FDA CIRCULAR
No. _____

SUBJECT : Guidelines for the Authorization of Vaporized Nicotine and Non-Nicotine Products and Novel Tobacco Products with Medicinal or Therapeutic Claims or Reduced Risk Statements Pursuant to Sections 12 (k), 12 (l), and 13 (c) of Republic Act No. 11900

I. RATIONALE

Sections 12 (k), 12 (l), and 13 (c) of Republic Act (RA) No. 11900 and its implementing rules and regulations (IRR) issued through Department Administrative Order No. 22-16, vaporized nicotine and non-nicotine products (VNNPs) and novel tobacco products (NTPs) bearing explicit medicinal or therapeutic claims, or reduced risk statements shall require approval from the Food and Drug Administration (FDA) pursuant to RA No. 9711 otherwise known as the "Food and Drug Regulation Act of 2009".

RA No. 11900 defines medicinal or therapeutic claims as "explicit statements made on any product presented as having properties for directly treating, curing, alleviating, or preventing diseases or disorders in persons" whereas reduced risk statements are defined as "explicit communication to consumers in the product label or marketing materials which states that the product presents less risk of harm to the user's health or is less harmful to the user's health than continued smoking of combustible cigarettes".

For products intended to reduce the risk of smoking-related diseases, the FDA notes that it should be able to assist users in quitting traditional cigarettes altogether. As such, VNNPs and NTPs intended to reduce the risk of smoking-related harm shall be primarily considered as smoking cessation aid with a secondary claim for reduced risk.

Thus, under FDA's current regulatory framework, VNNPs and NTPs under the jurisdiction of the FDA pursuant to RA No. 11900 shall be regulated as pharmaceutical products.

II. OBJECTIVE

This issuance aims to provide the guidelines for the regulation of VNNPs and NTPs that are marketed with medicinal or therapeutic claims or reduced risk statements pursuant to RA No. 9711 and RA No. 11900 and their IRRs, and other pertinent laws, rules, and regulations.

III. SCOPE AND COVERAGE

This issuance shall cover all establishments engaged or intending to engage in the manufacture, importation, exportation, sale, offering for sale, distribution, transfer, promotion, advertising, and/or sponsorship of VNNPs and NTPs with medicinal or therapeutic claims on its marketing materials or packaging. This shall also apply to VNNPs and NTPs used as smoking cessation aids with a secondary claim of reduced risk.

IV. DEFINITION OF TERMS

To establish clarity and uniformity in the implementation of this Circular, the following terms are hereby defined:

A. **Authorization -** refers to 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, transfer, and/or, where appropriate, the use, testing, promotion, advertising, or sponsorship of vaporized nicotine and non-nicotine product or novel tobacco product. 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.

B. **Distributor-Importer/Exporter** – refers to any establishment that imports or exports raw materials, active ingredients and/or finished products for its own use or for wholesale distribution to other establishments or outlets. If the distributor/importer/exporter sells to the general public, it shall be considered a retailer.

C. **Distributor-Wholesaler** – refers to any establishment that procures raw materials, active ingredients and/or finished products from local establishments for local distribution on wholesale basis.

D. **Establishment -** refers to a sole proprietorship, a partnership, a corporation, an institution, an association, or an organization engaged in the manufacture or importation, offer for sale, distribution, donation, transfer, use, testing, promotion, advertising, or sponsorship of tobacco products including the facilities and installations needed for its activities.

E. **Heated Tobacco Products (HTPs)** - also referred to as Heated Tobacco Product (HTP) Consumables or Heat-Not-Burn Product Consumables, shall refer to tobacco products that are intended to be consumed through heating tobacco, either electronically or through other means, sufficient to release an aerosol that can be inhaled, without combustion of the tobacco. HTP Consumables or Heat-Not-Burn Product Consumables may also include

liquid solutions and gels that are part of the product and are heated to generate an aerosol. HTPs may or may not operate by means of an HTP Device;

E. **Manufacturer -** refers to an establishment engaged in any and all operations involved in the production of vaporized nicotine and non-nicotine product or novel tobacco product including preparation, processing, compounding, formulating, filling, packing, repacking, altering, ornamenting, finishing, and labeling with the end in view of its storage, sale or distribution: Provided, that the term shall not apply to the compounding and filling of prescriptions in drugstores and hospital pharmacies. A trader shall be categorized as a manufacturer.

F. **Medicinal or Therapeutic Claims -** refers to explicit statements made on any product presented as having properties for directly treating, curing, alleviating, or preventing diseases or disorders in persons;

G. **Novel Tobacco Products (NTPs) -** refers to all non-combusted substances in solid or liquid form, and innovations, either made partly of tobacco leaf as raw material or containing nicotine from tobacco, intended to be used as a substitute for cigarettes or other combusted tobacco products;

H. **Product –** refers to VNNPs and NTPs as defined in this issuance.

I. **Post-Marketing Surveillance (PMS) -** refers to activities involved in safety, efficacy, and quality monitoring of regulated products and establishments. This shall also include, among others, adverse events reporting, product safety update reporting, collection and testing of vaporized nicotine and non-nicotine product or novel tobacco product in the market.

J. **Reduced Risk Statement -** refers to an explicit communication to consumers in the product label or marketing materials which states that the product presents less risk of harm to the user's health or is less harmful to the user's health than continued smoking of combustible cigarettes;

K. **Retailer** – refers to any establishment which sells or offers to sell any health product directly to the general public."

L. **Trader -** refers to an establishment that is a registered owner of a vaporized nicotine and non-nicotine product or novel tobacco product, procures the raw materials and packing components, provides the production, monographs, quality control standards, and procedures, but subcontracts the manufacture of such a product to a licensed Manufacturer. In addition, a trader may also engage in the distribution and/or marketing of its products.

M. **Vapor Products** - also referred to as Vapor Product Refills, refers to the liquid, solid, or gel, or any combination thereof, which may or may not

contain nicotine, that is transformed into an aerosol without combustion by a Vapor Product Device

N. **Vaporized Nicotine or Non-Nicotine Products** (VNNPs) - refers to both Heated Tobacco Products and Vapor Products, as defined herein, which are novel consumer goods that generate a nicotine-containing or non-nicotine-containing aerosol without combustion.

V. GENERAL GUIDELINES

A. The manufacture, importation, exportation, sale, offer for sale, distribution, transfer, and/or, the use, testing, promotion, advertising, or sponsorship of VNNPs and NTPs without License to Operate (LTO) covered in this issuance is prohibited.

B. Establishments of VNNPs and NTPs within the scope of this issuance shall secure a Certificate of Product Registration for the products they intend to market in the country.

C. Only FDA approved claims shall be placed or used on the label, packaging or marketing materials and activities of the VNNPs and NTPs. No VNNPs and NTPs that has not been registered or authorized shall be advertised, promoted or subjected to any marketing activities.

D. No claim in the advertisement, promotion and sponsorships, express communication and other marketing activities shall be made other than those contained in the approved label or packaging or advertising of VNNPs and NTPs.

E. Only scientifically proven claims and statements shall be authorized or approved by the FDA.

F. VNNP and NTP establishments shall ensure continuous and strict compliance with existing FDA laws, rules, regulations and applicable standards and conditions set forth, and coordinate with the agency on matters of post-marketing surveillance (PMS) including but not limited to adverse event reporting and product recalls.

G. VNNP and NTP establishments and their products shall be subject to inspection by FDA inspectors during office hours as part of the Agency's pre-licensing and/or post-marketing surveillance activities.

VI. SPECIFIC GUIDELINES

A. Licensing and Inspection of VNNP and NTP Establishments

1. Establishments within the scope of this issuance shall secure their License to Operate (LTO) following the current implemented Citizen's Charter (CC) for pharmaceutical products as posted in the official website of the FDA.

2. Inspection conducted by FDA inspectors for the purpose of issuance of LTO or part of the agency's post-marketing surveillance activities shall be based on applicable standards established for pharmaceutical establishments.

B. Product Registration

1. Products under the scope of this issuance shall be registered with the following the guidelines for pharmaceutical products provided in the current implemented CC as posted in the official website of the FDA.

2. Products which are authorized, validated, accepted, or permitted by reliable and mature national regulatory agencies to be marketed with the same classification and function/indication shall be taken into consideration by the FDA in its resolution of an application for an authorization and shall be resolved within eighteen (18) months.

3. Products which are recalled, withdrawn, or banned in the jurisdiction of the aforesaid reliable and mature national regulatory agencies taken into consideration by the FDA shall be automatically recalled, withdrawn, or banned in the country. Pending applications for registration of products that are subject of ban, recall, or withdrawal from their countries of origin shall be automatically rejected without prejudice to the refiling of the applications with a clear showing that the order for such ban, recall or withdrawal from the market has been lifted without conditions.

C. Post-Marketing Surveillance

1. VNNP and NTP establishments and their products issued with the appropriate authorizations shall be subject to the FDA's post-marketing surveillance activities following the current implemented FDA CC as posted in the official website of the FDA.

VII. MANDATORY REVIEW

This issuance shall be reviewed three (3) years after its implementation date or earlier as may be necessary to update the current regulatory framework.

VIII. PENALTIES

Violation to any provisions of this issuance 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. 11900, the Vaporized Nicotine and Non-Nicotine Products Regulations Act, and its implementing rules and regulations, and other penalties provided by other applicable laws.

IX. SEPARABILITY CLAUSE

If any provision in this issuance, or application of such provision to any circumstances, is held invalid, the remainder of the provisions in this issuance shall not be affected.

X. EFFECTIVITY

This issuance shall take effect fifteen (15) days after publication to the Official Gazette or a newspaper of general circulation, with three (3) copies to be filed with the U.P. Law Center pursuant to Section 3, Chapter 3, Book VII of Executive Order No. 292, Series of 1987 through this Department's records officer or its equivalent functionary.

DR. SAMUEL A. ZACATE
Director General

Office	**CDRR**	**PPS**
Initials	**JESUSA JOYCE N. CIRUNAY** Director IV	**IRENE V. FLORENTINO-FARIÑAS, RPh, MD, MNSA** Director III
Date		