SHOULD FILE SECRETARY

13TH CONGRESS OF THE REPUBLIC OF THE PHILIPPINES First Regular Session

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SENATE

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S. BILL NO. 1394

Introduced by Senator Ralph G. Recto

EXPLANATORY NOTE

Several legislations have been passed to strengthen the capabilities of the Bureau of Food and Drugs (BFAD). BFAD was created by Republic Act No. 3720, entitled as "An Act To Ensure The Safety And Purity Of Foods, Drugs, And Cosmetics Being Made Available To The Public By Creating The Food And Drug Administration Which Shall Administer And Enforce The Laws Pertaining Thereto. It was further amended by Executive Order No. 175 in 1987.

This bill seeks to strengthen capability of the Bureau of Food and Drugs by establishing adequate testing laboratories and field officers in all provinces and cities, upgrading its equipment, and creating a Drug Enforcement Unit under its operational and administrative control.

Specifically, this bill seeks to increase testing laboratories and establish at least one (1) testing laboratory in Luzon, Visayas and Mindanao, which shall have all the necessary and appropriate state-ofthe-art laboratory equipment and personnel complement. This bill also seeks to create a Drug Enforcement Unit (DEU) which will be composed of not less than ten (10) qualified personnel in every region.

The passage of this bill will help improve and maintain structures directed to protect and promote the right to health of the Filipino people, and help establish and maintain an effective food and drug regulatory system.

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

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S. BILL NO. 1394

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

1 SECTION 1. Title. - This Act shall be known as the "BFAD

2 Empowerment Act of 2004"

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SEC. 2. Declaration of Policy. - It is hereby declared a policy of the 3 State to adopt, support, establish, institutionalize, improve and maintain 4 structures, processes, mechanisms and initiatives that are aimed, directed 5 and designed to (a) protect and promote the right to health of the Filipino 6 7 people, and (b) help establish and maintain an effective food and drug 8 regulatory system and undertake appropriate health manpower 9 development and research, responsive to the country's health needs and 10 problems. Pursuant to this policy, the State must enhance its regulatory capacity and strengthen its capability with regard to the licensing, 11 12 registration and monitoring of drugs, food, cosmetics and hazardous substances. 13

SEC. 3. Increased Testing Facilities. - The Department of Health 14 (DOH) is hereby mandated to improve, upgrade and increase the 15 capability of the Bureau of Food and Drugs (BFAD) to test, assay and 16 examine samples of pharmaceutical, cosmetics and food products being 17 applied for registration, as well as monitor pharmaceutical, cosmetic and 18 food products already in the market. 19

For the purpose of achieving the above mandate, there shall be 20 established at least one (1) testing laboratory each in Luzon, Visayas and 21 Mindanao, which shall have al the necessary and appropriate state-of-22 the-art laboratory equipment and personnel complement. The main 23 testing laboratory at the Bureau's central office shall continue to be 24 25 maintained.

SEC. 4. BFAD's Regulatory Field Offices. - The BFAD shall establish 26 field offices in all provinces and cities to effectively implement its 27 regulatory functions. The present Regional Food and Drug Regulatory 28 Office (RFDRO) in every regional office of the DOH shall now be put under 29 the BFAD's sole administrative control. All Regional Food and Drug 30 Regulatory Officers (RFDROs) shall now be designated as Food and Drug 31 Regulatory Officers (FDROs) at-large and shall likewise be under the 32 BFAD's administrative control. The DOH, in collaboration with the BFAD, 33 34 shall seek the creation of additional plantilla positions as may be necessary to support the said BFAD Field Offices, subject to the rules and 35 regulations of the Civil Service Commission. 36

37 SEC. 5. Drug Enforcement Unit. – The BFAD shall establish a Drug Enforcement Unit (DEU) which will be composed of not less than ten (10) 38 qualified personnel in every region and who will be directly under the 39 supervision of the FDRO. They shall bear arms, wear official uniforms and 40

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.

44 SEC. 6. Work Program. – The DOH, the BFAD, the Department of 45 Budget and Management and the Department of Finance shall prepare 46 the necessary work programs to cover the staggered implementation of 47 this Act for a period not exceeding five (5) years.

48 SEC. 7. Appropriations. – The appropriations for the BFAD included in 49 the DOH under the current General Appropriations Act shall be used to 50 carry out the initial implementation of this Act. Thereafter, such sums as 51 may be necessary for its staggered implementation shall be included in 52 the annual General Appropriations 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 in 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 purchases of motor vehicles.

59 The fund may be augmented by grants, donations, endowments 60 from various sources, domestic or foreign, for purposes related to their 61 functions.

62 SEC. 8. Implementing Rules and Regulations. – The DOH, in 63 collaboration with the BFAD, shall promulgate the rules and regulations to 64 implement this Act within ninety (90) days from the approval of this Act.

65 SEC. 9. Separability Clues. If, for any reason, any provision or part of 66 this Act is declared unconstitutional or invalid, such other parts not 67 affected thereby shall remain in full force and effect.

68 SEC. 10. Repealing Clause. – All laws, presidential decrees, 69 administrative orders and executive issuances or parts thereof inconsistent 70 with the provisions of this Act are hereby repealed or modified 71 accordingly.

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

74 Approved,