



Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

JUN 14 2019

ADMINISTRATIVE ORDER

No. 2019-0007

SUBJECT: Revised Rules and Regulations on Electronic Nicotine and Non-Nicotine Delivery System (ENDS/ENNDS)

I. BACKGROUND/RATIONALE

Executive Order No. 102, Redirecting the Functions and Operations of the Department of Health (DOH), mandated the agency to be the over-all technical authority on health in the provision of the national policy direction and develop national plans, technical standards and guidelines on health. Furthermore, the DOH shall pursue and assure promotion of the health and well-being for every Filipino, prevention and control of diseases among population at risk and protection of individuals, families and communities exposed to health hazards & risks.

Republic Act No. (RA) 9711, otherwise known as The Food and Drug Administration Act (FDA) 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.

In line with the intent of RA 9711, the Department of Health (DOH) issued Administrative Order (A.O.) 2014-0008 entitled "Rules and Regulations on Electronic Nicotine Delivery System (ENDS) or Electronic Cigarettes" on 12 March 2014. Under the A.O., electronic cigarettes (e-cigarettes) were classified as health or consumer products under the jurisdiction of the FDA. The Order aims to ensure the safety and quality of ENDS or E-cigarettes by providing pertinent guidelines in the licensing of e-cigarette establishments and registration/notification of their products.

E-cigarettes, including both Electronic Nicotine and Non-nicotine Delivery Systems (ENDS/ENNDS), are used to deliver aerosolized solutions to the lungs, which is similar to the act of smoking. At present, the industry is commonly marketing ENDS/ENNDS as a "safer" or "less harmful" alternative to conventional tobacco products despite the significant level of uncertainty surrounding its safety. The available studies are not enough to clearly and unequivocally conclude that the long-term use of ENDS/ENNDS will not have any harmful effect to human health. There may still be undue harm to health that may be brought about by the use of these products thus, precautionary measures such as regulation by a competent authority is necessary for the protection of public health. Thus, the DOH recognizes the exigency to strengthen its policy for the effective regulation of ENDS/ENNDS products.

II. OBJECTIVES

This Order is being issued to provide an updated policy on ENDS/ENNDS which shall serve as a guide to all individuals, enterprises and businesses which seek to manufacture, distribute, import, export, sell, offer for sale, and/or use these products. It shall also guide other government units and offices, involved in the monitoring and regulation of ENDS/ENNDS use and distribution.

III. SCOPE

This Order shall apply to all individuals and the business sector, which intend to manufacture, distribute, import, export, sell, offer for sale, and/or use ENDS/ENNDS in the Philippines.

This Order does not apply to heated tobacco products (HTPs) and other similar innovations, which use tobacco products.

IV. DEFINITION OF TERMS

1. **Designated Vaping Area** refers to an area of a building or conveyance where vaping may be allowed, which may be in an open space or separate area with proper ventilation subject to the specific standards provided in this order.
2. **Drugs** refer to (a) articles recognized in official pharmacopeias and formularies, including official homeopathic pharmacopeias, or any documentary supplement to any of them, which are recognized and adopted by the FDA; (b) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; (c) articles (other than food) intended to affect the structure of any function of the body of humans or animals; or (d) articles intended for use as a component of any articles specified in clauses (a), (b), or (c) but do not include devices or their components, parts or accessories.
3. **Electronic Nicotine and Non-Nicotine Delivery Systems (ENDS/ENNDS)** are combinations of non-tobacco-containing e-liquids or refills and an electronic delivery device to produce an aerosol, mist, or vapor that users inhale by mimicking the act of smoking.
4. **FDA Electronic Registration Number (FERN)** shall refer to the product certification issued by the FDA to a company, firm or non-profit organization as an authorization to market specific ENDS/ENNDS products in the Philippines.
5. **Globally Harmonized System of Classification and Labelling of Chemicals (GHS)** refers to the system developed by the United Nations for standardizing and harmonizing the classification and labeling of chemicals.



6. **Health Claims** refers to the relationship between the use of ENDS/ENNDS products and reduced risk of disease or health-related condition.
7. **Health Products** means 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. It shall also refer to products that may have an effect on health which require regulations as determined by the FDA.
8. **Health-Related Device** refers to any device not used in health care but has been determined by the FDA to adversely affect the health of the people.
9. **Heated Tobacco Products (HTPs)** refers to a form of tobacco products that uses an electronic device to heat processed tobacco leaves, and produces aerosols for inhalation by mimicking the behavior of smoking conventional cigarettes.
10. **Household/Urban Hazardous Substances (HUHS)** refers to any substance or mixture of substances intended for individual or limited purposes and which is toxic, corrosive, an irritant, a strong sensitizer, is flammable or combustible, or generates pressure through decomposition, heat or other means, if such substance or mixture of substances may cause substantial injury or substantial illness during or as a proximate result of any customary or reasonably foreseeable ingestion by children, but shall not include agricultural fertilizer, pesticide, and insecticide, and other economic poisons, radioactive substance, or substances intended for use as fuels, coolants, refrigerants and the like.
11. **Minimum Allowable Age** shall refer to the age allowed by law to sell, purchase and use ENDS/ENNDS products.
12. **Marketing Authorization** shall refer to the document(s) that is issued by the FDA to a company, firm or non-profit organization as an authorization to market health products in the Philippines.
13. **Marketing Authorization Holder (MAH)** refers to a company, firm or non-profit organization that has been granted a marketing authorization by the FDA.
14. **Nicotine Shots/Concentrates** refers to high strength preparations of flavorless nicotine designed to be added to e-liquid preparations to increase its nicotine content.
15. **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.



16. **Smoking Cessation Aid** refers to pharmacological aids to smoking cessation; Smoking cessation aids which are approved prescription or non-prescription medication, which may form part of a comprehensive smoking cessation program or strategy which includes counselling, behavior change and/or various forms of support.

V. GUIDING PRINCIPLES

1. **Precautionary Principle.** The principle that the introduction of a new product or process whose ultimate effects are disputed or unknown should be treated with precaution. With insufficient scientific evidences on the safety profile of innovative products such as ENDS/ENNDS, the DOH shall take precautionary measures to ensure the protection of the right to health of the public. In this regard, e-cigarettes shall be classified as a health product and shall be regulated accordingly.
2. **Classification of Product.** E-liquids and refills, with or without the presence of nicotine, but bear therapeutic or health claims such as but not limited to cessation aide and/or harm reduction for smoking, or are marketed as such shall be classified as a drug product. E-liquids and refills, with or without the presence of nicotine, that do not bear therapeutic or health claims shall be classified as Household/Urban Hazardous Substances (HUHS). The electronic delivery devices, including its components used for modification shall be classified as health-related device.
3. **Research and Development.** Continuous research study and analysis shall be conducted by the DOH on ENDS/ENNDS, including emerging and novel tobacco products, to increase its competency for the development of new and existing policies for these products.
4. **Protection of the Bureaucracy Against Tobacco Industry Interference.** DOH-CSC Joint Memorandum Circular (JMC) 2010-001 shall be strictly observed in the implementation of this Order.
5. **WHO Framework Convention on Tobacco Control.** The FDA shall adhere to and promote the applicable agreements under the Framework Convention on Tobacco Control (FCTC) and other pertinent international agreements.

VI. GENERAL GUIDELINES

1. All establishments engaged in the manufacture, distribution, importation, exportation, sale including online sale, offering for sale, and transfer of ENDS/ENNDS products shall first secure a License to Operate (LTO), following

the procedure stipulated under Administrative Order 2016-0003 and its amendments.

2. Only establishments with a valid FDA-issued LTO can apply for a product marketing authorization, such as Certificate of Product Registration (CPR) or FDA Electronic Registration Number (FERN).
3. Establishments seeking to market e-liquids and refills classified as drug products shall comply with the regulatory requirements for pharmaceutical products under the Center for Drugs Regulation and Research.
4. No establishment shall engage in the manufacture, distribution, importation, exportation, sale, offering for sale, and transfer of ENDS/ENNDS products without first securing the necessary marketing authorizations.
5. 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 ENDS/ENNDS products, 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") unless with written permission from the agency.
6. All refills and devices shall be child-resistant, tamper resistant, and shall be protected against breakage and leakage.
7. Containers and packages of electronic delivery devices, e-liquids and refill shall contain appropriate health warnings, whose content, format, and specifications, are designated by the FDA, based on the declaration of ingredients or components of the same product. (see Annex A)
8. The FDA shall set standards and necessary restrictions on flavors and additives used in the manufacture of e-liquids and refills. The FDA shall also impose a ban on flavors and additives that are proven or suspected to be appealing to the youth, toxic, harmful, addictive, or sensitizing
9. The retail sale of nicotine shots and/or concentrates shall be strictly prohibited.
10. A comprehensive ban on any form of advertising, promotion and sponsorship, including corporate social responsibility campaigns by the industry, of ENDS/ENNDS products, shall be implemented upon approval of this Order.
11. Establishments shall be inspected by the FDA prior and/or after the issuance of the license.

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12. Purchase, sale, and use of ENDS/ENNDS below the minimum allowable age shall be strictly prohibited.
13. The distribution, sale and offering for sale and use of ENDS/ENNDS shall be strictly prohibited in places where sale and use of cigarettes are prohibited.
14. The use of ENDS/ENNDS shall be banned in places where smoking is prohibited.
15. Designated vaping areas (DVAs), including vaping lounges and the like, shall follow the same guidelines and requirements set for DSAs as provided under section 4 of Executive Order No. 26 s. 2017.
16. Local Government Units (LGUs), and other government units and offices involved in the monitoring and regulation of ENDS/ENNDS use, sale and distribution are enjoined to observe and implement the guidelines provided under this Order. LGUs shall have the authority to adopt or enact more stringent measures to exercise their power under the General Welfare clause.
17. The FDA shall not be precluded from the issuance of subsequent regulations or regulatory actions for the protection of public health.

VII. SPECIFIC GUIDELINES

A. Industry Application of FDA Electronic Registration Number (FERN) for HUHS E-liquids and Refills

1. The application process shall be through FDA's current licensing and registration system for ENDS/ENNDS products.
2. Application for FERN of e-liquids and refills shall be per formulation.
3. E-liquid and refills with Hazard Categories 1 and 2 in any of the health and environmental hazard classes under the prevailing GHS revision shall not be allowed for FERN application.
4. The maximum allowable nicotine content for e-liquids and refills shall be twenty (20) mg/mL.
5. E-liquid and refill containers, with or without nicotine, shall only be allowed to have a maximum volume of ten (10) mL.



6. Administrative and technical product documents as listed in **Annex B** shall be submitted as part of the FERN application process depending on the type of application.
7. Commercial product label shall follow the guidelines and requirements for labelling of hazardous substances stated under Administrative Order No. 311 s. 1977 and Republic Act 7394 s. 1992, while the Globally Harmonized System of Classification and Labeling of Chemicals shall be optional.
8. Schedule of fees is provided under **Annex C** of this Order.
9. Applications determined to have complied with FDA's requirements and standards shall be approved while applications deemed to be incomplete, inconsistent or incorrect shall automatically be disapproved.
10. Decision for the application, whether for the issuance of a FERN or Letter of Disapproval (LOD) shall be sent through FDA's current licensing and registration system, as may be applicable.
11. The MAH shall be responsible for ensuring the continuous compliance of their products placed on the market to FDA-issued standards and guidelines.

B. Industry Application of FDA Electronic Registration Number (FERN) for Electronic Delivery Devices

1. Application process will be through FDA's current licensing and registration system for ENDS/ENNDS products.
2. Tanks of electronic delivery devices shall only be allowed to have a maximum capacity of two (2) mL.
3. All documentary and technical requirements (**Annex D**) shall be submitted accordingly based on the type of application.
4. Schedule of fees is provided under **Annex C** of this Order.
5. Applications determined to have complied with FDA's requirements and standards shall be approved while applications deemed to be incomplete or incorrect shall automatically be disapproved.
6. Decision for the application, whether for the issuance of a FERN or Letter of Disapproval (LOD) shall be sent through FDA's current licensing and registration system.



7. The MAH shall be responsible for ensuring the continuous compliance of their products placed on the market to FDA-issued standards and guidelines.

VIII. CREATION OF THE FDA EXECUTIVE COUNCIL ON ENDS/ENNDS

The FDA shall create an Executive Council on ENDS/ENDDDS which will exercise oversight functions on the regulation of ENDS/ENNDS.

IX. LEGAL FUND

In the event that any legal action, suit, or proceeding arising from or related to this AO is initiated against the FDA or its officials and employees in the course of the exercise of their official functions and duties, the costs and expenses incurred in connection with such action, suit, or proceeding, including attorney's fees, shall be paid from the Legal Fund [pursuant to Section 18 of RA 9711 and Article II.B, Section 8 of its Implementing Rules and Regulations].

X. PENALTIES

Violation to any of the 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, and other penalties provided by other applicable laws.

XI. TRANSITORY PERIOD

A transitory period of not more than three (3) months from the date of effectivity of this Order shall be provided to allow all covered establishments to comply with the new guidelines.

ENDS/ENNDS products verified to be unregistered after the given grace period shall be subject to seizure, and persons, establishments including the officers and directors, responsible for their distribution or introduction in the Philippines shall be subject to the imposition of appropriate regulatory actions after due process.

XII. SEPARABILITY CLAUSE

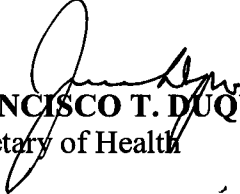
If, for any reason, any section or provision of this Order is declared invalid, illegal or unconstitutional, such invalidity or unconstitutionally shall not affect the other provisions of this Order, which will remain in full force and effect.

XIII. REPEALING CLAUSE

This policy repeals A.O. 2014-0008 entitled “Rules and Regulations on Electronic Nicotine Delivery System (ENDS) or Electronic Cigarettes.” Provisions of other existing Orders or issuances found inconsistent or contrary with this Order are hereby amended accordingly.

XIV. EFFECTIVITY

This Order shall take effect fifteen (15) days after its publication on newspaper/s of general circulation in the Philippines and filing with the Office of the National Administrative Register.


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

ANNEX A

Labelling Requirements for HUHS E-Liquids and Refills

Sample Package Labelling Template

Front Panel

- QR Code
 - * Instructions for use
 - * Notes to physician
 - * NPCC contact number
 - * FDA contact number
- 30 ml — Net weight/volume
- ABC — Brand Name
- Ice 70/30 — Variant
- 10mg/ml nicotine — Nicotine Concentration
- This product contains nicotine. Nicotine is an addictive chemical. — Health Warning
- Store at temperature not more than 30°C — Storage Requirement
- Keep out of reach of children — Precautionary Statement

Back Panel

- Ingredients: Propylene glycol, vegetable glycerine, nicotine, bean flavor
- Expiration Date & Batch Number
- Pictogram and Signal Word
- Hazard Statement
- Company Name
- Company Address
- Company Contact Details
- FDA Electronic Registration Number (FERN)
- FERN-0000001

Front and Left Panel

- FDA Contact Number
- National Poison Control Center Contact Number
- 30 ml — Net weight/volume
- ABC — Brand Name
- Ice 70/30 — Variant
- 10mg/ml nicotine — Nicotine Concentration
- This product contains nicotine. Nicotine is an addictive chemical. — Health Warning
- Keep out of reach of children — Precautionary Statement

Back and Right Panel

- Instructions for Use
- Notes to Physicians
- Ingredients: Propylene glycol, vegetable glycerine, nicotine, tobacco flavor
- Storage Requirements
- Company Name
- Company Address
- Company Contact Details

ANNEX B

List of Documentary Requirements for FDA Electronic Registration Number of HUHS E-Liquids and Refills

1. A validity of 1 year for initial issuance of FERN to HUHS e-liquids and refills, while renewal shall have an optional validity of one to three (1 to 3) years.
2. Product variations shall require initial filing of FERN application.
3. Products without variations can apply for the renewal of its FERN.

Initial Application	<ol style="list-style-type: none">1. Declaration and Oath of Undertaking and Accomplished Online Application Form2. Full Ingredient Listing (in descending order); In the product ingredient list, all ingredients must be specified by using the chemical names with CAS number. Botanicals and extracts of botanicals should be identified by its genus and species. The genus may be abbreviated. The functions and percentages of ingredients must be declared.3. Pack Sizes4. Technical Specifications of the Finished HUHS Product5. Certificate of Analysis of the Finished HUHS Product6. GHS Classification of Finished Product7. Primary and secondary commercial label bearing the following required information:<ol style="list-style-type: none">a. Brand Nameb. Variantc. Net Volumed. Full Ingredient Listing (<i>descending order</i>)e. Nicotine Strength (<i>if applicable</i>)f. Pictogram and Signal Word (<i>optional</i>)g. Hazard Statement (<i>optional</i>)h. Health Warningi. Precautionary Statementj. Batch Numberk. Expiry Datel. Storage Requirementm. FDA Electronic Registration Number (FERN)n. Name of marketing authorization holder (MAH)o. Registered address of MAH (as reflected on LTO)p. Contact details of MAHq. Instructions for User. First Aid Notes to Physicians. National Poison Control Center Contact Numbert. FDA Contact Number
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ANNEX B

List of Documentary Requirements for FDA Electronic Registration Number of HUHS E-Liquids and Refills

	<ol style="list-style-type: none">8. Stability Study (Accelerated or Real-time) per packaging type9. Payment
Renewal	<ol style="list-style-type: none">1. Declaration and Oath of Undertaking2. Accomplished Application Form3. Full Ingredient Listing (in descending order); In the product ingredient list, all ingredients must be specified by using the chemical names with CAS number. Botanicals and extracts of botanicals should be identified by its genus and species. The genus may be abbreviated. The functions and percentages of ingredients must be declared.4. Payment

ANNEX C

Schedule of Fees for the Licensing and FDA Electronic Registration Number (FERN) Application of ENDS/ENNDS

License to Operate (LTO)	
Retailers (<i>Retail Outlet, Online Sellers</i>)	₱ 5,000.00 + LRF per year
Distributors (<i>Importers, Exporters, Wholesalers</i>)	₱ 10,000.00 + LRF per year
Traders	₱ 10,000.00 + LRF per year
Manufacturers	₱ 15,000.00 + LRF per year
LTO Variation	
Major and/or Minor	₱ 1,000.00 + LRF / application

FDA Electronic Registration Number (FERN)	
Initial Application (1 year)	
HUHS E-Liquids and Refills	₱ 5,000.00 + LRF
Electronic Delivery Devices	₱ 10,000.00 + LRF
Renewal Application (maximum 5 years)	
HUHS E-Liquids and Refills	₱ 3,000.00 + LRF per year
Electronic Delivery Devices	₱ 8,000.00 + LRF per year

ANNEX D

List of Documentary Requirements for FDA Electronic Registration Number of Electronic Delivery Devices

1. Initial FERN issued to electronic delivery devices shall have a validity of one (1) year and a renewed FERN shall be valid for three (3) years.
2. Product variations shall require initial filing of FERN application.
3. Products without variations can apply for the renewal of its FERN.

Initial Application	<ol style="list-style-type: none">1. Declaration and Oath of Undertaking2. Accomplished Online Application Form3. Certificate of Conformity from DTI4. Technical Specifications of the Device<ol style="list-style-type: none">a. Detailed diagram of the device showing all partsb. Materials composition of the device5. Certificate of Analysis for the migration of specific metals6. Commercial Label containing the following<ol style="list-style-type: none">a. Brand Nameb. Device Modelc. Battery Capacityd. Name of marketing authorization holder (MAH)e. Registered Address of MAHf. Contact details of MAHg. Instructions for Useh. Maintenance Instructionsi. Instructions for Disposalj. Country of Manufacturek. Batch Numberl. FDA Electronic Registration Number (FERN)7. Payment
Renewal	<ol style="list-style-type: none">1. Declaration and Oath of Undertaking2. Accomplished Application Form3. Payment