

Republic of the Philippines
HOUSE OF REPRESENTATIVES
Quezon City

SEVENTEENTH (17th) CONGRESS
Second Regular Session

House Bill No. **7143**



Introduced by: **Representative Jose L. Atienza, Jr.**

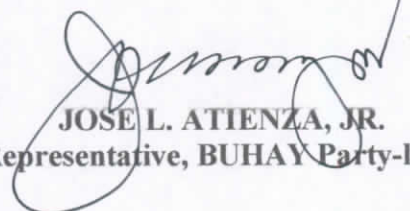
EXPLANATORY NOTE

Since its establishment under Republic Act (R.A.) 3720 in 1963, the Food and Drug Administration (FDA) has always been under the Department of Health (DOH).

This bill seeks to amend R.A. 3720, as amended by R.A. 9711, by creating an FDA that shall be separate and independent from the DOH. For too long, the FDA has been carrying out its mandate, but always under the supervision of the DOH. As such, not only has it taken them far too long to act on issues concerning the safety and efficacy of various food, drugs, devices, vaccines and other materials.

With this bill, the new FDA shall be empowered not only to issue cease and desist orders (CDOs), but to order the ban, recall, and/or withdrawal of any health product 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.

Incidents such as that of the Dengvaxia vaccine being found to be unsafe for the more than 700,000 children who had been inoculated, is a very valid case for an independent and stronger FDA that can immediately act on such cases of national import.


JOSE L. ATIENZA, JR.
Representative, BUHAY Party-list

Republic of the Philippines
Congress of the Philippines
Metro Manila

HOUSE OF REPRESENTATIVES

Seventeenth Congress
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House Bill No. 7143

Introduced by Rep. Jose L. Atienza, Jr.

**AN ACT CREATING A SEPARATE AND INDEPENDENT
FOOD AND DRUG ADMINISTRATION, AMENDING FOR SUCH
PURPOSE REPUBLIC ACT 3720, AS AMENDED BY
REPUBLIC ACT 9711**

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

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

"SEC. 4. To carry out the provisions of this Act, there is hereby created an office to be called the Food and Drug Administration (FDA), **which shall be separate and independent from the Department of Health (DOH)**. The FDA shall have the following functions, powers and duties:

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

"(b) To assume primary jurisdiction in the collection of samples of health products;

"(c) To analyze and inspect health products in connection with the implementation of this Act;

"(d) 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;

"(e) 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;

"x x x

"(h) To conduct appropriate tests on all applicable health products prior to the issuance of appropriate authorizations to ensure safety, efficacy, purity, and quality;

"(i) 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;

"(j) 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;

"(k) After due process, to order the ban, recall, and/or withdrawal of any health product 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;

"(l) To strengthen the post market surveillance system in monitoring health products as defined in this Act and incidents of adverse events involving such products;

"(m) To develop and issue standards and appropriate authorizations that would cover establishments, facilities and health products;

"(n) To conduct, supervise, monitor and audit research studies on health and safety issues of health products undertaken by entities duly approved by the FDA;

"(o) 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 as covered in this Act;

"(p) 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

"(q) To exercise such other powers and perform such other functions as may be necessary to carry out its duties and responsibilities under this Act."

Section 2. Section 7 of Republic Act No. 3720, as amended by Republic Act 9711, is hereby further amended to read as follows:

"The FDA shall review its staffing pattern and position titles, and may hire the required personnel to carry out its mandate under this Act, subject to existing civil service laws and regulations."

Section 3. – The budgetary requirement necessary for the operation of the FDA shall be included in the annual General Appropriations Act (GAA).

Section 4. - All laws, acts, decrees, executive orders, proclamations, rules and regulations, or part or parts thereof which are inconsistent with any of the provisions of this Act are hereby amended, modified or repealed.

Section 5. – If any part or provision of this Act is held unconstitutional or invalid, other parts or provisions thereof which are not affected shall continue to remain in full force and effect.

Section 6. This Act shall take effect fifteen (15) days following completion of its publication in at least two (2) newspapers of general circulation.

Approved.