

Republic of the Philippines
HOUSE OF REPRESENTATIVES
Quezon City

19TH CONGRESS
First Regular Session

HOUSE BILL NO. 5698



Introduced by Representative Michael L. Romero

EXPLANATORY NOTE

As a regulatory agency under the Department of Health, the **Food and Drug Administration**, created under Republic Act No. 3720, series of 1963, as amended by Executive Order 175, series of 1987, otherwise known as the “Food, Drugs and Devices, and Cosmetics Act”, and subsequently **Republic Act No. 9711** otherwise known as “The **Food and Drug Administration Act of 2009**”, is mandated to ensure the safety, efficacy or quality of health products which include food, drugs, cosmetics, devices, biologicals, vaccines, in-vitro diagnostic reagents, radiation-emitting devices or equipment, and household/urban hazardous substances, including pesticides and toys, or consumer products that may have an effect on health which require regulations as determined by the FDA.

Among others, the FDA is also mandated to enforce the provisions of the following laws:

- a) RA 9502, or The Universally Accessible Cheaper and Quality Medicine Act of 2008
- b) RA 6675, or The Generics Act Of 1988,
- c) RA 10918, or The Pharmacy Law,
- d) RA 9211, or The Tobacco Regulation Act of 2003
- e) RA 7394, or The Consumer Act of the Philippines
- f) RA 7581/10623, or The Price Act
- g) RA 10611, or The Food Safety Act of 2013
- h) RA 8172, or The ASIN Law,
- i) RA 8203, or The Special Law on Counterfeit Drug
- j) RA 8976, or The Food Fortification Law

- k)** RA 9165, or The Comprehensive Dangerous Drugs Act
- l)** RA 9257, or The Expanded Senior Citizens Act of 2003
- m)** PD No. 881, or The Household Hazardous Act
- n)** EO No. 51, or The Milk Code of the Philippines
- o)** RA 10354, or The Responsible Parenthood and Reproductive Health Bill of 2012
- p)** PD 856, or The Code of Sanitation of the Philippines

- a)** This House Bill seeks to protect and promote the right to health of the Filipino people by ensuring the safety, efficacy, quality, and purity of foods, drugs, devices, and cosmetics, and
- b)** To establish and maintain an effective health products regulatory system responsive to the country's health needs and problems, therefor providing for **stiffer penalties and sanctions**.

Thus, the early passage of this bill is earnestly requested.

A handwritten signature in black ink, appearing to read 'Michael L. Romero', with a long horizontal line extending to the right.

MICHAEL L. ROMERO

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AN ACT
AMENDING **REPUBLIC ACT NO. 9711** OTHERWISE KNOWN
AS “THE **FOOD AND DRUG ADMINISTRATION (FDA) ACT OF
2009**”, TO FOSTER THE IMPOSITION OF EXISTING POLICIES AND
GUIDELINES, INCREASING ITS PENALTIES AND SANCTIONS, AND
FOR OTHER PURPOSES

*Be it enacted by the Senate and House of Representative of the Philippines
in congress assembled:*

SECTION 1. Section 11 of Republic Act No. 9711, is hereby
amended to read as follows:

Section 11. Section 12, subsection (a) of Republic Act
No, 3720, as amended, is hereby further amended to
read as follows:

"SEC. 12. (a) Any person who violates any of the
provisions of Section eleven hereof shall, upon
conviction, suffer the penalty of imprisonment ranging
from four **(4)** years but not more than twelve **(12)** years
or a fine of not less than Two hundred thousand pesos
(Php 200,000.00) but not more than Five hundred
thousand pesos (P500,000.00), or both, at the
discretion of the court: *Provided*, That if the offender is
a manufacturer, importer or distributor of any health

product, the penalty of at least seven **(7)** years imprisonment but not more than twelve **(12)** years and a fine of at least one Million pesos **(Php 1,000,000.00)** but not more than Five million pesos (P5,000,000.00) shall be imposed *Provided, further*, That an additional fine of five percent **(5%)** of the economic value/cost of the violative product or violation, or Fifty thousand pesos **(Php 50,000.00)**, whichever is higher, shall be imposed for each day of continuing violation: *Provided, finally*, That health products found in violation of the provisions of this Act and other relevant laws, rules and regulations may be seized and held in custody pending proceedings, without hearing or court order, when the director-general has reasonable cause to believe from facts found by him/her or an authorized officer or employee of the FDA that such health products may cause injury or prejudice to the consuming public.

"x x x

"Should the offense be committed by a juridical person, the Chairman of the Board of Directors, the president, general manager, or the partners and/or the persons directly responsible therefore shall be penalized.

"Should the offense be committed by a foreign national, he/she shall, in addition to the penalties prescribed, be deported without further proceedings after service of sentence.

"x x x."

SECTION 2. Section 13 of Republic Act No. 9711, is hereby amended to read as follows:

. **Section 13.** Section 29-A of Republic Act No. 3720, as amended, is hereby further amended, and new subsections are added to read as follows:

"SEC. 29-A. *Administrative Sanctions.* - Where there is finding of prohibited actions and determination of the persons liable thereto, after notice and hearing, the

director-general is empowered to impose one or more of the following administrative penalties:

"(1) Cancellation of any authorization which may have been granted by the FDA, or suspension of the validity thereof for such period of time as the director-general may deem reasonable which shall not exceed one (1) year:

"(2) A fine of not less than two hundred Fifty thousand pesos (**Php 250,000.00**) but not more than Five hundred thousand pesos (P500,000.00). An additional fine of not **less** than fifty thousand pesos (**Php 50,000.00**) shall be imposed for each day of continuing violation; and

"(3) Destruction and/or appropriate disposition of the subject health product, and/or closure of the establishment for any violation of this Act, as determined by the director-general.

SECTION 3. SCOPE AND LIMITATION. - This Act shall govern all health products: *Provided*, that nothing in this Act shall be deemed to modify the sole and exclusive jurisdiction of other specialized agencies and special laws only insofar as the acts covered by these specialized agencies and laws, including, but not limited to, those covered by Republic Act No. 9211, Executive Order No. 245, Executive Order No. 18, and Presidential Decree No. 1468.

SECTION 4. IMPLEMENTING RULES AND REGULATIONS. - The departments and agencies charged with carrying out the provisions of this Act shall, within sixty (**60**) days after the effectivity of this Act, formulate the necessary rules and regulations for its effective implementation.

SECTION 5. REPEALING CLAUSE. - All laws, decrees, executive orders, rules and regulations, or parts thereof inconsistent with the provisions of this Act are hereby repealed or modified accordingly.

SECTION 6. SEPARABILITY CLAUSE. – If, for any reason, any section or provision of this Act is held unconstitutional or invalid, the other sections or provisions hereof shall not be affected thereby.

SECTION 7. EFFECTIVITY CLAUSE. – This Act shall take effect after fifteen (15) days from its publication in the Official Gazette or in at least two (2) national newspapers of general circulation whichever comes earlier.

Approved,