FDA Circular No. _____

SUBJECT: General Guidelines for the Regulation of 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(B) 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 heated tobacco products (HTPs), including 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) issue license to operate (LTO) to establishments; (c) formulate guidelines in the importation of these products, and (d) develop pertinent rules, regulations and standards thereto in the implementing guidelines.

HTPs deliver aerosolized substances to the lungs by mimicking the act of smoking. HTPs expose users to chemicals and toxins at levels that have health effects. Presented by industry as an alternative to combustible tobacco products, these products still contain and produce harmful and potentially harmful substances. There is currently insufficient evidence to demonstrate that 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.

Independent scientific evidence regarding the effectiveness of 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 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 HTPs.

II. OBJECTIVES

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

III. SCOPE

This issuance shall apply to all individuals, enterprises and businesses which intend to manufacture, distribute, import, export, sell, offer for sale, and advertise HTPs not classified as drug products in the Philippines.

IV. GUIDELINES

1. Market Authorization of HTPs

1.1. All establishments engaged in the manufacture, distribution, importation, exportation, retail sale, including online sale, of 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 FDA-licensed manufacturers, traders/importers, and distributors can apply for an FDA Electronic Registration Number (FERN) for their products.

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

1.5. Heated tobacco products shall be registered per refill/cartridge-device combination (e.g. refill/cartridge variant 1 + device model 1) and shall be filed under a single application, with the issuance of a FERN after compliance to the set standards and requirements.

1.6. HTPs not bearing, and not marketed with health claims (such as but not limited to: tobacco harm reduction, tobacco cessation aid claims) shall be required to undergo pre-application documentary evaluation (PADE) at least 3 months prior to applying for a FERN.

1.7. All batches of HTP refills and cartridges shall also be declared with the FDA through the batch declaration process prior to importation, distribution, or sale in the Philippines.

1.8. HTPs bearing, or are marketed with therapeutic or health claims (such as but not limited to: tobacco harm reduction, tobacco cessation aid claims) shall comply with the regulatory requirements and standards for drug/pharmaceutical products under the Center for Drug Regulation and Research (CDRR).

2. <u>Online Sale (Retail and Wholesale)</u>

2.1. Online sellers shall apply for a license to operate based on their intended activity (Manufacturer, Trader, Distributor, or Retailer) with the addition of online selling activity in their LTO.

2.2. Online sellers are required to declare a physical office address which shall be subject to FDA's pre and post licensing inspection and monitoring.

2.3. All online sellers shall require customers to register for a user account prior to allowing access to the online store.

2.3.1. For retail sellers, proper age verification, including the submission of a government issued identification card or certificate reflecting the age or date of birth of the person registering for a user account, shall be required.

2.3.1.1. Individuals below the age of twenty-one (21) years are not eligible to have a user account.

2.3.2. For online wholesalers, the submission of a valid FDA-issued LTO as retailer or distributor/wholesaler of HTPs, shall be required for the issuance of a user account.

2.3.3. Sufficient review of the request for a user account shall be conducted by the online seller prior to approval of the request. Automated issuance of user accounts shall not be allowed.

2.4. Only establishments with a license to operate as retailers can conduct online retail sales on their online platform.

2.5. Online wholesalers shall only sell to verified FDA-licensed retailers and distributors.

2.5.1. Products must only be delivered at the official address of the retailer or distributor/wholesaler as reflected on its LTO.

2.6. The distribution, shipping, transport and/or delivery of HTPs shall be strictly prohibited in places where the sale of such products are prohibited, as provided under Executive Order No. 26 s. 2017 as amended by Executive Order No. 106 s. 2020.

2.7. Under no circumstances shall an online wholesaler or retailer be allowed to transport or deliver HTPs to persons below twenty-one (21) years of age.

2.7.1. The courier shall only release the product to the account holder after proper verification of the recipient's identity and age by means of any valid government-issued photographic identification containing the date of birth.

2.8. All forms of advertising shall be restricted within the web address/site and shall not pop-up in other online platforms. The advertising of the online stores may be allowed provided that the platforms where it is advertised are not accessible and visible to individuals below twenty-one (21) years of age.

2.9. The FDA shall have the authority to access the web address/site and enter without delay and at reasonable hours the physical premise of the establishment to conduct routine or spot check inspections.

2.10. All establishments engaged in electronic commerce must ensure compliance with the requirements for product quality and safety and consumer data protection as provided under the DTI-DOH-DA Joint Administrative Order (AO) No. 1, otherwise known as the *"Rules and Regulations for Consumer Protection in a Transaction Covered by the Consumer Act of the Philippines (RA 7394) through Electronic Means under the E-commerce Act (RA 8792)", the* Data Privacy Act of 2012 (RA 10173), the FDA Act of 2009 (RA 9711), and other applicable laws.

3. Product Standards

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

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

4. Labelling and Packaging

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

5. Sale, Use, and Access Restrictions

5.1. Retail of ingredients for the purpose of modification of HTP refills and cartridges, such as but not limited to flavorings, nicotine shots, and other additives, shall be prohibited. These products shall not be allowed to be sold in retail stores.

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

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

5.4. The testing and use of HTPs shall be prohibited inside the premises of retail outlets and in other enclosed public places, except in designated smoking and vaping areas (DSVAs).

5.5. Smoking and vaping lounges and similar establishments 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.

5.6. Under no circumstances shall an establishment or individual be allowed to publish or otherwise communicate tutorials on adulterating, modifying, manufacturing, or otherwise tampering of HTPs through any print, physical, electronic, or online media.

5.7. The FDA shall collaborate with the National Telecommunications Commission, the Ads Standards Council, and other concerned enforcement agencies to remove any materials that communicate tutorials on adulterating, modifying, manufacturing, or otherwise tampering HTPs from general circulation.

6. Advertising, Promotion, and Sponsorship

6.1. 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 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").

6.2. Advertising activities shall be strictly prohibited except in FDA-licensed retail outlets/stores of HTPs.

6.3. Marketing materials shall not bear markings or characters that are likely to promote youth use such as the use of cartoons, anime, manga, animated characters, youth influencers, personalities and the like.

6.4. Only print media on fixed locations, within the premises of FDA-authorized 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. For HTP 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: "HTPs Available Here" shall be allowed.

6.5. Promotion of HTPs that implies health benefits may be derived from the use of the product or from its emissions shall be prohibited.

6.6. Modified risk descriptors (e.g., ''light,'' ''low,'' and ''mild'' descriptors) and unsubstantiated claims (e.g. healthy, low harm, less harmful, helpful to quit smoking, effective than other smoking cessation products, etc) are prohibited in the sale and distribution of products. These include misleading elements and notably any suggestions that a particular HTP is less harmful than other similar products (eg. claims that HTPs cut the risk of tobacco-related diseases and are less risky than continuing to smoke cigarettes, etc.).

6.7. Placing, posting, or displaying 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.

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

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

6.10. No establishment, organization, or juridical person shall engage an individual to promote HTPs through a testimonial or an endorsement, however displayed or communicated, including by means of packaging or advertising materials**.**

7. Enforcement

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

7.2. The FDA shall collaborate with the Department of Interior and Local Government through the local government units (LGUs), Philippine National Police, and Metropolitan Manila Development Authority, in the enforcement of the minimum allowable age for the use of HTPs. Sale of 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.

7.3. The LGUs and other government agencies and offices involved in the monitoring and regulation of the use, sale and distribution of HTPs are enjoined to observe and implement the guidelines provided.

V. EFFECTIVITY DATE AND TRANSITORY PERIOD

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.

Manufacturers, importers, distributors, and retailers are given an eighteen (18) month grace period, from the effectivity date of the rules and regulations implementing RA 11467, to comply with the new regulations.

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.

Keywords	Implementing Guidelines, Heated Tobacco Products, HTP, Heat-Not-Burn
Related Issuances, Laws, Directives	RA 9711, RA 11346, RA 11467, EO 106 s.2020