Republic of the Philippines
HOUSE OF REPRESENTATIVES
Quezon City

Seventeenth Congress
First Regular Session

HOUSE BILL NO. **3971**

Introduced by Honorable Doy C. Leachon

EXPLANATORY NOTE

This bill seeks to separate the Food and Drug Administration (FDA) from the Department of Health (DOH), amending for the purpose Republic Act (RA) No. 3720, otherwise known as the "*Food, Drug and Cosmetic Act*," as amended by RA 9711, otherwise known as the "*Food and Drug Administration Act of 2009*" to become an independent and autonomous office attached to the Office of the President of the Philippines.

It is the policy of the State to promote and protect the right to health of the Filipino people. In pursuit of this policy, Republic Act No. 3720, otherwise known as the "*Food, Drug and Cosmetic Act*" was passed in 1963. It aims to ensure the supply of safe, pure and quality food, drugs, cosmetics and other health products to the public. Thus, in order to carry out effectively the policies and objectives of this Act, the Food and Drug Administration (FDA) was created.

Under Executive Order No. 851 issued in 1982, FDA was abolished and replaced by the Bureau of Food and Drugs (BFAD). It absorbed all the functions of the former and expanded its operations. State of the art analytical instruments and modern experimental animal laboratory were acquired to strengthen its capabilities in research, analysis and inspection of food and health products.

In 2009, Republic Act No. 9711, otherwise known as the "*Food and Drug Administration (FDA) Act of 2009*" was passed to strengthen and rationalize the regulatory capacity of the Bureau of Food and Drug by establishing adequate testing laboratories and field offices and upgrading its human resources complement, giving authority to retain its income. The law renamed BFAD to Food and Drug Administration (FDA) and amended certain sections of RA 3720. RA 9711 also strengthened the law enforcement

capability of the agency by integrating the regional operatives under a single directorate and establishing a law enforcement unit that has functions, powers and responsibilities similar to the National Bureau of Investigation and the Philippine National Police under every regional office.

With these laws and other issuances set to enhance the capability of the FDA to perform its main goal to ensure the health and safety of food and drugs made available to the public, the effectiveness of the FDA is still being hampered by bureaucracy, meddling politicians and confusing budgetary lines.

The FDA is currently part of the Department of Health. Making it an independent and autonomous office, separate from DOH, would be a step in the right direction on public health. A single, independent and autonomous food and drugs safety agency will provide a focused and centralized leadership. It will be the primary voice on food and drugs, on safety standards and on compliance with those standards. It will establish clear lines of responsibility and accountability that will enhance both prevention of and responses to outbreaks of food borne illnesses. Finally, an independent FDA will ensure the flow of safe and healthy food, drugs, cosmetics, medical devices and household materials in the country.

The enactment of this bill will ensure a more efficient FDA in the discharge of its role and responsibilities. FDA will be the sole lead agency in the implementation of its mandate to administer and enforce the laws pertaining to safety and quality of food, drugs, health products, cosmetics and household products.

In view of the foregoing, immediate approval of this bill is earnestly sought.

DOY C. LEACHON

Republic of the Philippines
HOUSE OF REPRESENTATIVES
Quezon City

Seventeenth Congress
First Regular Session

HOUSE BILL NO. 3971

Introduced by Honorable Doy C. Leachon

AN ACT
SEPARATING THE FOOD AND DRUG ADMINISTRATION FROM THE DEPARTMENT OF HEALTH, AMENDING FOR THE PURPOSE REPUBLIC ACT NO. 3720, OTHERWISE KNOWN AS THE "*FOOD, DRUG AND COSMETIC ACT*," AS AMENDED BY REPUBLIC ACT NO. 9711, OTHERWISE KNOWN AS THE "*FOOD AND DRUG ADMINISTRATION ACT OF 2009*"

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

SECTION 1. Section 4 of Republic Act No. 3720, as amended by Section 5 of Republic Act No. 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) **[in the Department of Health (DOH)]**. THE FDA SHALL BE INDEPENDENT AND SEPARATE FROM THE DEPARTMENT OF HEALTH (DOH) AND ATTACHED TO THE OFFICE OF THE PRESIDENT FOR ADMINISTRATIVE PURPOSES ONLY. **[Said Administration shall be under the Office of the Secretary and shall have the following functions, powers and duties:]**

THE FDA SHALL EXERCISE THE FOLLOWING FUNCTIONS, POWERS AND DUTIES:

a) To administer the effective implementation of this Act, **[and of the same]** ITS IMPLEMENTING RULES and regulations AND OTHER ISSUANCES **[issued]** PROMULGATED pursuant to **[the same]** THIS ACT;

xxx xxx xxx."

SEC. 2. Section 6 of Republic Act No. 3720, as amended by Section 7 of Republic Act No. 8711, is hereby further amended to read as follows:

"SEC. 6. a) The FDA shall be headed by a director-general, with the rank of **[undersecretary]** A DEPARTMENT SECRETARY, who shall be A REGULAR MEMBER OF THE CABINET. THE DIRECTOR-GENERAL SHALL BE APPOINTED BY THE PRESIDENT SUBJECT TO CONFIRMATION BY THE COMMISSION ON APPOINTMENTS. THE DIRECTOR-GENERAL SHALL BE tasked, among others, to determine the needed personnel and to appoint personnel below the assistant director level in **[coordination]** ACCORDANCE with the **[Secretary of Health]** CIVIL SERVICE LAWS, RULES AND REGULATIONS;

b) xxx xxx xxx

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

i) xxx xxx xxx."

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

"SEC. 7. The FDA shall review its staffing pattern and position titles subject to the approval of the **[Secretary of Health]** PRESIDENT."

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

"SEC. 32. PURSUANT TO EXISTING RULES AND REGULATIONS GOVERNING APPEALS TO THE OFFICE OF THE PRESIDENT, the orders, rulings or decisions of the FDA shall be appealable to the **[Secretary of Health]** OFFICE OF THE PRESIDENT. An appeal shall be deemed perfected upon filing of the notice of appeal and posting of the corresponding appeal bond.

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

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

"SEC. 34. *Fees and Other Income.* –

a) Upon the sole approval of the **[Secretary]** PRESIDENT, the authorization and other fees shall annually be determined and reviewed by the FDA and any proposed increase shall be published in two (2) leading newspapers of general circulation.

b) xxx xxx xxx

c) The director-general of the FDA upon approval of the **[Secretary]** PRESIDENT, shall be authorized to promulgate rules and regulations governing the collection of the other related regulatory fees. Upon approval of the **[Secretary]** PRESIDENT, these fees shall likewise be reviewed periodically and any

proposed increase shall be published in two (2) leading newspapers of general circulation."

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

"SEC. 18. xxx xxx xxx

xxx xxx xxx

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

xxx xxx xxx."

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

"SEC. 35. xxx xxx xxx

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

laboratories are accredited by the Philippine Accreditation Office (PAO) of the Department of Trade and Industry (DTI) and the **[DOH]** FDA."

SEC. 8. Section 37 of Republic Act No. 3720, as amended by Section 20 of Republic Act No. 9711 is hereby further amended to read as follows:

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

SEC. 9. The FDA shall, in consultation with the DOH, promulgate the implementing rules and regulations of this Act within one hundred twenty (120) days after the passage of this Act.

SEC. 10. This Act shall take effect fifteen (15) days after its publication in the *Official Gazette* or in a newspaper of general circulation.

Approved,