



Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

DEC 01 2020

ADMINISTRATIVE ORDER

No. 2020-0055

SUBJECT: Regulation on Vapor Products and Heated Tobacco Products (HTPs) under the Food and Drug Administration (FDA)

I. RATIONALE

Republic Act (RA) No. 9711, otherwise known as *The Food and Drug Administration (FDA) 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 law, in defining health products, included products that may have an effect on health which require regulations as determined by the FDA, other than food, drugs, cosmetics, devices, biologicals, vaccines, in-vitro diagnostic reagents, and household/urban hazardous substances and/or a combination of and/or a derivative thereof.

Under Sections 144(B) and 144(C) of RA No. 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 RA No. 8424, as Amended, Otherwise Known as the National Internal Revenue Code of 1997, and For Other Purposes*", the 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 the sale to nonsmokers or persons below twenty-one (21) years old.

Likewise, Executive Order (EO) No. 106, s. 2020 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 EO No. 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 implementing the guidelines.

II. OBJECTIVES

This Order provides FDA's regulatory framework for the manufacture, distribution (including online distribution), importation, exportation, sale, offering for sale (including online sale), advertising, promotion, sponsorship, and/or use of vapor products and HTPs in the Philippines.

1

III. SCOPE OF APPLICATION

This issuance shall apply to all vapor products and HTPs, and the entities involved in the manufacture, importation, exportation, sale, offering for sale, distribution (including online distribution), advertising, promotion, sponsorship, and/or use of vapor products and HTPs as defined in RA No. 11467, its Implementing Rules and Regulations (IRR) and this Administrative Order (AO).

This Order shall also apply to the Department of Health (DOH) including its Bureaus, Centers, Services, Centers for Health Development (CHDs), DOH hospitals, Local Government Units (LGUs), other national government agencies (NGAs), private entities, and all others concerned, involved in the implementation of this Order.

IV. DEFINITION OF TERMS

- A. **Advertising** refers to the conceptualizing, presenting, making available, and communicating to the public, through any form of media platforms, any fact, data, or information about the attributes, features, quality, or availability of vapor products and HTPs.
- B. **Advertisement** refers to the form through which the advertising information is disseminated, which includes, but is not limited to print, broadcast, cinema, out-of-home, merchandising materials, digital, social media, and mobile ads.
- C. **Authorization** refers to the 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, implement the use, testing, advertising, promotion, 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 other similar document.
- D. **Batch declaration** refers to the marketing authorization, issued to each manufactured or imported batch of vapor products or HTPs prior to release for sale, offer for sale, or distribution of such particular batch of vapor products or HTPs.
- E. **FDA Electronic Registration Number (FERN)** refers to the product authorization issued by the FDA to FDA-licensed companies, firms, or non-profit organizations to market specific vapor products or HTPs classified as Household/Urban Hazardous Substances (HUHS) and health-related devices in the Philippines.
- F. **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. HTPs include liquid solutions and gels that are part of the product and are heated to generate an aerosol.
- G. **Industry** refers to manufacturers, traders, distributors (importers, exporters, wholesalers), and retailers of vapor products or HTPs.

- H. **Ingredient** refers to any substance that is added to the mixture and present in the finished product.
- I. **Marketing Authorization (MA)** refers to the FDA-issued product certification such as, but not limited to, batch declaration and FERN.
- J. **Marketing Authorization Holder (MAH)** refers to a company, firm, or non-profit organization that has been granted an authorization by the FDA.
- K. **Nicotine shots/concentrates** refer to nicotine in liquid or any other form/substances that may be added to or mixed with a vapor product or HTP refill or cartridge to increase the nicotine dosage or concentration in a refill or cartridge.
- L. **Package** refer to bottles, packs, boxes, cartons, or containers of any kind used on vapor products or HTPs being offered for sale to consumers.
- M. **Post-Marketing Surveillance (PMS)** refer to activities involved in the 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.
- N. **Primary Packaging** refer to any material, including printed material, employed in the packaging of the product, excluding any outer packaging used for transportation or shipment, that is *in direct contact* with the vapor product or HTP refills and cartridges.
- O. **Product Claims** refer to health or therapeutic claims of a product, which indicates 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.
- P. **Promotion** refer to an event or activity organized by or on behalf of a vapor product and/or HTP manufacturer, distributors (importer, exporter, wholesaler), seller or retailer with the aim of promoting vapor product and/or HTP, which event or activity would not occur but for the support given to it by or on behalf of the vapor product and/or HTP manufacturer, distributor (importer, exporter, wholesaler), seller or retailer. It may also refer to the display of vapor product and/or HTP or the manufacturer's name, trademark, logo, and the like on non-vapor product or non-HTPs. This includes the paid use of vapor products and/or HTPs bearing the brand names, trademarks, logos, and the like in movies, television, and other forms of entertainment.
- Q. **Refills and Cartridges** refer to articles, which may or may not contain nicotine, designed to be used in conjunction with vapor product or HTP electronic delivery devices for inhalation.
- R. **Secondary packaging** refer to any material, including printed material, employed in the packaging of the product, excluding any outer packaging used for

transportation or shipment, that is *not in direct contact* with the vapor product or HTP refills and cartridges (e.g. product inserts, tags, etc.).

- S. **Sponsorship** refer to any public or private contribution from vapor product and/or HTP industry in relation to an event, team or activity made with the aim of promoting a brand of vapor products and/or HTPs, 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 and/or HTP industry.
- T. **Vapor Products** shall mean electronic nicotine and non-nicotine delivery systems (ENDS/ENNDS), which are a combination of (i) a liquid solution or gel, that transforms into an aerosol without combustion through the employment of a mechanical or electronic heating element, battery or circuit that can be used to heat such solution or gel and includes but not limited to (ii) a cartridge, (iii) a tank, and (iv) the device without the cartridge or tank. It is commonly known as nicotine salt/salt nicotine, and conventional 'freebase' or classic nicotine, and other similar products.

V. GENERAL GUIDELINES

- A. All establishment covered under this Order shall first secure the appropriate authorizations from the FDA prior to the manufacture, distribution (including online distribution), importation, exportation, sale, offering for sale (including online sale), and advertisement, promotion, and sponsorship of vapor products and HTPs.
- B. The industry shall ensure continuous compliance of all their products with the product standards, including restriction on ingredients and flavors, packaging and labeling, advertising, promotion, sponsorship, as determined by the FDA prior to distribution and/or sale.
- C. 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.
- D. Under this Order, the FDA shall set-up a Novel Tobacco Regulatory Unit (NTRU) under the Center for Cosmetics Regulation and Research (CCRR), which shall develop and implement subsequent issuances and standards to further enhance the implementation of this Order. The unit shall also undertake and/or commission research and development, monitoring and evaluation activities on vapor products and HTPs to inform better decision-making process.
- E. The FDA shall issue implementing guidelines on advertising, promotion and sponsorship, product standards, and packaging and labelling, including primary and secondary packaging, and all other certifications pursuant to RA No. 9711, RA No. 11467 and EO No. 106 and its implementing rules and regulations.



- F. All offices concerned in the implementation of this Order shall adhere to and promote the applicable agreements under the Framework Convention on Tobacco Control (FCTC) and other pertinent international agreements.
- G. The WHO-FCTC Article 5.3 as reinforced by DOH-CSC Joint Memorandum Circular No. 2010-001 shall be strictly observed by all parties in the implementation of this Order.

VI. SPECIFIC GUIDELINES

A. FDA Authorizations

1. All establishments engaged in the manufacture, distribution, importation, exportation, retail sale, including online sale or distribution, of vapor products and/or HTPs shall first secure a License to Operate (LTO) from the Center for Cosmetics Regulation and Research (CCRR) of the FDA prior to operation.
2. All vapor products and HTPs for distribution or sale in the Philippine market shall be registered with the FDA through the FDA Electronic Registration Number (FERN) process.
3. All batches of vapor product and HTP refills and cartridges issued with a FERN certificate, and are for distribution and sale in the Philippines, shall be declared with the FDA through the batch declaration process.
4. The process flow for the issuance of FDA authorizations are provided under **Annex A** (*Authorization Process for Heated Tobacco Products*) and **Annex B** (*Authorization Process for Vapor Products*).
5. Vapor product refills and cartridges with or without nicotine, bearing product claims, such as but not limited to tobacco cessation claims, reduced risk/tobacco harm reduction claims, or containing nicotine concentrations above 65 mg/mL (>65mg/mL) shall comply with the regulatory requirements and standards for drug/pharmaceutical products under the jurisdiction of the Center for Drug Regulation and Research (CDRR).
6. 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 CDRR.

B. Access and Use Restriction

1. Retail of ingredients and materials for the purpose of modification of vapor products and/or 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.



2. No manufacturer, retailer, distributor, importer, exporter, or retailer of vapor products and/or HTPs shall sell to individuals under twenty-one (21) years of age.
3. The Department of Interior and Local Government (DILG), Local Government Units (LGUs), Philippine National Police (PNP), and other government offices involved in the implementation of policies and regulations for vapor products and HTPs, are enjoined to adopt and implement the minimum allowable age for the sale and use of vapor products and HTPs. The sale of vapor products and HTPs shall be made available only to an individual who is able to demonstrate that he/she is 21 years old or older, by presenting any valid government-issued ID that either includes the owner's birthdate or is presented in conjunction with a government-issued certificate supporting the claimed age of the customer.
4. The distribution, sale, offering for sale and use, promotion and advertisement 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.
5. The testing and use of vapor products and HTPs shall be prohibited in enclosed public places, except in approved designated smoking and vaping areas (DSVAs) compliant with the set standards provided under Executive Order No. 26 s. 2017 as amended by Executive Order No. 106 s. 2020.

VII. ROLES AND RESPONSIBILITIES

- A. The **Department of Health (DOH) – Office of the Secretary (OSEC)** shall:
 1. Oversee the FDA's implementation of the provisions under this Order.
 2. Monitor and evaluate the implementation of the provisions under this Order.
 3. Perform such other functions as maybe deemed necessary and consistent with the Department's mandate and jurisdiction.
- B. The following DOH Offices shall have the following the functions:
 1. The **Health Promotion Bureau (HPB)** shall:
 - ii. Develop the guidelines and templates for Graphic Health Warnings (GHWs) on vapor products and HTPs in collaboration with concerned stakeholders.
 - iii. Spearhead in developing policies, standards and guidelines; including promotional, advocacy, and information campaigns for health promotions for population-based health services in relation to the effective implementation of the specific provisions stated under this Order.
 - iv. Provide technical assistance to FDA and other enforcing agencies on the development and implementation of provisions consistent with the National Tobacco Control Strategy (NTCS).
 2. The **Bureau of International Health Cooperation (BIHC)** shall coordinate with the FDA on the pertinent policies, technical collaboration and updates in line with international treaties and conventions

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3. **The Centers for Health Development (CHDs)** shall:
 - i. Encourage Local Government Units (LGUs) and other government institutions within their catchment areas to cooperate and implement relevant provisions of this Order and other initiatives.
 - ii. Provide technical assistance to LGUs and other stakeholders as may be necessary
 - iii. Provide regular reports to the FDA and other DOH offices on activities undertaken relative to the provisions of this Order.

4. **The Food and Drug Administration** shall:
 - i. Take the lead in the regulation of vapor products and heated tobacco products (HTPs).
 - ii. Develop and adopt policies and standards based on evolving medical and scientific studies.
 - iii. Coordinate with the Department of Trade and Industry (DTI) for the adoption and development of standards for vapor products and HTPs.
 - iv. Evaluate applications for LTO, marketing authorizations, and other certifications.
 - v. Issue the appropriate authorizations to vapor product and HTP establishments and products.
 - vi. Coordinate with the Bureau of Internal Revenue (BIR) to streamline processes to complement the taxation process for vapor products and HTPs.
 - vii. Conduct of post market surveillance over vapor product and HTP establishments and products.
 - viii. Collaborate with LGUs and other law enforcement agencies such as, the Metropolitan Manila Development Authority (MMDA), in the monitoring and enforcement of industry compliance and implementation of the regulations.
 - ix. Conduct of research for policy development.
 - x. Establish a reporting system for vapor products and HTPs.

C. **Other Government Offices**

1. **Local Government Units (LGUs)** are enjoined to:
 - i. Develop, promote, and implement Local Smoking Cessation Programs in coordination with the DOH.
 - ii. Develop and implement policies to ensure the effective execution of the specific provisions of this Order.

2. **The Civil Service Commission (CSC)** is enjoined to include vapor products and heated tobacco products in the enactment of the provisions on smoking prohibition and designated smoking area as stated under CSC Memorandum Circular No. 17 s. 2009.

3. **The Land Transportation Franchising Regulatory Board (LTFRB)** is enjoined to include vapor products and heated tobacco products in smoking prohibition in public utility vehicles and transport/terminal area.

VIII. MANDATORY REVIEW

This Administrative Order shall be reviewed by FDA after three (3) years from its implementation date.

IX. TRANSITORY PERIOD

Manufacturers, importers, distributors, and retailers are given an eighteen (18) month transitory period, from the effectivity date of the rules and regulations implementing RA No. 11346 and RA No. 11467, to comply with the new regulations.

The FDA shall issue interim guidelines for the 18-month transitory period.

X. PENALTIES

Violation to any provisions of this Order 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. 11467, Executive Order No. 106 and other penalties provided by other applicable laws.

XI. SEPARABILITY CLAUSE

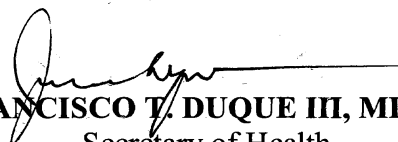
If any provision in this Order, or application of such provision to any circumstances, is held invalid, the remainder of the provisions in this Order shall not be affected.

XII. REPEALING CLAUSE

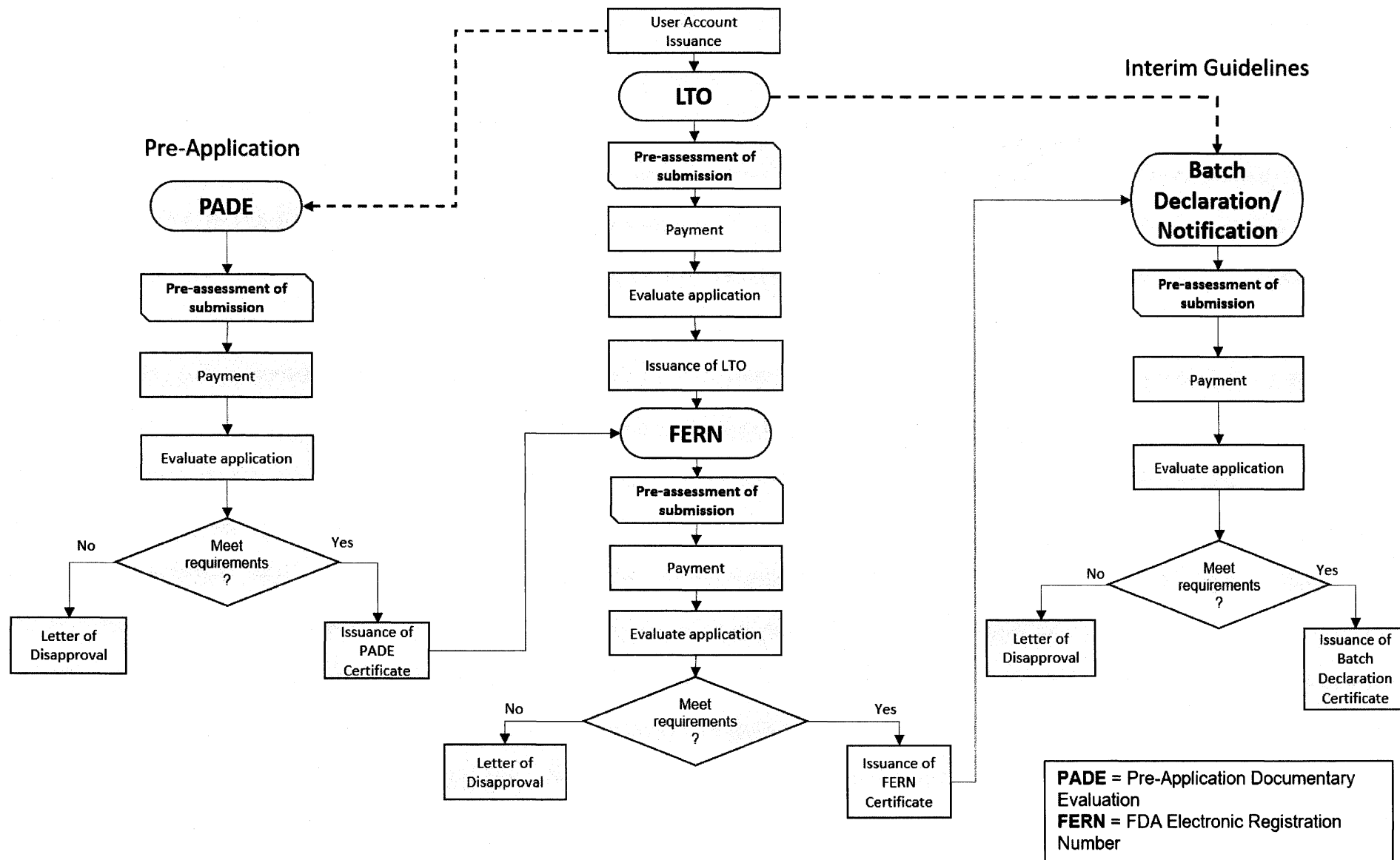
Provisions of other existing Orders or issuances found inconsistent or contrary with this Order are hereby amended accordingly.

XIII. EFFECTIVITY DATE

This Order shall take effect 15 days after publication in a newspaper of general circulation and filing copies thereof with the Office of National Administrative Register of the UP Law Center.

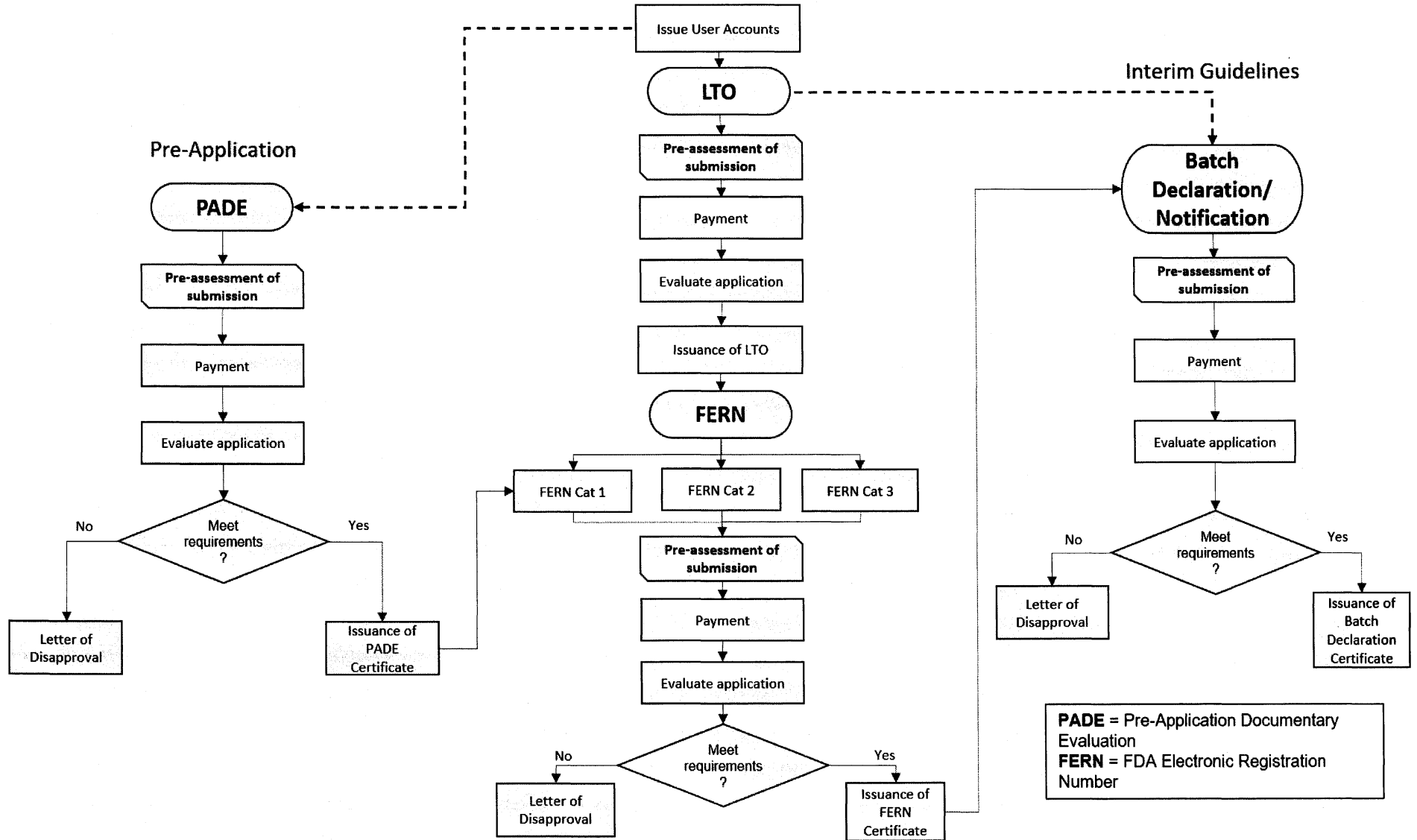

FRANCISCO T. DUQUE III, MD, MSc
Secretary of Health

Annex A
Authorization Process Flow for Heated Tobacco Products (HTPs)



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Annex B
Authorization Process Flow for Vapor Products



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