



Republic of the Philippines
House of Representatives
Quezon City

EIGHTEENTH CONGRESS

First Regular Session

House Bill No. 2277



Introduced by Representative Jose Enrique Garcia III

EXPLANATORY NOTE

International experts and health ministries worldwide are one in recognizing the detrimental effects of nicotine addiction and the health risks that unrestricted use, sale, distribution, advertisement, promotion, and sponsorship of electronic cigarette devices or e-cigarette and nicotine-containing e-liquids may have on the population.

In the recent Conference of Parties to the World Health Organization Framework Convention on Tobacco Control (FCTC), where the Philippines is a signatory, State parties were directed to regulate these evolving products either by banning or putting strict restrictions on their manufacturing, importation, distribution, presentation, and sale-taking into account the imperative of a high level of protection for human health.¹

More than 45 countries including Argentina, Austria, Belgium, Brazil, Brunei, Colombia, Egypt, Indonesia, Jordan, Malaysia, Mexico, Oman, Panama, Singapore, Taiwan, Tajikistan, Thailand, Turkey, United Arab Emirates, Uruguay, Venezuela have banned the use, sale and distribution e-cigarettes. Many more have established strong regulations that put public health interests-especially of the youth, who are most vulnerable to nicotine addiction-above commercial rights.

In the Philippines, the “backyard manufacturing” of e-cigarette flavorings and e-juices have become rampant². The fact that local manufacturers could mix their own juices and flavorings sans public disclosure of ingredients and solutions used is very alarming. Unless, sooner halted, this “backyard manufacturing” could no longer be controlled.

Electronic Nicotine and Non-nicotine Delivery Systems (ENDS/ENNDS), also known as e-cigarettes, are used to deliver aerosolized solutions to the lungs, which is similar to the act of

¹ Electronic Nicotine Delivery Systems and Electronic Non-Nicotine Delivery Systems (ENDS/ENNDS), Report by WHO, Conference of the Parties to the WHO Framework Convention on Tobacco Control, FCTC/COP/7/11 (Aug. 2016).

² Investigative Report dated 24 July 2013 from Rappler. Retrieved from www.rappler.com.

smoking.³ At present, the industry is commonly marketing e-cigarettes as “safer” or “less harmful” and “effective cessation device” alternative to conventional tobacco products despite the significant level of uncertainty surrounding their safety.

Electronic cigarette products are also not tested for electrical or mechanical safety and this has resulted to injuries, even death. In fact, media reports of exploding e-cigarette products have become increasingly common, with more than 200 reports of related explosions all over the world. In the Philippines, the recent case of a minor who fell victim to the explosion of an e-cigarette device attests to the need of subjecting these products to rigorous testing and quality control.

Retailers in the country rarely sell the products without nicotine. Most e-juices contain nicotine and some even have misleading descriptions. For instance, some locally manufactured e-juice state that they “may contain nicotine” in their labels.⁴ For a chemical that is known to be a health hazard and highly addictive, nicotine use is especially dangerous to the youth. Numerous scientific studies have shown that nicotine “rewires” the brain towards lifelong addiction, causing multiple negative behavioral and mental issues.⁵

Because the importation of e-cigarette products remains unregulated, there was also a reported incident of illegal importation at an airport of e-cigarette products which were found to contain illegal drugs.⁶

The widespread availability and popularity of flavored e-cigarettes among the youth is also undeniable. Vape shops’ close proximity to schools and other places frequented by minors is highly suggestive that e-cigarette manufacturers and retailers are targeting the younger segment of the population. Studies have shown that children and adolescents who take up the habit of e-cigarettes not only become addicted to the products but end up smoking cigarettes, as well.⁷

Numerous studies have consistently found that e-cigarette use re-normalizes and promotes cigarette smoking. As a matter of fact, while marketed as an alternative to tobacco use, a recent study by the University of California revealed that the use of e-cigarettes actually reduces the likelihood that people would quit smoking. Instead of quitting tobacco, they just eventually become dual users.⁸ This is also the experience in the United Kingdom based on a 12-month prospective study published in 2018.⁹ This correlation makes e-cigarettes especially dangerous to non-smokers and the youth.

Republic Act No. 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

³ World Health Organization. Electronic Nicotine Delivery Systems and Electronic Non-Nicotine Delivery Systems (ENDS/ENNDS): Report by WHO. Seventh session of the Conference of Parties to the WHO Framework Convention on Tobacco Control provisional agenda item 5.5.2. FCTC/COP/7/11 (August 2016).

⁴ Tobacco and E-Cigarette Industry Interference in Public Health Policy in the Philippines, p. 12.

⁵ Arain, M., Haque, M., Johal, L., Mathur, P., Nel, W., Rais, A., ... Sharma, S. (2013). Maturation of the adolescent brain. *Neuropsychiatric disease and treatment*, 9, 449–461. doi:10.2147/NDT.S39776.

⁶ GMA News Network dated 1 March 2018.

⁷ Palazzolo D. L. (2013). Electronic cigarettes and vaping: a new challenge in clinical medicine and public health. A literature review. *Frontiers in public health*, 1, 56. doi:10.3389/fpubh.2013.00056.

⁸ Glantz, S. A., & Bareham, D. W. (2018). E-Cigarettes: Use, Effects on Smoking, Risks, and Policy Implications. *Annual review of public health*, 39, 215–235. doi:10.1146/annurev-publhealth-040617-013757.


⁹ Conner, M. et al. “Do electronic cigarettes increase cigarette smoking in UK adolescents? Evidence from a 12-month prospective study.” Available at <https://www.ncbi.nlm.nih.gov/pubmed/28818839>.

of the Filipino people and help establish and maintain an effective health product regulatory system based on the country's health needs and problems.

However, there has been no single e-cigarette product which has been given the required Certificates by the FDA, making them unsafe for consumption.

For this reason, along with the widely documented adverse public health implications¹⁰ and their increasing popularity among Filipino youth,¹¹ the effective national regulation of e-cigarettes products has become urgent.

Support for this bill is therefore earnestly sought from my colleagues.


REP. JOSE ENRIQUE S. GARCIA III
Second District, Bataan

¹⁰ See U.S. Department of Health and Human Services. E-Cigarette Use Among Youth and Young Adults: A Report of the Surgeon General. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2016.

¹¹ Department of Health & Philippine Statistics Authority. Global Adult Tobacco Survey: Country Report 2015, at pp. 47-48.



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AN ACT
REGULATING THE MANUFACTURE, IMPORTATION, SALE,
DISTRIBUTION, USE, ADVERTISEMENT, PROMOTION AND
SPONSORSHIP OF ELECTRONIC CIGARETTES AND FOR OTHER
PURPOSES

Be it enacted by the Senate and House of Representatives of the Philippines in Congress assembled:

1 **SECTION 1. Short Title.** – This Act shall be known as the “*Electronic Cigarette*
2 *Regulation Act of 2019.*”

3
4 **SECTION 2. Declaration of Policy.** – It is hereby declared the policy of the State to
5 protect and promote the right to health and instill health consciousness among them.

6
7 It is further declared the policy of the State to adopt a preventive approach whereby
8 unless scientifically proven to be safe, the public shall not be exposed to products that may
9 have detrimental or hazardous effect on health. For these purposes, the government shall
10 regulate the manufacture, importation, sale, distribution, use, advertisement, promotion and
11 sponsorship of electronic cigarettes and heated tobacco products in order to promote a healthy
12 environment and protect the citizens from any hazards of electronic cigarettes and heated
13 tobacco products.

14
15 **SECTION 3. Construction.** – The paramount public’s right to health shall be considered
16 in the interpretation, application, implementation and enforcement of the provisions of this Act,
17 including its implementing rules and regulations.

18
19 **SECTION 4. Definition of Terms.** – For purposes of this Act, the following terms shall
20 mean:

21
22 a. “Advertising” refer to the business of conceptualizing, presenting, making
23 available, and communicating to the public, through any form of mass media, any fact, data, or
24 information about the attributes, features, quality, or availability of consumer products, services,
25 or credit. For the purpose of this Act, advertising shall be understood as electronic cigarette
26 advertising;

1
2 b. "Electronic cigarettes" or "e-cigarettes" refer to devices, often resembling
3 cigarettes, cigars or pipes, designed to deliver nicotine or related substances to users in the
4 form of vapor. They are also known as electronic nicotine delivery systems (ENDS) and
5 electronic non-nicotine delivery systems (ENNDS);
6

7 c. "Electronic liquid" or "e-liquid" and "refill" refers to the non-tobacco articles, which
8 may or may not contain nicotine, designed to be used in conjunction with vaporizers for
9 inhalation.
10

11 d. "Health Claims" means a communication to consumers in the product label or
12 marketing which represent explicitly or implicitly that the product presents a lower risk or is less
13 harmful than continued cigarette smoking;
14

15 e. "Health Products" refer to food, drugs, cosmetics, devices, biologicals, vaccines,
16 in-vitro diagnostic reagents and household urban hazardous substances and/or a combination
17 of and or a derivative thereof. It shall also refer to products that may have an effect on health
18 which require regulations as determined by the FDA;
19

20 f. "Ingredient" means any substance that is added to the mixture and present in
21 the finished product;
22

23 g. "Marketing Authorization" shall refer to the document(s) issued by the FDA to a
24 company, firm or non-profit organization as an authorization to market health products in the
25 Philippines.
26

27 h. "Nicotine" means nicotinic alkaloids, including any salt or complex of nicotine
28 whether derived from tobacco or synthetically produced;
29

30 i. "Nicotine mixture" means the nicotine-containing liquid, solid or other non-
31 tobacco substance in the product;
32

33 j. "Package" shall refer to packs, boxes, cartons, or containers of any kind in which
34 a nicotine product is offered for sale to consumers for use with an e-cigarette product system;
35

36 k. "Promotion" shall refer to an event or activity organized by or on behalf of an e-
37 cigarette manufacturer, importer, distributor, seller or retailer with the aim of promoting e-
38 cigarettes, which event or activity would not occur but for the support given to it by or on behalf
39 of the e-cigarette manufacturer, importer, distributor, seller or retailer. It may also refer to the
40 display of e-cigarettes or manufacturer's name, trademark, logo, and the like on non-e-cigarette
41 products. This includes the paid use of e-cigarette products bearing the brand names,
42 trademarks, logos, and the like in movies, television and other forms of entertainment. For the
43 purpose of this Act, promotion shall be understood as e-cigarette promotion;
44

45 l. "Refill container" means a container for holding nicotine mixture to refill certain
46 vaporized nicotine products;
47

48 m. "Sponsorship" shall refer to any public or private contribution from a third party
49 in relation to an event, team or activity made with the aim of promoting a brand of e-cigarette,
50 which event, team or activity would still exist or occur without such contribution. For the purpose
51 of this Act, sponsorship shall be understood as e-cigarette sponsorship.
52

53 n. "Vaping" shall refer to the act of using an e-cigarette.
54

1 **SECTION 5. Market Authorization Prior to Market Placing.** – Manufacturers, importers,
2 and distributors of e-cigarettes must comply with the following:
3

4 a. Three (3) months prior to placing e-cigarettes in the market, all manufacturers,
5 importers, and distributors must register and obtain a certificate of product registration (CPR)
6 or market authorization from the FDA.
7

8 b. For e-cigarettes that are already in-market, all manufacturers or importers shall
9 be given three (3) months from the effectivity of this Act to register their products and obtain
10 CPR or market authorization from the FDA.
11

12 No establishment shall engage in the manufacture, importation, distribution, sale, or
13 offering for sale of e-cigarettes without first securing the necessary CPR or market authorization
14 from the FDA.
15

16 The requirements for registration and application for CPR and market authorization shall
17 be prescribed by the FDA in the implementing rules and regulations to be promulgated pursuant
18 to this Act.
19

20 **SECTION 6. Product Standard Requirement.** – The FDA shall set standards and
21 necessary restrictions on flavors and additives used in the manufacture of e-liquids and refills
22 guided by the following minimum requirements:
23

24 a. nicotine-containing liquid may be placed on the market only in dedicated refill
25 containers not exceeding a volume of 10 ml, in disposable e-cigarettes or in single use
26 cartridges and that the cartridges or tanks shall not exceed a volume of 20 ml;
27

28 b. the nicotine-containing liquid shall not contain nicotine in excess of 20 mg/ml;
29

30 c. the nicotine-containing liquid shall not contain additives which are harmful to
31 health;
32

33 d. only ingredients of high purity shall be used in the manufacture of the nicotine-
34 containing liquid. Except for nicotine, only ingredients that do not pose risk to human health in
35 heated or unheated form shall be used in the nicotine-containing liquid; and
36

37 e. e-cigarettes shall deliver the nicotine doses at consistent levels under normal
38 conditions of use.
39

40 The FDA shall impose a ban on flavors and additives that are proven or suspected to
41 be appealing to the youth, toxic, harmful, addictive, or sensitizing.
42

43 **SECTION 7. Health Claims.** – Unless approved by the FDA, any health claims on e-
44 cigarette products are prohibited. For this purpose, the FDA may require manufacturers or
45 importers to submit proof of any health claims.
46

47 **SECTION 8. Packaging and Health Warnings.** - All manufacturers, importers, and
48 distributors duly issued with a CPR or market authorization by the FDA shall comply with the
49 following packaging requirements of their products:
50

51 a. unit packets of e-cigarettes and refill containers shall include a leaflet with
52 information on:
53

i. instructions for use and storage of the product, including a reference that the product is not recommended for use by young people and non-smokers;

ii. contra-indications;

iii. warnings for specific risks groups;

iv. possible adverse effects;

v. addictiveness and toxicity; and

vi. contact details of the manufacturer or importer and a legal or natural contact person within the Philippines.

b. unit packets and any outside packaging of e-cigarettes and refill containers shall:

i. include a list of all ingredients contained in the product in descending order of the weight, and an indication of the nicotine content of the product and the delivery per dose, the batch number and a recommendation to keep the product out of reach of children;

ii. bear the following health warnings:

"This product contains nicotine which is a highly addictive substance. It is not recommended for use by non- smokers."

or

"This product contains nicotine which is a highly addictive substance."

iii. display other applicable graphic health warnings to be prescribed by the FDA and the Department of Health (DOH) in the implementing rules and regulations of this Act.

c. containers and packages of electronic delivery devices, e-liquids and refill shall contain appropriate health warnings, whose content, format, and specifications shall be prescribed by the FDA, based on the declaration of ingredients or components of the same product.

SECTION 9. Tamper-proof and Child-proof Design. – All refills and devices shall be child-resistant, tamper resistant, and shall be protected against breakage and leakage.

SECTION 10. Minimum Age Sales and Purchase. – The minimum allowable age for the purchase, sale and use of e-cigarettes shall be twenty-five (25) years old.

It shall not be a defense for the person selling or distributing that he/she did not know or was not aware of the real age of the purchaser. Neither shall it be a defense that he/she did not know nor had any reason to believe that the product was for the consumption of a person below 25 years of age.

SECTION 11. Proof of Age Verification. - Retailers shall ascertain that no individual purchasing e-cigarette is below 25 years of age. In case of doubt, retailers shall verify the age of the buyer through any valid identification card exhibiting the buyer's photograph and age or date of birth.

SECTION 12. Prohibited Sale and Use in Public Places; Other Prohibitions – The sale and use of e-cigarettes in enclosed or partially enclosed public places, public buildings, public outdoor spaces, accommodation and entertainment establishments, workplaces, places of worship, hospitals or other healthcare centers, public conveyances, government offices, and

1 educational or recreational facilities exclusively intended for minors and government-owned
2 vehicles shall be absolutely prohibited.

3
4 As used in this section, the following shall be understood as follows:

5
6 a. Enclosed or partially enclosed public place refers to all places, which are
7 enclosed by one or more walls or sides whether covered by a roof or not, or even if open on all
8 sides is, nonetheless, covered by a roof, whether the structure is permanent or temporary in
9 nature, that are accessible or open to the public, whether by invitation or by payment, or all
10 places of collective use regardless of ownership or right to access, including but not limited to,
11 gasoline stations, banks, malls, shopping arcades, town squares, terminals, airports, seaports,
12 schools, places of worship, hospitals, medical clinics, movie houses, gymnasiums, covered
13 courts, funeral parlors, barber shops, cockpits, gaming areas, recreational facilities, pedestrian
14 overpass, indoor car parks, waiting sheds, sidewalks and other public places where people
15 usually congregate.

16
17 b. Public building refers to any building or structure owned by the government or
18 owned by a private person but used, leased or occupied by the government or any of its
19 branches, subdivisions or instrumentalities; or any building or structure used or controlled
20 exclusively for public purposes by any department or branch of government, local government
21 unit or barangay regardless of ownership of the building.

22
23 c. Public outdoor spaces refer to outdoor spaces that are open to the public or
24 places where facilities are available for the public or where a crowd of people gather or
25 congregate regardless of ownership or right to access such as, but not limited to, parks,
26 playgrounds, sports grounds, or centers, gaming areas, cockfighting areas, healthcare/hospital
27 compounds, cemeteries, gardens, resorts, beaches, pools, markets, streets, sidewalks, parking
28 areas, walkways, entrance ways, waiting areas, stairwells, and such other public outdoor
29 spaces as may be defined by the local government units (LGUs).

30
31 d. Public conveyances refer to any vehicle, whether mobile or stationary, used in
32 the transport of passengers, or available to the public as a mode of transport, such as, but not
33 limited to, jeepneys, buses, trains, vans, taxis, airplanes, ships and other modes of water
34 transportation, tricycles, motorcycles and other public utility vehicles whether covered by a
35 certificate of public convenience or not.

36
37 e. Accommodation and entertainment establishments refer to establishments that
38 provide food, accommodation, drinks, merchandise, entertainment, or other professionals
39 services including, but not limited to, restaurants, fast foods, eateries, hotels, motels, lodges,
40 inns, boarding houses, disco houses, videoke bars, resto bars, and movie houses, or any other
41 place with pleasant environment and atmosphere conducive to comfort, healthful relaxation and
42 rest, offering food and/or drinks, sleeping accommodation and recreation facilities to the public
43 for a fee.

44
45 f. Workplaces refer to areas, whether permanent or temporary, in which persons
46 perform duties of employment or work, regardless of whether the work is done for compensation
47 or on a voluntary basis, and includes private offices, common areas and any other area which
48 is generally used or frequented during the course of employment or work. Company-owned
49 vehicles used for transporting employees and guests or any vehicle used in the course of work
50 shall be considered workplaces.

51
52 The distribution, sale and offering for sale and use of e-cigarettes shall be strictly
53 prohibited in places where sale and use of cigarettes are prohibited.

1 The retail sale of nicotine shots and/or concentrates shall likewise be strictly prohibited.
2 Establishments shall be inspected by the FDA prior to and/or after the issuance of their license
3 to operate.
4

5 **SECTION 13. Standards for Designated Vaping Areas.** – Designated Vaping Areas
6 (DVAs) may be established not less than 100 meters from the perimeters of the places covered
7 by the immediately preceding section and in other places not mentioned therein.
8

9 All DVAs shall comply with the following minimum standards:

10
11 1. They shall be located in an open space with no permanent or temporary roof or
12 walls in an outdoor area;
13

14 2. They shall not be located within ten (10) meters of entrances, exits or any place
15 where people pass or congregate;
16

17 3. The DVA shall not have an area larger than five (5) square meters;
18

19 4. Each establishment shall not have more than one DVA in an outdoor area within
20 its premises;
21

22 5. Persons below 25 years of age shall not be allowed within the DVA;
23

24 6. Every DVA shall have the following signages highly visible and prominently
25 displayed:
26

27 a. "Vaping Area" signage;

28 b. Prohibition on entry of persons below 25 years old;

29 c. Health warning on the effects of hazardous substances on human health,
30 the text of which shall be prescribed by the FDA and the DOH.
31

32 7. Other standards and specifications as may be prescribed by the FDA and the
33 DOH.
34

35 Nothing in this Act shall compel owners, administrators, or persons-in-charge to
36 establish DVAs, or prevent them from instituting more stringent measures in regulating the use
37 of e-cigarettes within their premises.
38

39 **SECTION 14. Ban on Advertisements, Promotions and Sponsorships.** Except for point-
40 of-sale advertisement, all forms of advertisements, promotions, and sponsorship of e-cigarettes
41 are prohibited.
42

43 E-cigarette manufacturers, importers, sellers, distributors, and retailers are also
44 prohibited from directly or indirectly sponsoring any sport, concert, cultural, art, or any public
45 event. This ban includes sponsorship of any individual and team athletes, artists, or performers
46 for the purpose of promoting the products.
47

48 **SECTION 15. Point-of-Sale Signage.** - Point-of-sale establishments offering, selling, or
49 distributing e-cigarettes shall post the following statement in a clear and conspicuous manner:
50 "SALE/DISTRIBUTION TO OR PURCHASE BY PERSONS BELOW 25 YEARS OF AGE IS
51 UNLAWFUL" or "IT IS UNLAWFUL FOR E-CIGARETTES TO BE SOLD/DISTRIBUTED TO OR
52 PURCHASED BY PERSONS UNDER 25 YEARS OF AGE."
53

54 **SECTION 16. Absolute Ban on Importation of E-Cigarettes Banned or Restricted in**
55 *Other Countries.* – Any e-cigarette product whose use and/or sale has been banned, withdrawn

1 or restricted from its country of origin shall not be imported into the country. *Provided, That,*
2 those imported into the country prior to the declaration of the ban, withdrawal or restriction by
3 the country of origin and remain in market shall be confiscated and destroyed.
4

5 The companies whose manufacture, sale, and distribution of e-cigarettes were
6 subsequently banned in another country shall likewise be banned from manufacturing, selling,
7 or distributing their products in the country until such time that the ban in the other country is
8 lifted or the FDA subsequently certifies the safety of their products.
9

10 **SECTION 17. *Role of Local Government Units.*** – All LGUs concerned shall revoke any
11 business permit issued, or shall not issue or renew such business permit to any manufacturer,
12 importer, seller, or distributor of e-cigarettes who fail to comply with the prior FDA market
13 authorization mandated by this Act.
14

15 Recognizing the indispensable role of LGUs in the effective implementation of this Act
16 and consistent with their primary responsibility to maintain a healthy environment, all LGUs are
17 hereby authorized to issue any appropriate ordinances which they may deem necessary for the
18 ultimate protection of the health of their constituents against e-cigarettes.
19

20 Nothing in this provision shall be interpreted as infringing, restricting or diminishing the
21 autonomy of LGUs enshrined in the Constitution and in Republic Act No. 7160.
22

23 **SECTION 18. *Penalties.*** – The following penalties shall apply:
24

25 a. Violation of Sections 5, 6, 7, and 8 of this Act shall be subject to the penalties
26 provided under Book III, Article XI of the Rules and Regulations implementing Republic Act No.
27 9711 or The Food and Drug Administration Act of 2009.
28

29 b. Violation of Sections 10, 11 and 12. – (i) *Prohibited sale and purchase.* – On the
30 first offense, any person, business entity or establishment selling to, distributing or purchasing
31 e-cigarettes for persons under 25 years of age; selling or distributing e-cigarettes in prohibited
32 places; or selling or distributing nicotine shots and/or concentrates shall be fined the amount of
33 not more than Ten Thousand Pesos (P10,000.00) or imprisoned for not more than thirty (30)
34 days, or both, at the discretion of the court.
35

36 On the second offense, a fine of Twenty Thousand Pesos (P20,000.00) or an
37 imprisonment of not more than three (3) months, or both, at the discretion of the court shall be
38 imposed.
39

40 On the third offense, a fine of Forty Thousand Pesos (P40,000.00) or an imprisonment
41 of not more than six (6) months, or both, at the discretion of the court shall be imposed. In
42 addition, the business permits and licenses, in the case of business entities or establishments
43 shall be revoked or cancelled.
44

45 If the violation is committed by a business entity or establishment, the owner, president,
46 manager, or the most senior officer thereof shall be liable for the offense.
47

48 If the guilty officer is not a citizen of the Philippines, he shall, in addition to the penalties
49 imposed above, be deported after serving the sentence and shall be permanently barred from
50 re-entry into the Philippines.
51

52 If a minor is caught selling or buying e-cigarette, the provisions of Article 189 of
53 Presidential Decree No. 603 otherwise known as The Child and Youth Welfare Code, as
54 amended, shall apply.
55

1 (ii) *Prohibited use.* – On the first offense, a fine of not more than Five Thousand Pesos
2 (P5,000.00) shall be imposed.

3
4 On the second offense, a fine of Ten Thousand Pesos (P10,000.00) shall be imposed.

5
6 On the third offense, a fine of not more than Twenty Thousand Pesos (P20,000.00) or
7 imprisonment of not more than three (3) months, or both, at the discretion of the court shall be
8 imposed.

9
10 c. Violation of Section 13. – On the first offense, the owner, administrator, or
11 person-in-charge of the premises shall be fined the amount of Ten Thousand Pesos
12 (P10,000.00) or imprisoned for not more than thirty (30) days, or both, at the discretion of the
13 court.

14
15 On the second offense, a fine of Twenty Thousand Pesos (P20,000.00) or imprisonment
16 of not more than three (3) months or both, at the discretion of the court shall be imposed.

17
18 On the third, offense, in addition to the fine of Forty Thousand Pesos (P40,000.00), or
19 imprisonment of not more than six (6) months, or both, at the discretion of the court, the
20 business permits and licenses of the business entity or establishment shall be revoked or
21 cancelled.

22
23 If the guilty owner, administrator or person-in-charge is not a citizen of the Philippines,
24 he shall, in addition to the penalties imposed above, be deported after serving the sentence and
25 shall be permanently barred from re-entry into the Philippines.

26
27 d. Violation of Sections 14, 15 and 16. – On the first offense, a fine of not more
28 than Two Hundred Thousand Pesos (P200,000.00) or imprisonment of not more than one (1)
29 year, or both, at the discretion of the court shall be imposed.

30
31 On the second offense, a fine of Five Hundred Thousand Pesos (P500,000.00) or an
32 imprisonment of not more than two (2) years, or both, at the discretion of the court shall be
33 imposed.

34
35 On the third offense, in addition to a fine of not more than One Million Pesos
36 (P1,000,000.00) or imprisonment of not more than three (3) years, or both, at the discretion of
37 the court, the business permits and licenses of the business entity or establishment shall be
38 revoked or cancelled.

39
40 In the case of a business entity or establishment, the owner, president, manager or most
41 senior official thereof shall be held liable.

42
43 If the guilty officer is not a citizen of the Philippines, he shall, in addition to the penalties
44 imposed above, be deported after serving the sentence and shall be permanently barred from
45 re-entry into the Philippines.

46
47 **SECTION 19. *Implementing Agency.*** – The FDA shall be the implementing agency of
48 this Act. For this purpose, the FDA, in coordination with the DOH, Department of Interior and
49 Local Government, and the Department of Science and Technology, shall promulgate the
50 implementing rules and regulations (IRR) within thirty (30) days from the effectivity of this Act.
51 The IRR shall include standards on safety, efficacy and quality of the device, refill container,
52 ingredient, dose of nicotine, packaging and labelling, among others.

53
54 **SECTION 20. *Immediate Execution of FDA Decision.*** Notwithstanding an appeal to the
55 Secretary of Health, as may be permitted under existing laws, and in recognition of its

1 paramount duty to protect the right to health of the public, the decision of the FDA shall be
2 immediately executory. No court in the Philippines other than the Supreme Court shall have
3 jurisdiction to issue any restraining order or writ of preliminary injunction against the FDA in any
4 case, dispute or controversy arising from, necessary to, or in connection with the interpretation,
5 application, enforcement, and implementation of its mandate under this Act.
6

7 **SECTION 21. *Appropriation.*** – The amount as may be necessary to implement the
8 provisions of this Act shall be charged against the current year's appropriations of the FDA.
9 Thereafter, such funds as may be necessary for the continued implementation of this Act shall
10 be included in the budget of the FDA under the annual General Appropriations Act.
11

12 **SECTION 22. *Separability Clause.*** – If any provision or part of this Act is subsequently
13 declared unconstitutional or invalid, the remaining provisions or parts thereof not affected shall
14 remain in full force and effect.
15

16 **SECTION 23. *Repealing Clause.*** – All laws, decrees, ordinances, administrative orders,
17 rules and regulations, or any part thereof, which are inconsistent with this Act are hereby
18 repealed or modified accordingly.
19

20 **SECTION 24. *Effectivity.*** – This Act shall take effect fifteen (15) days after its publication
21 in the Official Gazette or in any newspaper of general circulation.
22

23 **Approved.**