FDA Circular No. _____

TO: **ALL HEATED TOBACCO PRODUCT MANUFACTURERS, TRADERS, AND IMPORTERS**

SUBJECT: **BATCH DECLARATION OF HEATED TOBACCO PRODUCT REFILLS AND CARTRIDGES**

I. BACKGROUND

In 2005, the Philippines ratified the World Health Organization (WHO) Framework Convention on Tobacco Control (FCTC), implementing the comprehensive, effective, and practical tobacco control measures enshrined in the legally binding international treaty. As a State Party to the treaty, the Philippines is compelled to develop and implement laws and strategies to combat illicit trade in tobacco products in accordance with the terms of Article 15 of the WHO FCTC. Furthermore, the Philippines is obliged to establish an effective national tracking and tracing system for all tobacco products that are manufactured in or imported into the country, with the use of unique identification markings to allow the monitoring of movement of such products, thereby securing the supply chain and assisting in the investigation of illegal trade.

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 batch declaration certificate for heated tobacco product (HTP) refills/cartridges manufactured or imported by establishments with valid FDA-issued electronic licenses to operate (e-LTOs) and product marketing authorizations using the FDA e-Portal System.

II. OBJECTIVES

This Circular is being issued to provide the guidelines on the submission of applications for batch declaration of HTP refills/cartridges with the appropriate FDA product authorization certificate.

III. SCOPE

This Circular shall apply to all manufacturers, traders, and importers of HTP refills/cartridges.

IV. GENERAL GUIDELINES

1. Only HTP refills/cartridges with valid FDA product authorization certificate may apply for batch declaration.

2. All batches of HTP refills/cartridges shall be declared with the FDA prior to importation, release, distribution, or sale.

3. Imported products of the same batch/lot number but of different shipment shall be applied separately.

4. Submission of application shall be done using the FDA e-Portal system (https://eportal2.fda.gov.ph).

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

   5.1. Documents must be in PDF format, while images must be in .png format. Files should be free from bugs and viruses that may pose risk in the FDA system.

   5.2. Documents must be scanned and saved in PDF file format at 100-150 dots-per-inch (dpi).

   5.3. Filenames of documents must contain less than 40 characters. Filenames must not contain the following characters \ ? / : * " > < |."

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

7. The Regional Field Offices shall have the authority to collect samples of particular batches of the HTP refills/cartridges which need further assessment.

V. SPECIFIC GUIDELINES

1. Procedural Guidelines the application of batch declaration.

   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 the option below to proceed to the application form:

1.1.2.1. Batch Declaration – Heated Tobacco Products (Initial Form)

1.1.3. Click on the dropdown icon and select the correct FDA product authorization certificate number for batch declaration.

1.1.4. The batch declaration application form is divided into several parts as provided below:

1.1.4.1. Declaration of Undertaking

1.1.4.2. Company and Product Information (pre-filled)

1.1.4.3. Particulars of the Product Batch

1.1.4.3.1. HTP Refill and Cartridge

1.1.4.3.1.1. Batch/Lot Number

1.1.4.3.1.2. Date of Manufacture

1.1.4.3.1.3. Date of Importation (for imported products)

1.1.4.3.1.4. Batch Size (Quantity)

1.1.4.3.1.5. Expiration Date

1.1.4.4. 1.1.4.3.1.6. Target Market (For Local Distribution or for Exportation) Documentary Requirements

1.1.4.4.1. Certificate of Analysis of the Finished Product reflecting the batch/lot number.

1.1.4.4.2. Picture of the actual product, clearly showing the commercial label and BIR tax stamp.

1.1.4.4.3. For imported products:

1.1.4.4.3.1. Clear copy of the commercial invoice and/or packaging list reflecting the batch/lot number and expiry date, or any proof of the actual volume of importation (Note that the actual volume of importation must correspond to the actual volume stated in the application form.)

1.1.4.4.3.2. Airway bill/bill of lading for the particular shipment

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 Batch Declaration 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 for batch declaration 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 AND PAYMENT

An amount of **One Thousand Pesos (P1,000.00) + 1% Legal Research Fee** per application payable through any payment options made available by the FDA shall be required prior to the processing of the application for a batch declaration.

VIII. EFFECTIVITY

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.