Republic of the Philippines
Department of Education
Region II – Cagayan Valley
Schools Division of Nueva Vizcaya

2 September 2024

DIVISION MEMORANDUM
No. 367 , s. 2024

REITERATION OF DM 111, s2019 PROHIBITING THE USE OF E-CIGARETTES AND OTHER ELECTRONIC NICOTINE AND NON-NICOTINE DELIVERY SYSTEM AND REITERATING THE ABSOLUTE TOBACCO SMOKING BAN IN SCHOOLS AND DEPED OFFICES

To: Assistant Schools Division Superintendent
School Governance and Operations Division Chief
Curriculum Implementation Division Chief
Education Program Supervisors
Public Schools District Supervisors/District In-Charge
Public and Private Elementary and Secondary School Heads
Secondary School Nurses/District Nurses
All others concerned

In accordance with the Department of Education (DepEd) Memo No. 111, s. 2019, **this memo serves to reiterate the prohibition on the use of electronic nicotine and non-nicotine delivery systems (ENDS/ENNDS) and to remind all personnel and learners of the absolute ban on tobacco smoking within all DepEd premises.**

1. Electronic Nicotine and Non-Nicotine Delivery Systems (ENDS/ENNDS)

The Department of Health (DOH), as the primary technical authority on health policies in the Philippines, issued Administrative Order No. 2019-0007 on June 14, 2019, titled "Revised Rules and Regulations on Electronic Nicotine and Non-Nicotine Delivery Systems (ENDS/ENNDS)." This AO provides an updated policy on the use and regulation of these devices.

Definitions:

- ENDS/ENNDS are defined as combinations of non-tobacco-containing e-liquids or refills and electronic delivery devices that produce aerosol, mist, or vapor, mimicking the act of smoking. Commonly, these devices are known as e-cigarettes or vapes.

Prohibitions:

- The DOH AO 2019-0007 strictly prohibits the distribution, sale, offering for sale, and use of ENDS/ENNDS in places where the sale and use of cigarettes are already prohibited.
- The use of ENDS/ENNDS is banned in places where smoking is prohibited.

2. Absolute Tobacco Smoking Ban

As reiterated in DepEd Order (DO) No. 48, s. 2016 (Policy and Guidelines on Comprehensive Tobacco Control), Civil Service Commission Memorandum Circular No. 17, s. 2009 (100% Smoke-Free Environment Policy), and DOH Administrative Order No. 2017-0023 (Guidelines in the Effective Implementation and Enforcement of Executive Order No. 26: Establishing Smoke-Free Environments in Public and Enclosed Spaces), the sale and use of cigarettes (smoking) are strictly and absolutely prohibited within all schools and offices of the Department of Education.

3. Compliance and Enforcement

All DepEd personnel, school heads, teachers, and students are hereby directed to comply strictly with these regulations. School heads and office administrators are responsible for enforcing this policy within their respective areas of jurisdiction.

Let us work together to ensure a safe and healthy environment for all members of our educational community.

For strict compliance.

ORLANDO E. MANUEL, PhD., CESO V
Schools Division Superintendent
Office of the Schools Division Superintendent

09-2024-249

09-13-24

DEPARTMENT OF EDUCATION
RELEASED
Date: 9/5/24
Time: 3:10
By:
DIVISION OF NUEVA VIZCAYA

Republic of the Philippines

Department of Education

30 AUG 2019

DepEd MEMORANDUM
No. 111 , s. 2019

PROHIBITING THE USE OF E-CIGARETTES AND OTHER ELECTRONIC NICOTINE AND NON-NICOTINE DELIVERY SYSTEM AND REITERATING THE ABSOLUTE TOBACCO SMOKING BAN IN SCHOOLS AND DEPED OFFICES

To: Undersecretaries
Assistant Secretaries
Bureau and Service Directors
Minister, Basic, Higher, and Technical Education, BARMM
Regional Directors
Schools Division Superintendents
Public and Private Elementary and Secondary School Heads
All Others Concerned

1. The Department of Health (DOH), as the over-all technical authority in the provision of the national policy direction on health, issued Administrative Order No. 2019-0007 entitled the **Revised Rules and Regulations on Electronic Nicotine and Non-Nicotine Delivery System (ENDS/ENNDS)** on June 14, 2019, providing an updated policy on ENDS/ENNDS (Enclosure No. 1).

2. As defined by the DOH AO 2019-0007, 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." These include devices that are commonly known as e-cigarettes or vapes.

3. DOH AO 2019-0007 provides that "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," and that "the use of ENDS/ENNDS shall be banned in places where smoking is prohibited."

4. It is reiterated that the **sale and use of cigarettes (smoking) are absolutely prohibited in schools and offices of the Department of Education (DepEd)**, pursuant to DepEd Order (DO) No. 48, s. 2016, or the Policy and Guidelines on Comprehensive Tobacco Control, Civil Service Commision Memorandum Circular No. 17, s. 2009, entitled Smoking Prohibition Based on 100% Smoke-Free Environment Policy, and DOH Administrative Order No. 2017-0023, or Guidelines in the Effective Implementation and Enforcement of Executive Order (EO) No. 26: Providing for the Establishment of Smoke Free Environments in Public and Enclosed Places.

5. In view thereof, **the distribution, sale and offering and use of ENDS/ENNDS are hereby prohibited in all schools and DepEd offices**.

6. DOH AO 2019-0007 further provides the following General Guidelines:

a. 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 (DOH AO 2019-0007).
b. Purchase, sale, and use of ENDS/ENNDS below the minimum allowable age shall be strictly prohibited.
c. Local Government Units are enjoined to observe and implement the guidelines provided under this Order (DOH AO 2019-0007). LGUs have the authority to adopt or enact more stringent measures to exercise their power under the General Welfare clause.

7. In line with DO 48, s. 2016, all schools, through their respective Child Protection Committees, and all regional and schools division offices, with the technical assistance of their designated Tobacco Control Coordinators, are directed to:

a. ensure the enforcement of the ban on the distribution, sale and offering, and use of ENDS/ENNDS and tobacco products (e.g., cigarettes) in all schools and DepEd offices;
b. ensure the implementation of the ban on any form of advertising, and promotion of ENDS/ENNDS and tobacco products, and on sponsorship, including corporate social responsibility by the ENDS/ENNDS or the tobacco industry, in all premises and activities of all schools and DepEd offices; and
c. coordinate and collaborate with their respective local government units, in observing and ensuring the implementation of the guidelines provided under DOH AO 2019-0007, including the prohibition of the use of ENDS/ENNDS among young people who are below the minimum allowable age, and in adopting or enacting more stringent measures, when necessary.

8. Violations committed by learners shall be handled in accordance with DO 40, s. 2012 entitled DepEd Child Protection Policy.

9. For violations committed by DepEd personnel, DO 49, s. 2006 entitled Revised Rules of Procedure in Administrative Cases, shall be followed. Violations of CSC MC 17, s. 2009, and the CSC-DOH Joint Memorandum Circular 2010-01, or the Protection of the Bureaucracy Against Tobacco Industry Interference may also be reported to the CSC through the Civil Service Commission's Guide for Resolving/Filing Cases of Tobacco Industry Interference in the Bureaucracy.

10. Learners and personnel who are in need of brief tobacco intervention and/or referral to cessation services shall continue to be provided with such services. Enclosed are information about the DOH Quitline (Enclosure No. 2).

11. To support the enforcement on the bans on ENDS/ENNDS, all schools, with the technical assistance of the concerned offices at the central, regional, and schools division offices, are also instructed to **educate learners about ENDS/ENNDS through curricular, co-curricular, and extra-curricular activities**, whenever appropriate and applicable. A compilation of reference materials and researches related to ENDS/ENNDS are accessible through bit.ly/endsandennds.

12. For more information, please contact the **Bureau of Learner Support Services-School Health Division**, 4th Floor, Mabini Building, Department of Education Central Office, DepEd Complex, Meralco Avenue, Pasig City through email at blss.shd@deped.gov.ph (using the Subject Title: ENDS/ENNDS) or telephone no. (02) 632-9935.

13. Immediate dissemination of this Memorandum is desired.

LEONOR MAGTOLIS BRIONES
Secretary

Encls.:
As stated

References:
DepEd Order: (Nos. 40, s. 2012; 49, s. 2006; 48, s. 2016)

To be indicated in the Perpetual Index
under the following subjects:

BUREAUS AND OFFICES
EMPLOYEES
HEALTH EDUCATION
OFFICIALS
POLICY
RULES AND REGULATIONS
SCHOOLS

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 ~~**21 years of age for the purpose of this Order**~~ 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.

12. ~~The minimum allowable age for purchase, sale, and use of ENDS/ENNDS shall be set at 21 years old.~~ 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 HUIIS 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 ~~ten (10)~~ twenty (20) mg/ml.

5. E-liquid and refill containers, with or without nicotine, shall only be allowed to have a maximum volume of ~~thirty (30) mL~~ 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 appr ved 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.

2019

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/ENDDS 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 unconstitutionality 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

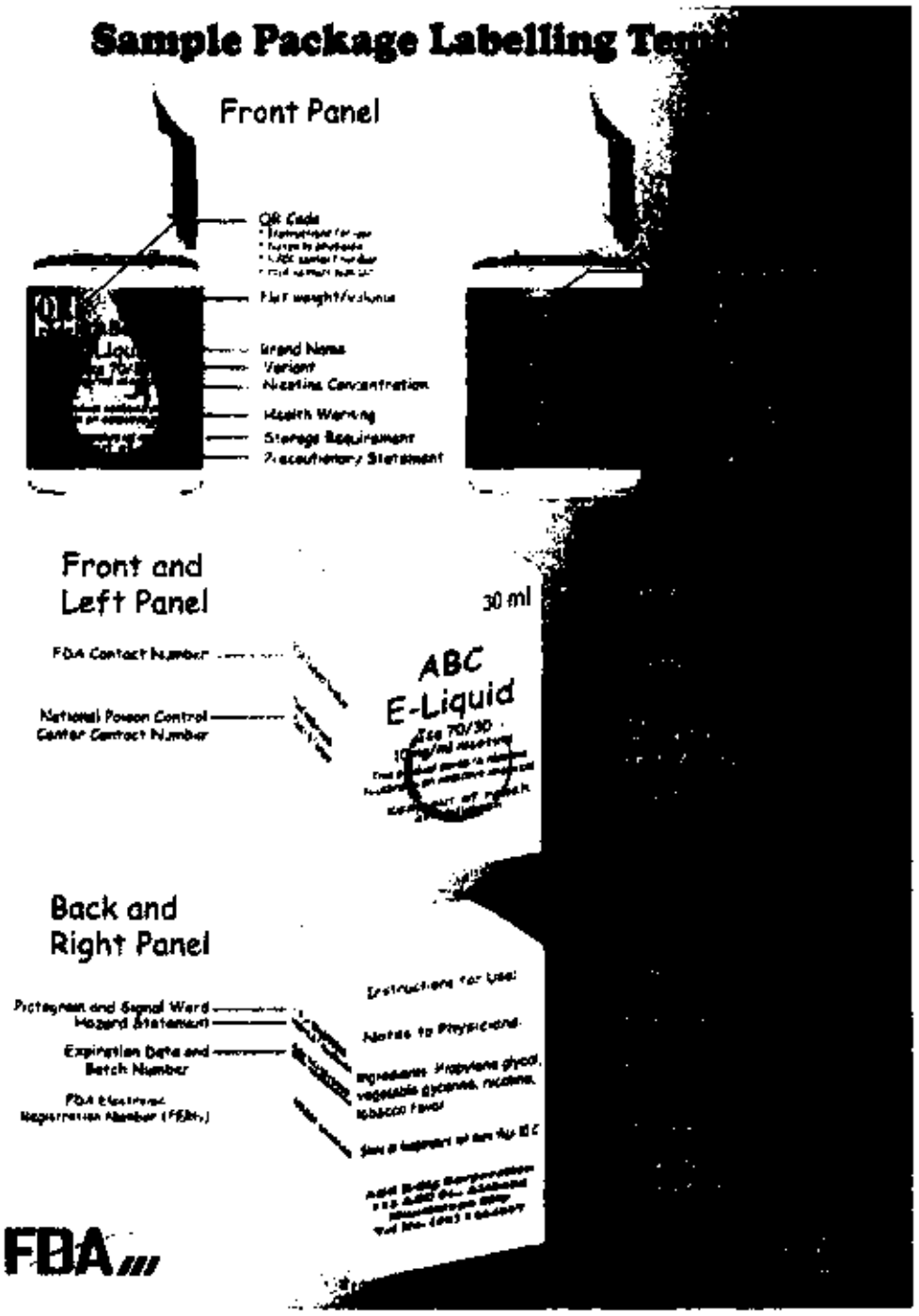
This Order shall take effect fifteen (15) days after its publication on newspaper/s of general circulation in the Philippines and filing with the Office of the National Administrative Register.

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

2013

ANNEX A

Labelling Requirements for HCHS E-Liquids and Refills



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	1. Declaration and Oath of Undertaking and Accomplished Online Application Form 2. 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 Sizes 4. Technical Specifications of the Finished HUHS Product 5. Certificate of Analysis of the Finished HUHS Product 6. GHS Classification of Finished Product 7. Primary and secondary commercial label bearing the following required information: a. Brand Name b. Variant c. Net Volume d. Full Ingredient Listing (*descending order*) e. Nicotine Strength (*if applicable*) f. Pictogram and Signal Word (*optional*) g. Hazard Statement (*optional*) h. Health Warning i. Precautionary Statement j. Batch Number k. Expiry Date l. Storage Requirement m. 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 MAH q. Instructions for Use r. First Aid Notes to Physician s. National Poison Control Center Contact Number t. FDA Contact Number

ANNEX B

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

	8. Stability Study (Accelerated or Real-time) per packaging type 9. Payment
Renewal	1. Declaration and Oath of Undertaking 2. Accomplished Application Form 3. 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 *(Retail Outlet, Online Sellers)*	₱ 5,000.00 + LRF per year
Distributors *(Importers, Exporters, Wholesalers)*	₱ 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	1. Declaration and Oath of Undertaking 2. Accomplished Online Application Form 3. Certificate of Conformity from DTI 4. Technical Specifications of the Device a Detailed diagram of the device showing all parts b Materials composition of the device 5. Certificate of Analysis for the migration of specific metals 6. Commercial Label containing the following a Brand Name b. Device Model c. Battery Capacity d. Name of marketing authorization holder (MAH) e. Registered Address of MAH f Contact details of MAH g. Instructions for Use h. Maintenance Instructions i Instructions for Disposal j Country of Manufacture k. Batch Number l FDA Electronic Registration Number (FERN) 7. Payment
Renewal	1. Declaration and Oath of Undertaking 2. Accomplished Application Form 3. Payment

DOH QUITLINE

CALL **165-364**

Free for Metro Manila callers ONLY

0921-2039534
(Smart/TNT/Sun)

0977-6277539
(Globe/TM)

QUIT SMOKING BEFORE IT KILLS YOU!

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