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

Article II, Section 15 of the 1987 Constitution expressly declares as a policy of the State to "protect and promote the right to health of the people and instil health consciousness among them". Pursuant to the above policy, Republic Act (RA) No. 11900 or the Vaporized Nicotine and Non-Nicotine Products Regulation Act adopted as a state policy to enact a balanced policy whereby these novel consumer products are properly regulated using internationally accepted product standards in order to protect the citizens from the hazards of regulated, unregulated and substandard Vapor Products and Heated Tobacco Products.

For this purpose, the government shall regulate the importation, assembly, manufacture, sale, packaging, distribution, use, advertisement, promotion and sponsorship of Vaporized Nicotine and Non-Nicotine Products (VNNPs), and their devices, and Novel Tobacco Products (NTPs) in order to promote a healthy environment, protect the citizens from any potential hazards of these novel consumer products, reduce the harm caused by smoking, and ensure that the sale to minors and the illicit trade of Vaporized Nicotine and Non-Nicotine Products, and their devices, and Novel Tobacco Products in the country are prevented.

Under Sections 12 (k), 12 (l), and 13 (c) of RA No. 11900 and its implementing rules and regulations (IRR), through Department Administrative Order No. 22-16, VNNPs and 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".

In view of the foregoing, the FDA hereby issues the guidelines for the authorization of VNNPs or NTPs intending to make medicinal or therapeutic claims on its marketing materials or packaging, or explicit reduced-risk statements pursuant to RA No. 11900 and its IRR.

II. OBJECTIVES

Option 1

This issuance aims to provide the guidelines on the FDA's regulatory framework for the issuance of authorizations for VNNPs and NTPs that are marketed with medicinal or therapeutic claims on its marketing materials or packaging, and/or explicit reduced-risk statements pursuant to RA No. 11900 and its IRR.

Option 2

This issuance aims to establish guidelines for seeking approval from the FDA prior to making explicit Reduced Risk Statements in the marketing materials or packaging of VNNPs or NTPs in order to protect consumers against misleading or deceptive Reduced Risk Statements.

III. SCOPE

Option 1

This issuance shall apply to all establishments engaged or intending to engage in the manufacture or importation of VNNPs and NTPs with medicinal or therapeutic claims on its marketing materials or packaging, or explicit reduced-risk statements in the country.

Option 2

This issuance shall cover manufacturers, traders and importers of VNNPs and NTPs that propose to make explicit Reduced Risk Statements as defined herein in the packaging, product label or marketing materials of such products.

IV. DEFINITION OF TERMS

For the purpose of this issuance, the term 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 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.

B. **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.

C. **Health Claim** - refers to medicinal or therapeutic claims which are explicit statements made on any product presented as having properties for directly treating, curing, alleviating, or preventing diseases or disorders in persons

D. **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;

D. **Importer -** refers to any establishment that imports raw materials, active ingredients and/or finished products for wholesale distribution to other local FDA-licensed establishments

E. **Manufacturer -** refers to any establishment engaged in any and all operations involved in the production of health products 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 -** shall refer 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 health products 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. **Reduced Risk Statement Authorization (RRSA) -** refers to a document issued by the appropriate regulatory authority in more mature jurisdictions to a company, firm or non-profit organization as an authorization to market products with Reduced Risk Statements in countries such as [insert name of the country]

K. **Trader -** refers to an establishment that is a registered owner of a health 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.

L. **Vapor Products** - also referred to as Vapor Product Refills, refer 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

M. **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 FDA shall issue the operational guidelines for Section 12 (k), 12 (l) and Section 13 (c) of RA No. 11900, including the appropriate standards and requirements, and oversee its implementation and enforcement.

B. Establishments (manufacturers, importers, traders) that have secured the required authorizations to market VNNPs and NTPs with explicit medicinal or therapeutic claims, and/or reduced-risk statement in the country shall ensure continuous compliance with existing laws as well as with regulations, applicable standards, and conditions set forth for such products.

C. Only VNNPs and NTPs that have secured the appropriate authorizations shall be allowed to be marketed with explicit medicinal or therapeutic claims, and/or reduced-risk statements in the country. More particularly, only the medicinal or

therapeutic claims, and/or reduced-risk statement approved for use shall be placed on the product label or marketing materials.

D. The agency shall observe the necessary requisites in its policy development and ensure the right to health of the Filipino. All personnel and officials shall strictly abide by the agency's policies on conflict of interest and rules of engagement when interacting with the regulated establishments and their representatives.

VI. SPECIFIC GUIDELINES

Option 1

A. ON COMMUNICATING REDUCED RISK STATEMENTS

Manufacturers, distributors, and importers of VNNPs and NTPs proposing to make explicit Reduced Risk Statements shall undergo the Reduced Risk Statement Authorization (RRSA) application process if Reduced Risk Statements are to be made on the packaging, product label or in marketing materials of VNNPs or NTPs.

1. A Reduced Risk Statement may only be made if authorized by the FDA in accordance with the procedure laid down under this section and following the application process provided for under Appendix A of this issuance.

2. The FDA shall, with respect to an application submitted under this section, issue a RRSA order that a Reduced Risk Statement may be used in the relevant material only if the FDA determines that the statement is appropriately substantiated and the manufacturer has demonstrated that such product, as it is actually used by consumers, will:

    a. significantly reduce harm and the risk of smoking related disease to individual product users; and

    b. benefit the health of the population as a whole taking into account both smokers and persons who do not currently smoke.

3. In making determinations under V.2.a above, the FDA shall take into account the relative health risks to individuals of the Product compared to the use of cigarettes;

4. Applications subject to an order under V.2.a shall be limited to a term of not more than five (5) years from the issuance of the RRSA Order, but may be renewed upon a finding by the FDA that the requirements of this section continue to be satisfied based on the filing of a new application.

5. Each applicant who receives RRSA Order must conduct post market surveillance and studies to identify and collect information on the effect of the issuance of the order on consumer perception, behavior, and health, including unanticipated and undesired events related to the VNNPs and NTPs once it is introduced to the market. Applicants granted a RRSA Order must submit protocols for required post market surveillance for FDA concurrence within 60 days after receiving notice that they are required to conduct such surveillance. All applicants granted RRSA Order must submit the results of post market surveillance annually, which shall not be later than the end of the second calendar month of the following year.

6. Reduced Risk Statements which are authorized, validated, accepted, or permitted by reliable and mature national regulatory agencies for VNNPs and NTPs shall be taken into consideration by the FDA in its resolution of an application for a RRSA Order and shall be resolved within a non-extendible period of 6 months. This abbreviated procedure for authorizing Reduced Risk Statements shall only proceed after determination by the FDA that the Product from the same manufacturer (1) has the same characteristics as another product for which the claim has been authorized; or (2) has different characteristics but does perform similarly.

7. The RRSA Order issued shall remain valid unless otherwise revoked, upon due process, by the FDA in light of new scientific evidence that expressly invalidates the existing Reduced Risk Statement being used by a Product. RRSA Order shall only be revoked after due notice and hearing has been given to the manufacture, trader or importer.

8. The final disposition on the Reduced Risk Statements application evaluations issued by the Director General of the FDA is subject to re-examination upon written request of the applicant. The applicant shall give written notice to the Director General of the FDA that said applicant wishes to request a re-examination within 15 days of receipt of the disposition. The grounds for the re-examination request must be forwarded to the FDA within 60 days of receipt of the disposition.

9. Under no circumstances shall evaluations with favorable dispositions be deemed to mean that VNNPs and NTPs subject of the application are safe. Any industry promotion, advertisement, or communication, explicit or implicit, indicating that the product is “FDA approved” shall be grounds for immediate and final denial of active VNNPs and NTPs applications associated with the offender’s Reduced Risk Statement application.

Option 2

1. Evidence for reduced-risk statements shall be evaluated on a per product basis, and shall follow the current rules and regulations for the authorization of drug products and its industries.

2. Products which are authorized, validated, accepted, or permitted by reliable and mature national regulatory agencies to be marketed with reduced-risk statements 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; and

3. The FDA shall review the current regulatory framework, and assess other processes that may be considered as more suitable for the authorization of products with reduced-risk statements.

4. Subject to the results of the review of the current regulatory framework, the FDA may consider the issuance of a separate implementing guidelines for the authorization of products that are marketed with explicit reduced-risk statements, including the conduct of post-market surveillance and adverse event reporting in accordance with Department Order No. 2015-0284 entitled "Revised Rules and Procedures on the Preparation and Approval of Administrative Issuances in the Department of Health" and other pertinent issuances.

5. In the development of new guidelines, the FDA shall consider a weight of evidence approach based on a comprehensive scientific assessment that may include but not limited to the following;

    a. Conduct of a thorough literature search, literature quality assessment, evidence synthesis to assess causality for health effects, application of a framework for levels of evidence affected by user behaviour, and short and long-term health effects.

    b. Studies that show significantly reduced harm and the risk of smoking related disease to individual product users;

    c. Benefit the health of the population as a whole taking into account both smokers and persons who do not currently smoke; and

    d. Other important parameters such as exclusive and poly-use, etc.

B. **ON COMMUNICATING HEALTH CLAIMS**

Option 1

No VNNPs or NTPs shall have a medicinal or therapeutic claim on its marketing or labelling materials, such as "this product is safe" or "is an effective smoking cessation device" unless such claim is approved by the FDA pursuant to Republic Act No. 3720, as amended.

Option 2

Products that will have medicinal or therapeutic claims on its marketing or labelling materials such as but not limited to for smoking cessation shall follow the prescribed existing rules and regulations for drug products.

VII. FEES

TBD

VIII. ENFORCEMENT ACTION AGAINST FALSE OR NOT SCIENTIFICALLY SUBSTANTIATED FORMS OF CONSUMER COMMUNICATION

Violation of any provisions of this issuance shall be subject to the penalties/sanctions provided under RA 11900 and its Implementing Rules and Regulations and other penalties provided by other applicable laws. In addition, the FDA shall take all appropriate measures to prohibit the marketing or use of unsubstantiated or false claims and the withdrawal from the market of the subject products.

IX. MANDATORY REVIEW

This issuance shall be reviewed three (3) years after its implementation date or earlier as may be necessary.

X. 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, and other penalties provided by other applicable laws.

XI. 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.

XII. 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.