THIRTEENTH CONGRESS OF THE)
REPUBLIC OF THE PHILIPPINES)
First Regular Session)

SENATE

S. No. **1093**

Introduced by Senator Ma. Ana Consuelo A. S. Madrigal

EXPLANATORY NOTE

In a policy review and program implementation of the ***Generics Law*** which was envisioned to extend to our people safe, effective, affordable and accessible medicines, and the national drug policy of the government conducted by policy experts and scholars, it was disclosed that the ***quality assurance*** and ***rational drug use,*** two of the five (5) component pillars and strategies of implementing the *Generics Law,* were greatly affected because of the lack of administrative and technical capability of the ***Bureau of Food and Drugs*** (BFAD) to effectively perform its regulatory functions of licensing, registration and monitoring.

Considered as most crucial to this is its capability to perform *bioavailability* and *bioequivalence tests,* which was often raised by multinational companies through the *Pharmaceutical Healthcare Association of the Philippines* (PHAP) and the *Philippine Medical Association* (PMA) as this aspect contributes to the perception of poor quality of generic products. The latter has been relentless in challenging BFAD to provide them with scientific data such as what these tests can yield to prove that generic drugs are as safe and as potent as the tested brand and products that they are using.

As most of us know, BFAD is the regulatory agency of the government tasked to ensure the quality of medicines and pharmaceuticals, among other products, that are made available to the public. Its two main divisions, namely, the *Inspection and Licensing Division* and *Laboratory Division* are tasked to ensure that before drugs are allowed to be circulated for sale to the market, they are cleared up for licensing and product registration. Once they are already in the market, monitoring is periodically conducted.

The critical points in drug quality assurance are the following: (a) Good Manufacturing Practices (GMP) as the basis for licensing; (b) Product registration or renewal wherein the safety, efficacy and quality of drugs are evaluated and tested; (c) Bioavailability and bioequivalence testing of drugs with reported bioavailability problems, and; (d) Quality monitoring of products on the market consisting of random sampling of drug supply in government facilities, at the drug outlets and on suspected drug products submitted by doctors, institutions and consumers.

If these procedures are strictly and efficiently followed, then quality control by BFAD will be sufficient to ensure safety and efficacy.

There is, therefore, a need to transform BFAD into a more and credible regulatory agency, one whose integrity and credibility are above reproach and if possible, beyond any reasonable doubt. To achieve this, it is vital, among other things, not only to provide adequate funding for the agency but more importantly to introduce

major administrative reforms in BFAD to strengthen the capability of BFAD's regulatory functions of licensing, registration and monitoring, and more specifically in the following aspects (1) Human resources in the field (2) Augmentation of existing laboratories and upgrading their equipment (3) Operational budget, and (4) Creation of a drug enforcement unit under its operational and administrative control which must be made separate and distinct from the Philippine National Police (PNP) whose enforcement powers will be strictly limited to the implementation of BFAD's regulatory functions.

This bill is intended to specifically address these ever-growing and urgent concerns and also to continue and conclude previous legislative initiatives to help government in its tasks of ensuring an effective drug regulatory system and undertaking the appropriate health manpower development and research, responsive to the country's health needs and problems.

Support for the passage and approval of this bill is thus earnestly sought.

MA. ANA CONSUELO A.S. MADRIGAL
Senator

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S. B. No. **1093**

Introduced by Senator Ma. Ana Consuelo A. S. Madrigal

AN ACT
STRENGTHENING THE CAPABILITY OF THE BUREAU OF FOOD AND DRUGS (BFAD) BY ESTABLISHING ADEQUATE TESTING LABORATORIES AND FIELD OFFICES IN ALL PROVINCES AND CITIES, UPGRADING ITS EQUIPMENT, CREATING A DRUG ENFORCEMENT UNIT (DEU) UNDER ITS OPERATIONAL AND ADMINISTRATIVE CONTROL, AND APPROPRIATING FUNDS THEREFOR

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

SECTION 1. *Title.* - This Act shall be known as the ***"BFAD Empowerment Act of 2004"***.

SEC. 2. *Declaration of Policy.* - It is hereby declared a policy of the State to 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 food and drug regulatory system and undertake appropriate health manpower development and research, responsive to the country's health needs and problems. Pursuant to this policy, the State must enhance its regulatory capacity and strengthen its capability with regard to the licensing, registration and monitoring of drugs, food, cosmetics and hazardous substances.

SEC. 3. *Increased Testing Facilities.* - The Department of Health (DOH) is hereby mandated to improve, upgrade and increase the capability of the Bureau of Food and Drugs (BFAD), to test, assay and examine samples of pharmaceutical, cosmetics and food products being applied for registration, as well as monitor pharmaceutical, cosmetic and food products already in the market.

For the purpose of achieving the above mandate, there shall be established at least one (1) testing laboratory each in Luzon, Visayas and Mindanao, which shall have

all the necessary and appropriate state-of-the-art laboratory equipment and personnel complement. The main testing laboratory at the Bureau's central office shall continue to be maintained.

SEC. 4. *BFAD's Regulatory Field Offices.* - The BFAD shall establish field offices in all provinces and cities to effectively implement its regulatory functions. The present *Regional Food and Drug Regulatory Office* (RFDRO) in every regional office of the DOH shall now be put under the BFAD's sole administrative control. All *Regional Food and Drug Regulatory Officers* (RFDRO's) shall now be designated as *Food and Drug Regulatory Officers* (FDROs) at-large and shall likewise be under the BFAD's administrative control. The DOH, in collaboration with the BFAD, shall seek the creation of additional plantilla positions as may be necessary to support the said BFAD Field Offices, subject to the rules and regulations of the Civil Service Commission.

SEC. 5. *Drug Enforcement Unit.* - The BFAD shall establish a *Drug Enforcement Unit* (DEU) which will be composed of not less than ten (10) qualified personnel in every region and who will be directly under the supervision of the FDRO. They shall bear arms, wear official uniforms and insignias and shall be classified as law enforcement agents. Their authority and functions shall be strictly limited to the implementation of BFAD's regulatory functions.

SEC. 6. *Work Program.* - The DOH, the BFAD, the Department of Budget and Management and the Department of Finance shall prepare the necessary work programs to cover the staggered implementation of this Act for a period not exceeding five (5) years.

SEC. 7. *Appropriations.* - The appropriations for the BFAD included in the DOH under the current General Appropriations Act shall be used to carry out the initial implementation of this Act. Thereafter, such sums as may be necessary for its staggered implementation shall be included in the annual General Appropriation Act.

All receipts derived from registration and licensing fees, sale of publications and services, assessment, fees, fines, penalties and other fees and charges authorized and imposed under this Act are hereby constituted as a special account in the General Fund, for the implementation of this Act: *Provided,* That no amount shall be disbursed to cover personal services expenses and purchase of motor vehicles.

The fund may be augmented by grants, donations and endowments from various sources, domestic or foreign, for purposes related to their functions.

SEC. 8. *Implementing Rules and Regulations.* - The DOH, in collaboration with the BFAD, shall promulgate the rules and regulations to implement this Act within ninety (90) days from the approval of this Act.

SEC. 9. *Separability Clause.* - If, for any reasons, any provision or part of this Act is declared unconstitutional or invalid, such other parts not affected thereby shall remain in full force and effect.

SEC. 10. *Repealing Clause.* - All laws, presidential decrees, administrative orders and executive issuances or parts thereof inconsistent with the provisions of this Act are hereby repealed or modified accordingly.

SEC. 11. *Effectivity.* - This Act shall take effect fifteen (15) days after its publication in at least two (2) newspaper of general circulation.

Approved,