

Republic of the Philippines
HOUSE OF REPRESENTATIVES
Quezon City

19TH CONGRESS
First Regular Session

HOUSE BILL NO. 5697



Introduced by Representative Michael L. Romero

EXPLANATORY NOTE

The **Food and Drug Administration (FDA)** of the Philippines, formerly the **Bureau of Food and Drugs BFAD**, is a health regulatory agency under the **Department of Health** created on 1963 by **Republic Act No. 3720**, amended on 1987 by Executive Order 175 otherwise known as the “Food, Drugs and Devices, and Cosmetics Act”, and subsequently reorganized by **Republic Act No. 9711** otherwise known as “**The Food and Drug Administration Act of 2009**”. The agency is responsible for licensing, monitoring, and regulation of cosmetics, drugs, foods, household hazardous products, medical devices^[2] and electromagnetic radiation emitting devices, pesticides, tobacco and related products, and vaccines for safety, efficacy, and quality in the Republic of the Philippines.

The Philippine FDA is led by the Director General appointed by the President of the Philippines and two deputies for Internal Management and Field Regulatory Operations.

The FDA has its central office in Alabang, Muntinlupa. The agency has 4 centers located at its central office, and 5 clusters of field regulatory operations and 4 laboratories located throughout the archipelago. The agency also grants accreditation to private sector laboratories for testing of COVID-19

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This House Bill seeks to provide **Modernization Funding** to the **Food and Drug Administration (FDA)**, to guarantee the safety, quality, purity, efficacy of products in order to protect and promote the right to health of the general public.

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 flourish extending to the right.

MICHAEL L. ROMERO

Republic of the Philippines
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HOUSE BILL NO. 5697

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AN ACT

PROVIDING FOR MODERNIZATION FUNDINGFOR THE **FOOD AND
DRUG ADMINISTRATION (FDA)**, INCREASING AND
REORGANIZING ITS ADMINISTRATION, TO GUARANTEE THE
SAFETY, QUALITY, PURITY, EFFICACY OF PRODUCTS IN ORDER
TO PROTECT AND PROMOTE THE RIGHT TO HEALTH OF THE
GENERAL PUBLIC AND FOR OTHER PURPOSES

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

SECTION 1. DECLARATION OF POLICY – It shall hereby be a declared policy of the State that the **FDA** 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.

The state shall continually improve the effectiveness of our Quality Management System towards equitable development for improved quality of life for all.

The state shall formulate policies for the efficient and effective administration and management of all manpower, skills and competencies to ensure compliance.

SECTION 2. MODERNIZATION FUNDING. – The amount of Five Hundred Million Pesos (**Php 500,000,000.00**) for the operation and administration of the **Food and Drug Administration (FDA)** shall be chargeable against funds for the purpose and other sources recommended by the **Department of Budget and Management (DBM)**. Thereafter, appropriations for the **Food and Drug Administration (FDA)** shall be included in the budget proposals under the Department of Health (**DOH**).

The Department of Budget and Management (**DBM**) shall rationalize the existing organizational structure and staffing pattern of the **Food and Drug Administration (FDA)** in accordance with the provisions of this Act and relevant compensation and position classification laws, rules and regulations.

Thereafter, the amount needed for the continued implementation of the modernization program, shall be included in the annual General Appropriations Act (**GAA**).

SECTION 3. FOOD AND DRUG ADMINISTRATION (FDA) MODERNIZATION FUND – There is hereby created the (**FDA**) *Modernization Fund* to be used exclusively for the (**FDA**) *Modernization Program*.

The **(FDA)** *Modernization Fund* shall be administered by the Secretary of the **DOH** in accordance with existing government budgeting, accounting and auditing rules and regulations.

SECTION 4. PROGRESS REPORT – The Secretary of **DOH** shall prepare an annual report on the status of the implementation of the **(FDA)** *Modernization Programs* which shall be submitted, to the Office of the President and to the Chairpersons of the Committee on Health of the Senate and the House of Representatives.

SECTION 5. PERIOD OF IMPLEMENTATION – The modernization program under this Act shall be implemented for an initial period of two **(2)** years:

Provided, that payments for multi-year contract obligations incurred under this Act may extend beyond this period:

Provided, further, That the **Food and Drug Administration (FDA)** shall continue to develop, modernize and constantly update its operational capabilities to keep pace with best global practices.

SECTION 6. POWERS AND FUNCTIONS. – The **Food and Drug Administration (FDA)** shall continue to exercise and uphold the following powers and functions; but not limited to:

To prevent international spread of diseases of global impact with minimum interference to international travel and trade through:

In order to protect and promote the right to health of the Filipino people and to establish and maintain an effective health products regulatory system responsive to the country's health needs and problems, the FDA shall perform the following functions as provided by existing laws:

- a)** To establish safety or efficacy standards and quality measures for foods, drugs and devices and cosmetics and other health product;
- b)** To undertake appropriate health manpower development and research, responsive to the country's health needs and problems;
- c)** To assume primary jurisdiction in the collection of samples of health products;
- d)** To analyze and inspect health products;
- e)** To establish analytical data to serve as basis for the preparation of health products standards, and to recommend standards of identity, purity, safety, efficacy, quality and fill of container;
- f)** To issue certificates of compliance with technical requirements to serve as basis for the issuance of appropriate authorization and spot-check for compliance with regulations regarding operation of manufacturers, importers, exporters, distributors, wholesalers, drug outlets, and other establishments and facilities of health products, as determined by the FDA;
- g)** To conduct appropriate tests on all applicable health products prior to the issuance of appropriate authorizations to ensure safety, efficacy, purity, and quality;
- h)** To require all manufacturers, traders, distributors, importers, exporters, wholesalers, retailers, consumers, and non-consumer users of health products to report to the FDA any incident that reasonably indicates that said product has caused or contributed to the death, serious illness or serious injury to a consumer, a patient, or any person;

- i)** To issue cease and desist orders motu proprio or upon verified complaint for health products, whether or not registered with the FDA Provided, That for registered health products, the cease and desist order is valid for thirty (30) days and may be extended for sixty (60) days only after due process has been observed;
- j)** To order the ban, recall, and/or withdrawal of any health product, after due process, found to have caused the death, serious illness or serious injury to a consumer or patient, or is found to be imminently injurious, unsafe, dangerous, or grossly deceptive, and to require all concerned to implement the risk management plan which is a requirement for the issuance of the appropriate authorization;
- k)** To strengthen the post market surveillance system in monitoring health products as defined in this Act and incidents of adverse events involving such products;
- l)** To develop and issue standards and appropriate authorizations that would cover establishments, facilities and health products;
- m)** To conduct, supervise, monitor and audit research studies on health and safety issues of health products undertaken by entities duly approved by the FDA;
- n)** To prescribe standards, guidelines, and regulations with respect to information, advertisements and other marketing instruments and promotion, sponsorship, and other marketing activities about the health products;
- o)** To maintain bonded warehouses and/or establish the same, whenever necessary or appropriate, as determined by the director-general for confiscated goods in strategic areas of the country especially at major ports of entry; and

- p) To exercise such other powers and perform such other functions as may be necessary to carry out its duties and responsibilities

SECTION 7. INCREASE OF PERSONNEL. – The **FDA** shall maintain the sufficient staffing pattern. Hence, it is authorized to increase its manpower to meet such required and may continue to increase personnel per percentage rate increase of committed mandates annually or as the need arises.

SECTION 8. TRANSITORY PROVISION – Existing industries, businesses and offices affected by the implementation of this Act shall be given six **(6)** months transitory period from the effectivity of the IRR or such other period as may be determined, to comply with the requirements of this Act.

SECTION 9. 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 10. 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 11. 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 12. 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,