



THIRTEENTH CONGRESS
First Regular Session

House Bill No. 3570

Introduced by HON. ANTONIO P. YAPHA JR., MD

EXPLANATORY NOTE

To ensure safe and good quality of food, drug and cosmetics, and to regulate the production, sale and traffic of the same in order to protect the health of the people, the Food and Drug Administration (now the Bureau of Food and Drugs) under the Department of Health was created by virtue of Republic Act No. 3720, as amended.

Under the 1987 Constitution, Section 12, Article XIII thereof expressly provides that: "The State shall establish and maintain an effective food and drug regulatory system and undertake appropriate health manpower development and research, responsive to the country's health needs and problems." This is in conjunction to the Declared Policy of the State embodied in Section 15, Article II that: "The State shall protect and promote the right to health of the people and instill health consciousness among them."

However, because the Bureau of Food and Drugs (BFAD) was created decades ago, the law creating and giving BFAD its mandate is now deemed as not responsive to the ever increasing demands of the times. This predicament is compounded further by the passage of a lot of other laws giving more work and responsibilities to BFAD without a corresponding increase in financial resources, equipment and personnel.

There is, therefore, a need to strengthen and augment its resources and capabilities, in terms of regulatory powers and functions, its manpower complement, equipment and facilities and transform the BFAD into a more credible regulatory agency to efficiently and expeditiously perform its mandate.

The support for the passage and approval of this is, thus, earnestly sought.


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Introduced by HON. ANTONIO P. YAPHA JR., MD

AN ACT STRENGTHENING THE REGULATORY CAPACITY OF THE BUREAU OF FOOD AND DRUGS BY FURTHER AMENDING REPUBLIC ACT 3720, AS AMENDED BY EXECUTIVE ORDER NO. 175, AND APPROPRIATING FUNDS THEREOF.

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

SECTION 1. *Short title* – This Act shall be known as the “BFAD Regulatory Act 2004”.

SECTION 2. *Declaration of Policy* - It is the policy of the state to ensure the quality, safety, accessibility and affordability of health care products facilities and services for each and every Filipino. To attain these goals, government must have the mandate and capability to monitor and regulate an ever evolving and developing health products, facilities and services. Pursuant to this policy, the state must enhance its monitoring and regulatory capacity and capability with regard to these health products, particularly food, drugs, devices, cosmetics and household hazardous substances.

SECTION 3. *Objectives* - The act has the following objectives:

- (a) To enhance the administrative and technical capacity of government in health regulations;
- (b) To strengthen the government monitoring, regulatory and control powers in implementing health regulations;
- (c) To ensure government monitoring and regulatory coverage over health and health-related technology, devices and facilities, particularly involving food, drugs, devices, cosmetics and household hazardous substances; and
- (d) To provide coherence in the government regulatory system for foods, drugs, devices, cosmetics, and household hazardous substances.

SECTION 4. Section 4 of Republic Act No. 3720, as amended, is hereby further amended by adding thereto the following subsections:

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- (h) To require all importers, distributors and retailers of food, drugs, devices, cosmetics, and household hazardous substances to submit any incident that reasonably suggest a probability that a drug, food, cosmetic and hazardous substance or device caused or contributed to death, serious illness or serious injury **to a consumer** or patient;
- (i) To call upon manufacturers, **importers, exporters, distributors and retailers of foods, drugs, devices, cosmetics and household hazardous substances to cease and desist, from manufacturing, importing, exporting, selling, offering for sale, distribution, or transfer of any foods, drugs, devices, cosmetics and household hazardous substances, motu proprio, or upon verified complaint by any aggrieved party, and after proper investigation and verification if in its judgment the act or practice may cause injury or prejudice to the consuming public or violations of the provisions of Republic Act No. 3720 as amended and other relevant laws, rules and regulations implemented by the Bureau.**
- (j) To issue recall orders to food, drugs, devices, cosmetics, and household hazardous substances that were deemed, after review and analysis, to have caused the death, serious illness or serious injury to a consumer or patient. **In connection hereto, the Bureau shall require all manufacturers, importers and/or distributors to submit a Product Recall Plan as part of the requirement for the issuance of a License to Operate.**
- (k) To establish a Pharmaco-vigilance System to monitor incidents of adverse or safety issues of drugs and cosmetics in the market.

SECTION 5. Section 5 of Republic Act 3720, as amended, is hereby further amended to read as follows:

SECTION 5. Effective Food and Drug Regulation – There shall be established as a separate food regulation system and drug, device and cosmetic, regulation system in the Bureau. The operation of each system will be done by a management group, each consisting of three (3) separate divisions, namely, the Licensing and Compliance Division, Laboratory Services Division, and Registration Division.

Each management group shall be headed by a Deputy Director for Food and a Deputy Director for Drugs, Devices and Cosmetics, respectively.

SECTION 6. Subsections (d), (e) and (g) of Section 10 of Republic Act No. 3720 as amended are hereby amended and subsection (x) is hereby added thereto to read as follows:

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- (d) "Household hazardous substance" is any substance or mixture of substance which is (i) toxic, (ii) corrosive, (iii) an irritant, (iv) a strong sensitizer, (v) is flammable or combustible, or (vi) generates pressure through decomposition, heat or other means, if such substance or mixture of substances may cause substantial injury or substantial illness during or as a proximate result of any customary or reasonably foreseeable ingestion by children **but should not include fertilizer, pesticide, insecticide and other economic poison such as yard and home products;**
- (e) **"Food" means any processed substance which is intended for human consumption and includes drink for man, beverages, chewing gum and any substance which has been used as an ingredient in the manufacture, preparation or treatment of food.**
- (g) "Device" shall mean any invasive, non-electric and non-motor driven instrument, apparatus, or contrivances, including their components, part, and accessories, intended (1) for use in the diagnoses, cure, mitigation, treatment, or prevention of disease in man or animals; or (2) to affect the structure or any function of the body of man or animals.

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- (x) "Regulatory officers" shall refer to BFAD personnel tasked to implement the regulatory functions of the Bureau.

SECTION 7. Sub-sections (a), (j), (k), and (l) of Section 11 of Republic Act No. 3720, as amended, are hereby further amended and subsection (n) is hereby added thereto to read as follows:

- (a) The manufacture, importation, exportation, sale, offering for sale, distribution, transfer of any food, drug, device, cosmetic **or household hazardous substances** that is adulterated, misbranded.

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- (j) The manufacture, importation, exportation, sale, offering for sale, distribution, transfer or **advertisement** of any **food**, drug or device, **cosmetic or household hazardous substances** which is not registered with the Bureau pursuant to this Act.

- (k) The manufacture, importation, exportation, sale, offering for sale, distribution, transfer of any **food, drug, device, cosmetic or household hazardous substances** by any person without a license to operate from the Bureau required under this Act.
- (l) The **importation, exportation**, sale, offering for sale, distribution or **transfer** of any **food, drug, device, cosmetic or household hazardous substances** beyond its expiration or expiry date.

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SECTION 8. Sub-section (a) of Section 12 of Republic Act No. 3720, as amended, is hereby further amended to read as follows:

Section 12. XXX

- i) Any person who shall violate any of the provisions of Section 11 hereof shall, upon conviction, suffer the penalty of imprisonment ranging from six (6) months to five (5) years, or a fine of not less than Fifty Thousand Pesos (P50,000.00), but not more than Five Hundred Thousand Pesos (P500,000.00) or both at the discretion of the court.

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

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SECTION 9. Subsections (d) and (f) of Section 26 of Republic Act No. 3720, as amended, are hereby further amended, and the provision of the previous subsection (f) is hereby re-numbered as subsection (g) to read as follows:

- (d) **Upon initial findings of the conduct of prohibited act/s, the Director shall issue the proper notices to the person or persons concerned and such person or persons shall be given an opportunity to be heard before the Bureau without prejudice to the outright confiscation of the food, drugs, devices, cosmetics, and household hazardous substances for evidence purposes.**

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- (f) **When an administrative action is instituted arising from the violation complained of in the criminal action, such administrative action may proceed independently of the criminal proceedings and regardless of the result of the latter.**
- (g) **The Secretary is hereby authorized to call on the assistance of any Department, Office or / agency for the effective implementation of the provisions of this Act.**

SECTION 10. Section 29-A of Republic Act No. 3720, as amended, is hereby further amended to read as follows:

In case where there is finding of prohibited actions and determination of the persons liable thereto, **after notice and hearing**, the Secretary, through the Director, is authorized to impose any or all of the following administrative sanctions:

- i) suspension of product registration and/or license of the establishment;
- ii) revocation of product registration and/or license of the establishment;
- iii) destruction of the confiscated food, drugs, device, cosmetic and household hazardous substance; **Provided, that if a criminal action is likewise instituted pertinent samples thereof shall be kept for evidence purposes and the remaining items shall be subject to destruction;**
- iv) a fine of not less than **fifty thousand pesos (P50,000.00) but not more than five hundred thousand pesos (P500,000.00);**
- v) closure of manufacturing site, distribution offices, and any other facility used for production, labeling and distribution;
- vi) filing of criminal charges against persons liable; and
- vii) permanent disqualification from owning, operating or having any other interest in an establishment within the jurisdiction of the bureau.

SECTION 11. Section 31, Chapter XIII of RA 3720 is hereby amended to read as follows:

SECTION 31. Fees and Authority to Retain Income.

- (a) The registration and/or license fees shall annually be determined **and reviewed for any proposed increase** and to be published in two (2) leading newspapers of general circulation upon approval of the Secretary;
- (b) Additional fees to be known as "Over and Above Regulatory Fees" for facilitated processing, registration, licensing and other sources of fees and charges shall be determined; and
- (c) The Director, with the approval of the Secretary, shall be authorized to promulgate rules and regulations governing the collection of the "Over and Above Regulatory Fees". These fees shall likewise be reviewed periodically for any proposed increase and to be published in two (2) leading newspapers of general circulation upon the approval of the Secretary.
- (d) The Bureau of Food and Drugs shall be authorized to retain and use **at least fifty percent (50%) of all income generated**, subject to the usual accounting and auditing procedures.

SECTION 32. Health Regulatory Fund

- (a) For a more effective and expeditious implementation of its mandate a special BFAD regulatory fund shall be established. The fund shall be sourced from the income retained pursuant to Subsection (d) of the preceding Section, which shall be separate from the Bureau's annual budget, shall be deposited and maintained in a separate account or fund, which may be used or disbursed directly by the Director.
- (b) The fund shall be allowed to accept donations and all other endowments in accordance with pertinent laws, rules and regulations; and
- (c) The fund shall be deposited and maintained in a separate account, which may be used or disbursed directly by the Director subject to existing accounting and auditing rules and regulations. Semi-annual reports on the disbursement and utilization shall be submitted to the Committee on Health of the House of Representatives and the Senate, respectively.

SECTION 12. New sections are added as follows:

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CHAPTER XIV– REGULATORY STRENGTHENING

SECTION 33. Regulatory Quality Assurance Laboratories – Regional laboratories for testing and monitoring the safety, purity and quality of food and drugs are to be established nationwide which are to be piloted in Cebu City and Davao City, respectively, within two (2) years subsequent to the enactment of this Act. The Secretary of Health shall determine the total number and location of regional laboratories based on the appraisals and studies of the BFAD.

SECTION 34. Regulatory Officers – Three hundred (300) plantilla positions for regulatory officers are hereby created subject to the rules and regulations of the Civil Service Commission (CSC).

The distribution of the newly created positions shall be subject to the discretion of the Secretary of Health upon the recommendation of the Director of BFAD.

SECTION 13. Sections 32, 33 and 34 of Republic Act 3720, as amended are hereby renumbered as Sections 36, 37 and 38, respectively.

SECTION 14. Appropriations

- (a) Three hundred million pesos (P300,000,000.00) is hereby exclusively appropriated for the regional quality assurance laboratories from the next General Appropriations Act (GAA) as additional appropriations for the Department of Health.
- (b) One Hundred Million pesos (P100,000,000.00) is hereby exclusively appropriated for the Three hundred (300) newly created plantilla positions for regulatory officers which shall constitute new and additional appropriations for the Department of Health in all GAAs subsequent to the enactment of this Act.
- (c) All other appropriations necessary for the implementation of this law shall be included in the next and all future General Appropriations Act.

SECTION 15. Implementing Rules – The Department of Health shall promulgate, in consultation with the Bureau of Food and Drugs, the implementing rules and guidelines of this Act within ninety (90) days after the passage of the Act.

SECTION 16. Separability Clause – If any part, section or provision of this Act shall be declared invalid or unconstitutional, other provisions or parts thereof which are not affected thereby shall remain in full force and effect.

SECTION 17. Repealing Clause – Laws or part of laws, executive orders, circulars, regulations and memoranda inconsistent with this Act are hereby repealed or amended accordingly.

SECTION 18. Effectivity – This act shall take effect fifteen (15) days after publication in the Official Gazette or in two (2) newspapers of general circulation.

Approved,