

SEVENTEENTH CONGRESS OF THE)
REPUBLIC OF THE PHILIPPINES)
Second Regular Session)

SENATE
S.B. No. 1631

17 DEC -7 A10:51

Introduced by Senator JOSEPH VICTOR G. EJERCITO

RECEIVED

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AN ACT
INSTITUTING FOOD AND DRUG ADMINISTRATION AS AN
INDEPENDENT AGENCY AND SEPARATE FROM THE DEPARTMENT
OF HEALTH, AMENDING CERTAIN SECTIONS OF REPUBLIC ACT NO.
3720, AS AMENDED BY REPUBLIC ACT NO. 9711, AND FOR OTHER
PURPOSE

EXPLANATORY NOTE

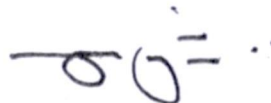
Republic Act No. 9711, otherwise known as the Food and Drug Administration (FDA) Act of 2009 states that it is a declared policy of the State adopt, support, establish, institutionalize, improve and maintain structures, processes, mechanisms and initiatives that are aimed, directed and designed to: (a) protect and promote the right to health of the Filipino people; and (b) help establish and maintain an effective health products regulatory system and undertake appropriate health manpower development and research, responsive to the country's health needs and problems.

The FDA Act of 2009 expressly provides that FDA shall be under the Office of the Secretary of Health. However, the current organizational structure of the Department of Health having FDA as one of its attached agencies breeds potential conflict that can compromise the neutrality of FDA.

To further enhance FDA's regulatory capacity and strengthen its capability with regard to the inspection, licensing and monitoring of establishments, and the registration and monitoring of health product, it is rational to institute FDA as an independent and autonomous body. As such

proposed bill seeks to separate FDA from the Department of Health and instead attached it to the Office of the President for administrative purposes only.

In view of the foregoing, the passage of this measure is earnestly sought.

A handwritten signature in black ink, appearing to read 'J. Ejercito', with a horizontal line extending to the left of the first letter.

JOSEPH VICTOR G. EJERCITO

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

1 SECTION 1. Section 4 of Republic Act No. 3720, as amended by Section 5 of
2 Republic Act No. 9711, is hereby further amended to read as follows:

3
4 "SEC. 4. To carry out the provisions of this Act, there is hereby
5 created an office to be called the Food and Drug Administration
6 (FDA) [in the Department of Health (DOH)]. THE FDA SHALL
7 BE INDEPENDENT AND AUTONOMOUS FROM THE
8 DEPARTMENT OF HEALTH. IT SHALL BE ATTACHED TO
9 THE OFFICE OF THE PRESIDENT FOR ADMINISTRATIVE
10 PURPOSES ONLY. IT SHALL EXERCISE THE FOLLOWING
11 FUNCTIONS, POWERS AND DUTIES [Said Administration
12 shall be under the Office of the Secretary and shall have the
13 following functions, powers and duties:]
14

15 "(a) To administer the effective implementation of this Act and of
16 the rules and regulations issued pursuant to the same;
17

18 xxx xxx xxx

19
20 SEC. 2. Section 6 of Republic Act No. 3720, as amended by Section 7 of Republic
21 Act No. 9711, is hereby further amended to read as follows:
22

1 "(a) The FDA shall be headed by a director-general, with the rank
2 of [undersecretary,] A DEPARTMENT SECRETARY WHO
3 SHALL BE A MEMBER OF THE CABINET. THE DIRECTOR-
4 GENERAL SHALL BE APPOINTED BY THE PRESIDENT
5 SUBJECT TO CONFIRMATION BY THE COMMISSION ON
6 APPOINTMENTS. THE DIRECTOR-GENERAL [who] shall be
7 tasked, among others, to determine the needed personnel and to
8 appoint personnel, below the assistant director level in
9 [coordination with the Secretary of Health] ACCORDANCE
10 WITH THE CIVIL SERVICE LAW;"

11
12 xxx xxx xxx

13
14 "(h) Each center and field office shall be headed by a director who
15 shall be assisted by an assistant director. These directors shall be
16 appointed by the [Secretary of Health] DIRECTOR-GENERAL.

17
18 SEC. 3. Section 7 of Republic Act No. 3720, as amended by Section 8 of Republic
19 Act No. 9711, is hereby further amended to read as follows:

20
21 "The FDA shall review its staffing pattern and position titles
22 subject to the approval of the [Secretary of Health] PRESIDENT."

23
24
25 SEC. 4. Section 32 of Republic Act No. 3720, as amended by Section 15 of
26 Republic Act No. 9711, is hereby amended to read as follows:

27 SEC. 32. The orders, rulings or decisions of the FDA shall be
28 appealable to the [Secretary of Health] OFFICE OF THE
29 PRESIDENT. An appeal shall be deemed perfected upon filing of
30 the notice of appeal and posting of the corresponding appeal bond.

31 "An appeal shall not stay the decision appealed from unless an
32 order from the [Secretary of Health] OFFICE OF THE
33 PRESIDENT is issued to stay the execution thereof."

34
35 SEC. 5. Section 34 of Republic Act No. 3720, as amended by Section 17 of
36 Republic Act No. 9711, is hereby further amended to read as follows:

37 "SEC. 34. *Fees and Other Income.* -

38 "(a) Upon the sole approval of the [Secretary] PRESIDENT, the
39 authorization and other fees shall annually be determined and

1 reviewed by the FDA and any proposed increase shall be
2 published in two (2) leading newspapers of general circulation.

3 xxx xxx xxx

4 "(c) The Director-General of the FDA, upon approval of the
5 [Secretary] PRESIDENT, shall be authorized to promulgate rules
6 and regulations governing the collection of the 'other related
7 regulatory fees'. Upon approval of the [Secretary] PRESIDENT,
8 these fees shall likewise be reviewed periodically and any
9 proposed increase shall be published in two (2) leading
10 newspapers of general circulation."

11 SEC. 6. Section 18 of Republic Act No. 9711 is hereby amended to read as
12 follows:

13 xxx xxx xxx
14 xxx xxx xxx

15
16 The retention, use and application of this fund shall not be
17 delayed, amended, altered or modified, or affected in any way by
18 an order or directive from any executive office, but will be subject
19 only to the general accounting rules and guidelines by the
20 Commission on Audit (COA). The primary purpose of the fund as
21 herein stated shall prevail over any other purpose that may be
22 pursued by the FDA on its own initiative or through an order or
23 directive by any higher office. The FDA shall submit to the
24 [Secretary of Health] PRESIDENT, the Secretary of Budget and
25 Management and the Congressional Oversight Committee,
26 created under Section 23 of this Act, a report on how the funds
27 were utilized, including its accomplishments.

28
29 xxx xxx xxx
30

31 SEC. 7. Section 35 of Republic Act No. 3720, as amended by Section 20 of
32 Republic Act No. 9711, is hereby further amended to read as follows:

33
34 SEC. 35. xxx xxx xxx

35 "The testing laboratories may be increased by the director-general,
36 upon approval of the [Secretary] PRESIDENT. Moreover, the
37 director-general, upon approval of the [Secretary] PRESIDENT,
38 may call upon other government and private testing laboratories
39 to conduct testing, calibration, assay and examination of samples
40 of health products: *Provided*, That the private testing laboratories

1 are accredited by the Philippine Accreditation Office (PAO) of the
2 Department of Trade and industry (DTI) and the FDA."

3 SEC. 8. Section 35 of Republic Act No. 3720, as amended by Section 20 of
4 Republic Act No. 9711, is hereby further amended to read as follows:

5
6 "SEC. 37. The FDA, with the approval of the [Secretary]
7 PRESIDENT, shall create organizational units which are deemed
8 necessary to address emerging concerns and to be abreast with
9 internationally acceptable standards. There shall be created
10 additional plantilla positions to augment the human resource
11 complement of the FDA, subject to existing rules and regulations."
12

13 SEC. 9. *Separability Clause.* - If any provision of this Act is held invalid or
14 unconstitutional, other provisions not affected thereby shall continue to be in
15 full force and effect.
16

17 SEC. 10. *Repealing Clause.* - All laws, decrees, executive orders or parts thereof
18 inconsistent with the provisions of this Act are hereby repealed, amended or
19 modified accordingly.
20

21 SEC. 11. *Effectivity Clause.* - This Act shall take effect fifteen (15) days after its
22 complete publication in the *Official Gazette* or in a national newspaper of general
23 circulation.
24

25 Approved,
26