FDA Circular No. _____

SUBJECT: General Guidelines for the Regulation of Vapor Products and Heated Tobacco Products

I. BACKGROUND/RATIONALE

Republic Act No. (RA) 9711, otherwise known as The Food and Drug Administration 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 State must enhance its regulatory capacity and strengthen its capacity for the regulation of health products and its industry

Under Sec. 144(C) of Act No. (RA) 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 Republic Act No. 8424, as Amended, Otherwise Known as the National Internal Revenue Code of 1997, and For Other Purposes"*, the Food and Drug Administration (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 banning of flavors, and the sale to nonsmokers or persons below twenty-one (21) years old.

Likewise, Executive Order No. 106 (EO 106) 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 Executive Order No. 26 (EO 26 s. 2017) and for Other Purposes,*" mandates the Philippine FDA to (a) develop the regulatory framework for ENDS/ENNDS and HTPs and their components (b) issuance of license to operate (LTO) to establishments; (c) guidelines in the importation of these products and (d) pertinent rules, regulations and standards thereto in the implementing guidelines.

Vapor products, including Electronic Nicotine and Non-nicotine Delivery Systems (ENDS/ENNDS), and HTPs are a form of health products used to deliver aerosolized substances to the lungs by mimicking the act of smoking. Vapor products and HTPs are not likely to be risk free, and may expose users to chemicals and toxins at levels that have the potential to cause health effects. Presented by the industry as an alternative to conventional tobacco products, these products still contain and produce harmful and potentially harmful substances. There is currently insufficient evidence to demonstrate that vapor products or

HTPs are effective in assisting people to quit smoking and no brand of these products have been approved by the World Health Organization (WHO) or any National Regulatory Agency (NRA) for this purpose. The scientific evidence regarding the effectiveness of vapor products or HTPs as a smoking cessation aid is scant and of low certainty, making it difficult to draw credible inferences. Furthermore, current studies are not yet enough to conclude that the long-term use of vapor products and HTPs will not have any effect on human health. Concerns have been raised on the possibility that novel tobacco products may provide a gateway to nicotine addiction or tobacco product use, or that they may renormalize smoking. To ensure the protection of public health, the FDA shall establish science-based policies and regulations that limit youth access to vapor products and HTPs.

II. OBJECTIVES

This Memorandum is being issued to stipulate FDA's regulatory framework to all individuals, enterprises and businesses seeking to manufacture, distribute, import, export, sell, offer for sale, advertise, and/or use vapor products and heated tobacco products (HTPs) in the Philippines.

III. SCOPE

This issuance shall apply to all entities within the industry, which intend to manufacture, distribute, import, export, sell, offer for sale, and advertise vapor products, and HTPs in the Philippines.

IV. GUIDELINES

1. Market Authorization of Vapor Products and HTPs

1.1. All establishments engaged in the manufacture, distribution, importation, exportation, retail sale of vapor products and HTPs shall first secure a License to Operate (LTO) from the Center for Cosmetics Regulation and Research (CCRR).

1.2. No establishment shall engage in activities beyond what was approved by the FDA in its issued LTO.

1.3. Only establishments with a valid FDA-issued LTO can apply for a product marketing authorization, such as Certificate of Product Registration (CPR), FDA Electronic Registration Number (FERN) and/or Batch Notification.

1.4. No establishment shall engage in the manufacture, distribution, importation, exportation, sale, offering for sale, and advertising of vapor products and HTPs without first securing the necessary authorizations from the FDA.

1.5. HTP refills and cartridges, and its electronic delivery device shall be required to undergo Pre-Market Authorization (PMA) at least three (3) months prior to applying for a CPR. A CPR will be issued after compliance to set requirements.

1.6. Vapor product refills, and cartridges with or without the presence of nicotine, bearing therapeutic or health claims, such as but not limited to tobacco cessation claims, reduced risk/tobacco harm reduction claims, and/or nicotine concentrations above 20 mg/mL but not more than 65 mg/mL in its formulation shall be subject to PMA three (3) months prior to submission for CPR. A CPR will be issued after compliance to set requirements.

1.7. Vapor product refills, and cartridges with or without the presence of nicotine, that are not marketed with therapeutic or health claims, with nicotine content not exceeding 20 mg/mL, an FDA Electronic Registration Number (FERN) shall be issued upon compliance to set requirements.

1.8. Vapor product electronic delivery devices, shall be issued a FERN upon compliance to set requirements including the certificate of conformity issued by the Department of Trade and Industry (DTI).

1.9. No establishment shall operate and distribute/sell its products in the Philippines without the appropriate market authorizations from the FDA.

2. Product Standards

2.1. All vapor products and HTPs must be compliant with the set standards provided under **Annex A - *"Vapor Product Refill and Cartridge Standards"***, and **Annex B - *"Heated Tobacco Product Refill and Cartridge Standards"*** prior to release for distribution and/or sale in the Philippines.

2.2. The FDA shall set and issue pertinent standards on vapor product and HTP refills and collaborate with the DTI for the issuance of standards on the electronic delivery devices, guided by current available scientific evidence and international standards.

3. Labelling and Packaging

3.1. All containers and packages of vapor product and HTP refills and cartridges and electronic delivery devices shall contain appropriate information and health warnings compliant with the guidelines provided under **Annex C** - ***"Labelling Requirements for Vapor Product and Heated Tobacco Product Refills and Cartridges"***, and **Annex D** - ***"Labelling Requirements for Vapor Product and Heated Tobacco Product Electronic Delivery Devices"***.

4. Sale, Use, and Access Restrictions

4.1. Online sale of vapor products and HTPs shall not be allowed.

4.2. Retail sale of pure nicotine and nicotine shots/concentrates shall be strictly prohibited.

4.3. No manufacturer, retailer, distributor, importer, exporter, or retailer of vapor products and HTPs shall sell to individuals under twenty-one (21) years of age.

4.4. The distribution, sale, offering for sale and use of vapor products and HTPs shall be strictly prohibited in places provided by Executive Order No. 26 s. 2017 as amended by Executive Order No. 106 s. 2020.

4.5. The testing and use of vapor products and HTPs shall be prohibited inside the premises of retail outlets and in other enclosed public places, except in Designated vaping areas (DVAs).

4.6. Designated vaping areas (DVAs), including vaping lounges and the like, shall follow the same guidelines and requirements provided under this circular and section 4 of EO 26 s. 2017 as amended by EO 106 s. 2020.

5. Advertising, Promotion, and Sponsorship

5.1. No person, establishment or organization, shall use the FDA logo, the words "Food and Drug Administration" or "Philippine FDA", the initials "FDA", or any imitation of such words, initials, or logo in print and other forms of broadcast media, including the internet, in connection with any vapor products and HTPs merchandise, impersonation, solicitation, or commercial activity in a manner that convey that such use is approval, endorsement, or authorization by the FDA (e.g. "FDA approved" or "This product is approved by the FDA").

5.2. Advertising activities shall be strictly prohibited except in FDA-licensed retail outlets for vapor products and HTPs.

5.3. Marketing materials shall not bear markings or characters that are likely to promote youth use such as the use of cartoons, animé, manga, animated characters or the likes.

5.4. Only print media on fixed locations, within the premises of retail establishments shall be allowed. Free product samples, hand-outs, flyers, and other print media for distribution to store patrons and passers-by, shall be strictly prohibited.

5.5. Placing, posting, or displaying vapor products, HTPs, and its advertising materials in any place of retail outlets that is open and visible to the general public, especially the youth, such as but not limited to stalls, kiosks, booths, or stands is strictly prohibited. For such retail outlets, only the use of a signage displaying the name of the establishment, menu cards for the list of products offered (to be presented to verified customers), and placement of a single simple sign with white background and black font and not exceeding twelve inches by eighteen inches (12"x18") in size stating only the following: Vapor products/HTPs Available Here" shall be allowed.

5.6. Promotion and sponsorship, including corporate social responsibility campaigns/activities by the vapor product and HTP industry shall be strictly prohibited.

5.7. Other products and merchandises, such as but not limited to clothing, bags, accessories, toys, foods, and beverages, especially those generally intended for the consumption of children and the youth shall not bear names, logos, or other indicia of vapor product and/or HTP brand nor shall it be presented in such a way that it resembles vapor products or HTPs shall be strictly prohibited.

6. Enforcement

6.1. The FDA, through a subsequent Order, shall form a specialized unit under the Center for Cosmetics Regulation and Research, to implement and co-develop the provisions of this policy.

6.2. The FDA shall conduct post market surveillance (PMS) activities for verification of industry compliance and enforcement of FDA rules and regulations.

6.3. The DILG through the LGUs, PNP, and MMDA, shall enforce the minimum allowable age for the use of vapor products and HTPs. Sale of vapor products and HTPs, shall be made only to an individual who demonstrates that he/she is more than 21 years of age, through (a) any valid government ID; (b) a valid passport issued by the Department of

Foreign Affairs or any other country; or (c) an identification card issued by the FDA for the use of such products.

6.4. The local government units (LGU), and other government agencies and offices involved in the monitoring and regulation of the use, sale and distribution of vapor products and HTPs are enjoined to observe and implement the guidelines provided.

V. EFFECTIVITY

This Circular shall take effect immediately.

VI. 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, Republic Act No. 11346, Republic Act No. 11467, Executive Order No. 106 and other penalties provided by other applicable laws.

VII. 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.

ROLANDO ENRIQUE D. DOMINGO, MD
Director General, Food and Drug Administration

Keywords	Implementing Guidelines, Vapor Products, Heated Tobacco Products, HTP, Heat-Not-Burn, Electronic Nicotine Delivery System, Electronic Non-Nicotine Delivery System, ENDS/ENNDS, Vape, E-Cigarettes, E-Liquids, Vapor Products
Related Issuances, Laws, Directives	RA 9711, RA 11346, RA 11467, EO 106 s.2020

ANNEX E

GLOSSARY

1. **Advertising** shall refer to the conceptualizing, presenting, making available and communication to the public, through any form of media platforms, any fact, data, or information about the attributes, features, quality or availability of consumer products, services, or credit.

2. **Authorization** means a permission embodied in a document granted by the FDA to a natural or juridical person who has submitted an application to implement the manufacture, importation, exportation, sale, offer for sale, distribution, and/or, where appropriate, the use, testing, promotion, advertising, or sponsorship of health products. The authorization can take the form of a permit, a license, a certificate of registration, of accreditation, of compliance, or of exemption, or any similar document.

3. **Designated Vaping Area** shall refer to an area where the use of vapor products shall be allowed.

4. **FDA Electronic Registration Number (FERN)** shall refer to the product authorization issued by the FDA to FDA-licensed companies, firms or non-profit organizations to market specific vapor products classified as HUHS and health-related devices in the Philippines.

5. **Health Claims** shall refer to the beneficial effects to promote good health by enhancing/improving body function, improving a function, enhancing or preserving health and/or reducing the risk of health-related conditions of diseases.

6. **Heated Tobacco Products (HTPs)** refer to tobacco products that may be consumed through heating tobacco, either electrically or through other means sufficiently to release an aerosol that can be inhaled without burning or any combustion of the tobacco. Heated tobacco products include liquid solutions and gels that are part of the product and are heated to generate an aerosol.

7. **Industry** refers to manufacturers, traders, distributors (importer, exporter, wholesaler), and retailers of vapor products and/or heated tobacco products.

8. **Ingredient** means any substance that is added to the mixture and present in the finished product

9. **Marketing Authorization Holder (MAH)** refers to a company, firm or non-profit organization that has been granted an authorization by the FDA.

10. **Nicotine Shots** refer to nicotine in liquid or any other form/substances that is added to or mixed with vapor product refills or cartridges that has the effect of increasing the dosage or nicotine concentration in a refill or cartridge.

11. **Package** shall refer to packs, boxes, cartons, or containers of any kind used on vapor products, which is offered for sale to consumers.

12. **Post-Marketing Surveillance (PMS)** refers to activities involved in safety, efficacy, and quality monitoring of health products. This shall also include, among others, adverse events reporting, product safety update reporting, collection and testing of health products in the market.

13. **Promotion** shall refer to an event or activity organized by or on behalf of an vapor product manufacturer, distributors (importer, exporter, wholesaler), seller or retailer with the aim of promoting vapor products, which event or activity would not occur but for the support given to it by or on behalf of the vapor product manufacturer, distributor (importer, exporter, wholesaler), seller or retailer. It may also refer to the display of vapor products or the manufacturer's name, trademark, logo, and the like on non-vapor products. This includes the paid use of vapor products bearing the brand names, trademarks, logos, and the like in movies, television, and other forms of entertainment.

14. **Refills and Cartridges** are articles, which may or may not contain nicotine, designed to be used in conjunction with vapor product or HTP electronic delivery devices for inhalation;

15. **Sponsorship** shall refer to any public or private contribution from vapor product industry in relation to an event, team or activity made with the aim of promoting a brand of vapor products, which event, team or activity would still exist or occur with or without contribution. This shall also include corporate social responsibility (CSR) activities by the vapor product industry.

16. **Vapor Products** shall mean any liquid solution or gel which contains nicotine that transforms into an aerosol without combustion through employment of a mechanical heating element, battery or circuit that can be used to heat such solution or gel, and includes but is not limited to, a cartridge, a tank, and a device without

a cartridge or tank. It is commonly known as ‘e-liquids’ or ‘e-cigarettes’. It also includes electronic nicotine and non-nicotine delivery systems (ENDS/ENNDS) which are combinations of non-tobacco containing e-liquids or refills which contain up to sixty-five milligrams per milliliter (65mg/mL) of nicotine in the e-liquid or refill and an electronic delivery device to produce an aerosol, mist or vapor that users inhale by mimicking the act of smoking.