Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA ADVISORY
No. 20221072

18 MAY 2022

TO : **ALL CONCERNED VAPOR PRODUCT AND HEATED TOBACCO PRODUCT STAKEHOLDERS, GOVERNMENT AGENCIES, AND THE GENERAL PUBLIC**

SUBJECT : **INTERIM PROCESS FOR INTENDED LICENSE TO OPERATE VARIATION APPLICATIONS FOR VAPOR PRODUCT AND HEATED TOBACCO PRODUCT ESTABLISHMENTS**

In accordance with the implementation of Administrative Order No. 2020-0055 entitled *"Regulation on Vapor Products and Heated Tobacco Products (HTPs) under the Food and Drug Administration (FDA)"*, and FDA Circular No. 2021-016 entitled *"Licensing Guidelines for Vapor Product and Heated Tobacco Product Establishments under the Center for Cosmetics and Household/Urban Hazardous Substances Regulation and Research (CCHUHSRR)"*, the Food and Drug Administration (FDA) is currently updating its guidelines and the ePortal system v.2 to enable License to Operate (LTO) variation applications for vapor product and heated tobacco product (HTP) establishments. Variation refers to changes or amendments made on the information submitted by the marketing authorization holder (MAH) to the FDA during the application for a marketing authorization (e.g., License to Operate). The specific types of LTO variations which require notification with the FDA are provided under the ***Annex***.

To ensure continuous delivery of service and up-to-date information on the LTO, the FDA shall implement a provisional process for the notification of LTO variations to the FDA. Vapor product and HTP establishments intending to apply for an LTO variation shall notify the FDA through ntru@fda.gov.ph, following the format provided below:

(Subject of the email)
License to Operate Number _____ Variation Notice

(Body of the email)
Name of the Establishment:
License to Operate Number:

Declaration of LTO variation:

Type of Variation *(for the Type of Variation, kindly refer to the **Annex**)*	**Previous** *(previous information declared in the ePortal System v.2 during the application for an LTO)*	**New** *(new information to replace/be added to the information previously declared in the ePortal System v.2)*

The information declared in the email shall be consistent with the information declared during the application for an LTO. An acknowledgement email shall be sent by the FDA to the MAH upon assessment of the submitted information. Once the guidelines and the system are released and updated by the FDA, the MAH shall apply for an LTO variation for all acknowledged variation notices through the interim process. This acknowledgement, however, shall not equate to an authorization and shall not result in an automatic approval of the variation application.

This advisory is issued to give all vapor product and HTP stakeholders the guidance for the interim notification process of intended LTO variations. Your kind understanding on the above matter is highly appreciated.

DR. OSCAR G. GUTIERREZ, JR.
Officer-in-Charge, Director General

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