Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

17 MAY 2021

FDA Circular No. 2021-010

SUBJECT: **Issuance of FDA Certifications for Vapor Products and Heated Tobacco Products (HTPs)**

I. BACKGROUND/RATIONALE

Pursuant to Republic Act (RA) No. 11346, RA No. 11467, and its implementing rules and regulations, the Bureau of Internal Revenue (BIR) has issued its Revenue Regulations providing the guidelines for the administration of excise tax on vapor products and HTPs.

Administrative Order (AO) No. 2020-0055 provides the Food and Drug Administration (FDA) the mandate to regulate Vapor Products and Heated Tobacco Products (HTPs). Under this order, the FDA is tasked to coordinate with the BIR to streamline processes to complement the taxation process for these products.

II. SCOPE

This issuance shall apply to all stakeholders seeking to secure an FDA certification in the assessment and processing of excise tax collection under the BIR for their vapor products and HTPs.

III. GUIDELINES

1. The FDA shall accept and process applications for the issuance of a certificate for the BIR excise tax collection purposes only and shall not be construed as a marketing authorization from the FDA.

2. The certification process shall be through online application, conducted under a simplified Product Batch Declaration (PBD) scheme throughout the eighteen (18) month transitory period following the procedure provided under Annex A of this issuance.

3. Applications shall be submitted for each batch of vapor product or HTP refills and cartridges. For imported products, applications shall be processed per importer per shipment per batch/lot number.

4. Products containing substances or ingredients prohibited under existing national laws, policies and standards shall not be allowed.

5. Schedule of Fees:

Description	Fee (PhP)
Heated Tobacco Product – PBD Application	1,000.00 + LRF
Vapor Product – PBD Application	1,000.00 + LRF

*LRF = Legal Research Fee

IV. 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.

V. EFFECTIVITY DATE

This order shall take effect after fifteen (15) days following its publication in a newspaper of general circulation and upon filing three (3) certified copies to the University of the Philippines Law Center.

ROLANDO ENRIQUE D. DOMINGO, MD
Director General

ANNEX A

Application Process for FDA Certification

1. Establishments applying for an FDA Certification for excise tax purposes shall first secure a **user account** following the procedure below:

    1.1. Follow the link: **bit.ly/ePortal2**.
    1.2. Attach a *valid* Proof of Business Ownership, in PDF file format, to the registration form.
    1.3. The User Account credentials will be sent to the email address provided in the registration form. The User Account credentials is valid for one (1) year.
    1.4. Issuance of the User Account is within three (3) working days upon receipt of the complete and compliant request.

2. Once the user account details are received via the registered email, the applicant can now log-in to access the home tab.

3. On the home tab, under the navigation pane, select "Product Batch Declaration Certification" option to proceed to the application form.

4. The online application form shall provide the following information to be declared by the applicant:

    4.1. General Information

        4.1.1. Name of Company and Address
        4.1.2. Contact Information
        4.1.3. Product Source Information
            4.1.3.1. Name of Manufacturer/Source
            4.1.3.2. Address and Country of Manufacturer/Source
            4.1.3.3. Shipment Date as reflected on Invoice (for imported products)

    4.2. Particulars of the Product

        4.2.1. Brand Name and Variant (if applicable)
        4.2.2. Nicotine Type (freebase/salt nicotine/others) *
        4.2.3. Nicotine Strength in mg/mL *
        4.2.4. Net Volume/Weight per Unit
        4.2.5. Batch Size/Shipment Quantity per Batch
        4.2.6. Batch/Lot Number
        4.2.7. Manufacturing Date

        * *Applicable for vapor products only*

    4.3. Product Formulation

        4.3.1. Complete ingredient listing with function and amount in percentage of each ingredient.

5. Upload a copy of the safety data sheet (SDS) of the product.

5.1. Documents uploaded to the system must conform with the following specifications:

5.1.1. The filename of the document to be uploaded shall follow the provided format below:

Documentary Requirement	Filename
Safety Data Sheet	"SAFETY DATA SHEET"

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

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

6. All required information for declaration and documentary attachment must be provided. The applicant shall be responsible for the completeness and correctness of the declaration.

7. Once the application is submitted, an assessment slip will be electronically generated on the application interface.

7.1. Download and print the computer-generated assessment slip which will serve as reference for the payment of the application.

8. Pay application through any payment options made available by the FDA.

9. The result of the application can be downloaded from the 'On-Process' folder of the applicant.

10. Applications will be processed within seven (7) working days from 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.