FDA CIRCULAR
No. _____

TO : **ALL MANUFACTURERS/ TRADERS/ IMPORTERS OF HEATED TOBACCO PRODUCTS.**

SUBJECT : **APPLICATION PROCEDURE FOR PRODUCT MARKETING AUTHORIZATIONS THROUGH THE FDA ELECTRONIC PORTAL (E-PORTAL) SYSTEM.**

I. BACKGROUND

Pursuant to Republic Act No. 9711, otherwise known as the "FDA Act of 2009", Section 144 of Republic Act No. 11467, Section II of Executive Order No. 106 and consistent with the provision of Republic Act No. 11032, otherwise known as the "Ease of Doing Business and Efficient Government Service Delivery Act of 2018" on the development of electronic versions of licenses, clearances, permits, certifications, or authorizations promoting transparency and reducing red tape in business and non-business transactions in government, the FDA hereby implements this Circular for the issuance of product marketing authorization to all heated tobacco products (HTPs) by establishments with a valid FDA-issued electronic license to operate (e-LTO) using the FDA E-Portal System.

II. OBJECTIVE

The objective of this Circular is to provide the procedural guidelines and documentary requirements for the FDA product marketing authorization application through the FDA E-Portal System.

III. SCOPE AND COVERAGE

This Circular shall cover all manufacturers, traders, and importers of HTPs applying for product marketing authorizations under the Center for Cosmetics Regulation and Research.

IV. GENERAL GUIDELINES

1. Only those establishments with *valid* e-LTO as manufacturer, trader or importer can apply for product marketing authorizations.

2. Heated tobacco products (HTPs) not bearing and not marketed with therapeutic or health claims shall be registered per refill/cartridge-device combination (e.g. refill/cartridge variant 1 + device model 1) and shall be filed under a single application, with the issuance of an FDA Electronic Registration Number (FERN) after compliance to the set standards and requirements.

3. Identical products manufactured in different sites or imported by different companies shall be registered separately.

4. Applicants are required to provide true, correct, updated, and complete information pertaining to their type of application.

5. Submission of application shall be done using the FDA e-Portal system, accessible through https://eportal2.fda.gov.ph.

6. Documents uploaded to the system must conform to the following specifications:

    6.1. Documents must be in PDF file format and .png (for images), free from bugs, viruses, and the like that may jeopardize the system of the FDA.
    6.2. Documents must be scanned and saved in PDF file format at 100-150 dots-per-inch (dpi).
    6.3. Document filenames of documents shall be less than 40 characters in length, and shall not contain the following characters: \ ? / : * “ > < |.”

7. Incomplete and/or incorrect submissions shall immediately be disapproved.

8. No HTP refill and cartridges and refill/cartridge-device combinations shall be distributed or sold in the Philippines without the appropriate product marketing authorizations from the FDA.

V. SPECIFIC GUIDELINES

1. Procedural Guidelines for Product Marketing Authorization Application of HTPs

    1.1. Submission of Product Marketing Authorization Application

        1.1.1. Log-in by entering the issued username and password.
        1.1.2. On the home tab, under the navigation pane, select among the following options to proceed to the application form:
            1.1.2.1. FERN - HTP (Initial Registration Form)

1.1.3. The product marketing authorization application form is divided into several parts as provided by the application wizards. These include:

1.1.3.1. Declaration of Undertaking

1.1.3.2. Local Company Responsible for Placing the Product in the Market

1.1.3.3. Product Source

1.1.3.4. Particulars of the Product

1.1.3.5. Full Component Listing indicating the function of each component

1.1.3.6. Documentary Requirements (for uploading)

1.1.3.6.1 For FERN Applications:

1.1.3.6.1.1 Product Information File **(see Annex A)**

1.1.3.6.1.2 Pre-Application Documentary Evaluation (PADE) Certification *(see guidelines for the issuance of PADE certification)*

1.1.4. Accomplish the application form as provided in parts.

1.1.5. An application summary will appear to review the provided information and the attached documentary requirements.

1.1.6. Assessment slip will be generated at the end of the step.

1.1.6.1. The computer-generated assessment slip will be viewed through a flash window.

1.1.6.2. Print and download the file as reference for payment.

1.1.6.3. To continue with the application, click 'Next' to delegate the application to payment posting. The application will then move to the Processed folder in the navigation pane.

1.1.6.4. The status of the application may be checked in the Processed folder as indicated by the Task column.

1.1.7. To complete the application submission, the applicant must delegate the application to the FDA Cashier/Accounting.

1.2. Payment of Application

The application may be paid through any payment options made available by the FDA.

1.3. Results of Application

The result of the application may either be approved (issuance of an FDA product authorization certificate) or disapproved. The result of the application shall be downloaded from the On-Process folder of the applicant.

1.3.1. Open the case number of the application and a flash window reflecting the output document will appear.

1.3.2. Download and print the document and click 'Next' to end the task.

VI. PROCESSING TIME

Applications will be processed within twenty (20) working days. The timeline begins at the time the payment transaction reference number or the official receipt number has been verified by the FDA Accounting/Cashier, and ends at the time the result of the application has been forwarded to the On-Process folder of the applicant.

VII. FEES

Applications shall be charged with the fees pursuant to the schedule of fees stated under **Annex B** of this issuance.

VIII. EFFECTIVITY DATE

This Circular shall take effect 15 days after publication in a newspaper of general circulation and the Office of National Administrative Register of the UP Law Center.

IX. PENALTIES

Violation to any provisions of this Circular shall be subject to the penalties/sanctions provided under Book III, Article XI of the Rules and Regulations Implementing Republic Act No. 9711, The Food and Drug Administration Act of 2009, and other penalties provided by other applicable laws.

X. SEPARABILITY CLAUSE

If any provision in this Circular, or application of such provision to any circumstances, is held invalid, the remainder of the provisions in this Circular shall not be affected.