14 JUL 2021

FDA CIRCULAR
No. 2021-016

SUBJECT : **Licensing Guidelines for Vapor Product and Heated Tobacco Product Establishments under the Center for Cosmetics and Household/Urban Hazardous Substances Regulation and Research (CCHUHSRR)**

I. RATIONALE

Republic Act (R.A.) No. 9711, otherwise known as *The Food and Drug Administration (FDA) Act of 2009*, declares as a policy that the State shall protect and promote the right to health of the Filipino people and help establish and maintain an effective health product regulatory system based on the country's health needs and problems. Thus, the law, in defining health products, included products that may have an effect on health which require regulations as determined by the FDA, other than food, drugs, cosmetics, devices, biologicals, vaccines, in-vitro diagnostic reagents, and household/urban hazardous substances and/or a combination of and/or a derivative thereof.

Under Sections 144(B) and 144(C) of R.A. No. 11467 entitled *"An Act Amending Sections 109, 141, 142, 143, 144, 147, 152, 263, 263-A, 265, and 288-A, and Adding a New Section 290-A to R.A. No. 8424, as Amended, Otherwise Known as the National Internal Revenue Code of 1997, and For Other Purposes"*, the FDA is mandated to periodically determine and regulate, consistent with evolving medical and scientific studies, the manufacture, importation, sale, packaging, advertising, and distribution of vapor products and heated tobacco products (HTPs), including the sale to nonsmokers or persons below twenty-one (21) years old.

In accordance with Executive Order (E.O.) No. 106, s. 2020 entitled *"Prohibiting the Manufacture, Distribution, Marketing, and Sale of Unregistered and/or Adulterated Electronic Nicotine/Non-Nicotine Delivery Systems, Heated Tobacco Products, and Other Novel Tobacco Products, Amending EO No. 26 s. 2017 and for Other Purposes,"* Section 3 stated that all establishments engaged in the manufacture, distribution, importation, marketing and sale of ENDS/ENNDS, HTPs, or their components, shall secure a license to operate from the FDA. Likewise, under Section 6-A(1) of Administrative Order (A.O.) No. 2020-0055, all establishments engaged in the manufacture, distribution, importation, exportation, retail, and sale, including online sale or distribution, of vapor products and/or HTPs shall first secure a License to Operate (LTO) from the FDA, prior to the involvement in the aforementioned activities.

II. OBJECTIVES

This Circular is being issued to provide the FDA's guidelines for the licensing of vapor product and HTP establishments under the jurisdiction of the Center for Cosmetics and Household/Urban Hazardous Substances Regulation and Research (CCHUHSRR).

III. SCOPE

This Circular shall apply to all individuals, organizations, and entities engaged in the manufacture, distribution, importation, exportation, sale, offering for sale, including online sale/distribution of vapor products and HTPs, under the CCHUHSRR pursuant to A.O. No. 2020-0055.

IV. DEFINITION OF TERMS

For the purpose of implementing this Circular, the terms shall be defined for the purpose of greater clarity:

A. **FDA user account** refers to the FDA-issued online account to a company in order to access the FDA ePortal system for the application and processing of FDA authorizations.
B. **License to Operate (LTO)** refers to the authorization issued by the FDA to establishments prior to engagement in manufacture, distribution, importation, exportation, retail, and sale, including online retailing/ wholesaling.
C. **Onsite inspection** refers to regulatory visits conducted by authorized personnel of the Field Regulatory Operations Office (FROO) or the Regulatory Enforcement Unit (REU) on a company's declared premise to verify compliance to current regulations of the FDA.
D. **Post Licensing Inspection (PLI)** refers to the onsite inspection conducted by the FROO at any time within the validity of the company's LTO.
E. **Pre-assessment** is the process whereby the FDA evaluates and verifies the documents submitted by the establishments for completeness prior to the processing of the application.
F. **Site Master File (SMF)** refers to the specific information about the quality assurance, the production and/or quality control of manufacturing operations carried out at the named site and any closely integrated operations at adjacent and nearby buildings.
G. **Verified Customer account** refers to the account created and owned by customers that have been evaluated and approved by the establishments for compliance to the implementing rules and regulations of the FDA.

V. GUIDELINES

A. License to operate (LTO)

1. All establishments engaged in the manufacture, distribution, importation, exportation, retail, and sale, including online retailing/wholesaling, as

described under **Annex A** *(Description of Activities)* of vapor products and HTPs shall secure the appropriate License to Operate (LTO) from the FDA.

2. Applications shall be submitted electronically through the FDA ePortal system, following the procedure provided under **Annex B** *(Procedure on the Application for License to Operate for Vapor Product and Heated Tobacco Product Establishments through the Food and Drug Administration (FDA) Electronic Portal (E-Portal) System)* of this issuance prior to operation.
3. The actual physical business address shall be declared in the LTO application. The declared address must be consistent with the address reflected on the submitted documentary requirements. Virtual and PO box addresses shall not be allowed.
4. The applicant shall be responsible in ensuring that the declarations and attachments provided in the application are complete and correct. The specifications and list of documentary requirements for LTO application is provided under **Annex C** *(Documentary Requirements for LTO Applications)* of this issuance.
5. A pre-assessment of the submitted application prior to payment shall be conducted by the FDA to check for completeness of the submission. Pre-assessed applications with incomplete submissions will not proceed to the next step of the process. An e-mail notification stating the reason/s and reference/s for the disapproval of the application shall be sent to the applicant. Pre-assessed applications with complete submissions will be issued an electronic assessment slip for payment of the applicant.
6. Applications will be processed within twenty (20) working days. The timeline begins upon the verification of the payment transaction reference number or the official receipt number by the FDA Accounting/Cashier, and ends once the result of the application has been forwarded to the "On-Process" folder of the applicant.
7. Onsite inspection shall not be mandatory for the issuance of an LTO. Post licensing inspection (PLI) shall be conducted by the Field Regulatory Operations Office (FROO) for the verification and monitoring of compliance of licensed establishments.
8. In lieu of onsite inspection for manufacturers, the company's Site Master File (SMF) shall be submitted as part of the documentary requirements for LTO application.

B. Online selling/distribution

1. Establishments engaged in the conduct of online selling/distribution shall have full responsibility in ensuring that all transactions and activities conducted online, from providing access to customers down to the delivery of the product, are compliant with FDA rules and regulations.
2. For online retailing activities, only FDA-licensed retailers with an approved secondary activity as "online retailer" shall be allowed.
3. For online wholesaling activities, only FDA-licensed manufacturers, traders, or distributors with an approved secondary activity as "online wholesaler" shall be allowed.

4. Online retailers/wholesalers shall only operate and sell on platforms that require customers to have a verified customer account to access the content of the online store.
    a. Online retailers/wholesalers shall ensure that the customer is verified prior to the issuance of a customer account.
        i. For online retailers, the review of a government-issued identification card or certificate reflecting the age or date of birth of the individual registering for a customer account shall be part of the verification procedure.
            (1) Only individuals twenty-one (21) years old and above shall be granted customer accounts with access to the online store.
            (2) Application of a customer account for the sole purpose of age verification shall only be required to individuals accessing vapor products and HTPs through online platforms.
    b. For online wholesalers, the review of the company's LTO registering for a customer account shall be part of the verification procedure.
    c. Considering the Use and Restriction stated under A.O. No. 2020-0055 Section B(2), this shall only be applied to individuals purchasing vapor products and HTPs. Other products sold by the establishment, if any, shall not be affected.
5. The shipping, transport, and/or delivery of vapor products and HTPs shall comply with the same guidelines and restrictions provided for the sale and distribution of these products provided under E.O. No. 26 s. 2017 as amended by E.O. No. 106 s. 2020 and other pertinent Laws and policies.

VI. FEES

The schedule of fees for LTO application is provided under **Annex D** *(Schedule of Fees for Vapor Product and Heated Tobacco Product (HTP) Establishment LTO Applications)* of this issuance.

VII. 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 R.A. No. 9711, R.A. No. 11346, R.A. No. 11467, E.O. No. 106 s. 2020, and other penalties provided by other applicable laws.

VIII. 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.

IX. TRANSITORY CLAUSE

This issuance shall be enforced eighteen (18) months from the effectivity of the implementing rules and regulations of Republic Act Nos. 11346 and 11467.

X. EFFECTIVITY

This issuance shall take effect fifteen (15) days after publication in a newspaper of general circulation and the Office of National Administrative Register (ONAR) of the University of the Philippines Law Center.

ROLANDO ENRIQUE D. DOMINGO, MD
Director General

ANNEX A

Description of Activities

Manufacturer	Means an establishment engaged in any and all operations involved in the production of vapor products and/or heated tobacco products, including preparation, processing, compounding, formulating, filling, packaging, repackaging, altering, ornamenting, finishing and labeling with the end in view of its storage, sale or distribution.
Trader	Means any establishment which is a registered owner of a vapor product and/or heated tobacco product and procures the raw materials and packing components, and provides the production monographs, quality control standards and procedures, but subcontracts the manufacture of such product to a licensed manufacturer. In addition, a trader may also engage in the distribution and/or marketing of its products.
Distributor/ Importer	Means any establishment that imports vapor products and/or heated tobacco products for wholesale distribution to other establishments or outlets.
Distributor/ Exporter	Means any establishment that exports vapor products and/or heated tobacco products to other countries.
Distributor/ Wholesaler	Means any establishment that procures vapor products and/or heated tobacco products from a local establishment for local distribution on wholesale basis.
Retailer	Means any establishment which sells or offers to sell vapor products and/or heated tobacco products directly to the general public.
Online retailer	Means any establishment which sells or offers to sell vapor products and/or heated tobacco products directly to the general public through the internet using online selling platforms/websites
Online Wholesale	Means any establishment which sells or offers to sell vapor products and/or heated tobacco products in bulk to other FDA-licensed distributor-wholesalers/exporters or FDA-licensed retailers, through the internet using online selling platforms/ websites.

ANNEX B

Procedure on the Application for License to Operate for Vapor Product and Heated Tobacco Product Establishments through the Food and Drug Administration (FDA) Electronic Portal (E-Portal) System

1. USER ACCOUNT REQUEST

To access the FDA electronic portal (e-portal) system, establishments shall first secure a user account following the procedure outlined below:

1.1. Follow the link **bit.ly/ePortal2** to access the online registration form for the issuance of a user account.

1.2. Provide all the required information in the user's registration form.

1.3. Attach a *valid* Proof of Business Ownership, in PDF file format, to the registration form.

1.4. 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.

1.5. Issuance of the User Account is within three (3) working days upon receipt of the complete and compliant request.

1.5.1. The security and integrity of the user accounts shall be the responsibility of the owner. Applicants must ensure that only authorized personnel have access to their user accounts.

2. APPLICATION FOR A LICENSE TO OPERATE

Once a user account is issued, establishments can initiate applying for a license to operate (LTO) through the FDA e-portal system following the outlined procedure below:

2.1. Access the FDA e-portal system through the link **https://eportal2.fda.gov.ph**.

2.2. Log-in by entering the issued username and password to proceed to the application home tab.

2.3. In the home tab, under the navigation panel, select ***"New Application"*** and click on ***"e-License to Operate (Initial Application)"*** to proceed to the LTO application form.

2.4. The online application form is composed of the following parts:

2.4.1. Declaration of Undertaking

2.4.2. General Information

2.4.3. Establishment Information

2.4.4. Establishment Addresses

2.4.5. Product Line (for Manufacturer)

2.4.6. List of Personnel

2.4.7. Documentary Requirements

2.5. Accomplish the online application form and upload all documentary requirements for the application.

2.6. An application summary will appear for final review prior to submission.

2.6.1. The applicant must check and ensure that all information and attachments are complete and correct.

2.7. Continue with the application by clicking 'Next' to submit the application for pre-assessment.

2.8. Pre-assessed applications with complete submissions will be issued an electronic assessment slip for payment:

2.8.1. The computer-generated assessment slip can be viewed through a flash window.

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

2.9. To complete the application's submission, the applicant must pay the required fee at FDA-designated payment channels.

2.10. Once paid, the application will be automatically forwarded to the FDA Cashier for posting.

2.11. The status of the application may be checked in the "Processed" folder, under the Task column.

2.12. After evaluation, a notification email will be sent to the registered email address of the user account for the results of application.

3. RESULTS OF APPLICATION

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

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

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

ANNEX C

Documentary Requirements for LTO Applications

Manufacturer	Distributor/Trader	Retailer
Accomplished application form for Manufacturers	Accomplished application form for Traders/Distributors	Accomplished application form for Retailers
Payment	Payment	Payment
Proof of Business Name Registration (DTI/SEC)	Proof of Business Name Registration (DTI/ SEC)	Proof of Business Name Registration (DTI/SEC)
Proof of Business Address *(if actual address is not reflected on the proof of business name)*	Proof of Business Address *(if actual address is not reflected on the proof of business name)*	Proof of Business Address *(if actual address is not reflected on the proof of business name)*
Proof of Income (Latest Audited Financial Statement with Balance Sheet) or Sworn Statement of Initial Capital	Proof of Income (Latest Audited Financial Statement with Balance Sheet) or Sworn Statement of Initial Capital	Proof of Income (Latest Audited Financial Statement with Balance Sheet) or Sworn Statement of Initial Capital
Site Master File	N/A	N/A
Additional Requirements for Online Selling Activity		
Standard Operating Procedure (SOP) on Review and Issuance of User Accounts	SOP on Review and Issuance of User Accounts	SOP on Review and Issuance of User Accounts
SOP on Delivery of Products	SOP on Delivery of Products	SOP on Delivery of Products

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

1. Documents/ files/ information uploaded must be free from bugs, viruses, and the like that may compromise the FDA system.
2. Documents must be scanned and saved in PDF file format at 100-150 dots-per-inch (dpi).
3. The filename of the document to be uploaded shall follow the provided format below:

Documentary Requirement	Filename
Proof of Business Name Registration (DTI/SEC)	"BUSINESS NAME REGISTRATION"
Proof of Business Address	"BUSINESS ADDRESS"
Proof of Income (Latest Audited Financial Statement with Balance Sheet) or Sworn State of Initial Capital	"FINANCIAL STATEMENT"
Site Master File	"SITE MASTER FILE"
Standard Operating Procedure (SOP) on Review and Issuance of User Accounts	"SOP USER ACCOUNT"
Standard Operating Procedure (SOP) on Delivery of Products	"SOP PRODUCT DELIVERY"

*If the document file size exceeds the maximum file size allowed, you may split the files as long as they are properly labeled (e.g., FINANCIAL STATEMENT - Part 1, FINANCIAL STATEMENT - Part 2).

ANNEX D

Schedule of Fees for Vapor Product and Heated Tobacco Product (HTP) Establishment LTO Application

LICENSE TO OPERATE (LTO)	Fees (in PhP)*	
	Initial (3 years)	**Renewal (5 years)**
Vapor Products		
Retailer	7,500.00	12,500.00
Distributor (Importer/Exporter/Wholesaler)	30,000.00	50,000.00
Trader	36,000.00	60,000.00
Manufacturer	45,000.00	75,000.00
Variation - Major (with inspection)*		15,000.00 per variation
Variation - Minor (without inspection)*		1,000.00 per variation
Heated Tobacco Products		
Retailer	7,500.00	12,500.00
Distributor (Importer/Exporter/Wholesaler)	60,000.00	100,000.00
Trader	75,000.00	125,000.00
Manufacturer	120,000.00	200,000.00
Variation - Major (with inspection)*		40,000.00 per variation
Variation - Minor (without inspection)*		1,000.00 per variation

*for Variation classifications, please refer to Annex C of Administrative Order No. 2020-0017, entitled *"Revised Guidelines on the Unified Licensing Requirements and Procedures of the Food and Drug Administration Repealing Administrative Order No. 2016-0003"*