicated remarks to surrender the original copy of printed CPR of previously approved products processed through the old portal. This shall be processed accordingly.

b. Prior to filing a request for correction of CPR through E-Portal Version 2, a copy of a letter request for CPR correction shall be submitted to the Food and Drug Action Center (FDAC) with attached previously issued CPR, if applicable.

c. To apply for the correction of CPR, the online portal through https://eportal.fda.gov.ph shall be accessed. The company-specific Username and Password shall be provided and the specific product in the Inbox tab shall be double-clicked.

d. The "CPR Correction" as the type of application from the drop-down menu after "Declaration" shall be selected.

e. The Document Tracking Number of the letter requesting CPR Correction shall be provided by the proponent. A copy of this letter may also be uploaded to E-Portal Version 2 for FDA's reference.

f. The application shall be forwarded to the "Checking" step.

g. If the request for correction of CPR is approved, a system-generated notification stating the approval of the request shall be sent to the applicant's registered e-mail. The corrected CPR through the Generated Documents tab in the application summary may be directly printed or can be accessed by opening the case number in the Inbox tab and click on "Open" to download the system-generated CPR.

h. If the request for correction of CPR is disapproved, a system-generated notification stating the reasons on "why changes in the CPR are not allowed" shall be sent to the applicant's registered e-mail. The notification may also be downloaded through the Generated Documents tab in the application summary.

8. Cancellation of CPR

a. Cancellation of CPR shall only be applicable to products approved through E-Portal Version 2. This shall be processed accordingly.

b. To apply for the cancellation of CPR, access the online portal through https://eportal.fda.gov.ph. The company-specific Username and Password shall be provided by the proponent. The specific product in the Inbox tab shall be selected.

c. The "CPR Cancellation" as the type of application shall be clicked from the drop-down menu after "declaration".

d. A scanned copy of original letter signed by the owner of the Market Authorization Holder (MAH) stating the reason for cancellation of CPR shall be uploaded.

e. The application shall be forwarded to the "Checking" step.

f. If the request for cancellation of CPR is approved, a system-generated notification stating the approval of the request shall be sent to the applicant's registered e-mail address. The cancelled case number shall be closed; hence, no succeeding applications shall be filed using the same case number.

g. If the request for cancellation of CPR is disapproved, a system-generated notification stating the reason "why the cancellation of CPR was not allowed" shall be sent to the applicant's e-mail address. The case number shall be sent back to the Inbox tab.

VI. 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 be in full force and in effect.

VII. REPEALING CLAUSE

The FDA Circular No. 2014-022 *"Notification of Registered Imported Wines with New Vintage"*; FDA Circular No. 2016-007 "*Notification of Sources for Raw Materials, Low Risk, Medium Risk and High Risk Prepackaged Processed Food Products*", and other FDA issuances inconsistent with this Circular are hereby repealed accordingly.

VIII. EFFECTIVITY

This Circular shall take effect fifteen (15) days after its publication in the Official Gazette or in any newspaper of general circulation and upon filing with the University of the Philippines Law Center Office of the National Administrative Register.

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Director General

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