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REPUBLIC OF THE PHILIPPINES
HOUSE OF REPRESENTATIVES
Quezon City

THIRTEENTH CONGRESS
First Regular Session

HOUSE BILL No. 613



Introduced by REP. FRANCIS G. ESCUDERO

EXPLANATORY NOTE

The National Drug Policy is aimed at rationalizing the drug industry and drug consumption in the Philippines. One crucial point to its success is the strengthening of the Bureau of Food and Drugs. The Bureau, which is under the Department of Health, is tasked with the strict enforcement of the country's numerous laws concerning food and drugs, including the Generic Act.

Furthermore, Section 12 Article 13 of the 1987 Constitution provides that *"the State shall establish and maintain an effective food and drug regulatory system and undertake appropriate health power development and research, responsive to the country's health needs and problems."* The Bureau has been perceived to be the Agency to implement this food and drug regulatory system.

However, R.A. 3720 as amended by R.A. 7394 or the Consumer Act of the Philippines which created and provided for the responsibilities of the Bureau failed to clothe the Bureau with the power or authority to administer the law and the rules and regulations issued pursuant thereto effectively. The existing laws further failed to clarify the extent of the Bureau's regulatory powers making it hesitant and therefore ineffective to implement existing rules and regulations perceived to be beyond the Agency's rule-making authority.

In view of the foregoing, the immediate passage of this Bill is earnestly requested.

A handwritten signature in blue ink, consisting of a stylized 'F' and 'E' intertwined.

FRANCIS G. ESCUDERO

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AN ACT
STRENGTHENING AND VESTING THE BUREAU OF FOOD AND DRUGS
WITH QUASI-JUDICIAL POWERS AND FOR OTHER PURPOSES
AMENDING CERTAIN SECTIONS OF REPUBLIC ACT NUMBERED
THIRTY-SEVEN HUNDRED AND TWENTY, OTHERWISE KNOWN AS THE
"FOODS, DRUGS AND DEVICES, AND COSMETIC ACT"

*Be it enacted by SENATE and HOUSE OF REPRESENTATIVES of the
Philippines in Congress assembled:*

SECTION 1. Section 4, 12 (a), 26 (c) and 29-A of Republic Act No3720, otherwise known as the "Foods, Drugs, Devices, and Cosmetics Act," as amended are hereby amended to read:

"SECTION 4. To carry out the purposes of this Act, there is hereby created an office to be called the Bureau of Food and Drugs in the Department of Health. Said Bureau shall be under the Office of the Secretary of Health and shall have the following functions, powers and duties:

- (a) To administer and supervise the implementation of this Act and of the rules and regulations issued pursuant to the same;
- (b) To inspect, collect, and analyze samples of food, drugs, devices and cosmetic to ensure pure, safe and good quality supply of food and cosmetics; and pure, safe, effective and good quality supply of drugs and devices;
- (c) To inspect and issue license to operate to persons and establishments engaged in the manufacture, distribution, importation, exportation and sale of drugs and devices; and to persons or establishments engaged in the manufacture or processing and importation of food and cosmetic after their compliance with technical standards and requirements;
- (d) To establish analytical data to serve as basis for the preparation of food, drug and cosmetic manufacturers and establishments;
- (e) To register foods, drugs, devices and cosmetic unless, by regulation, the Secretary of Health exempts such food, drug, device or cosmetic from registration;
- (f) To levy, assess and collect fees for licensing of persons or establishments, registration, analysis of products or materials submitted in compliance with the provisions of this Act;
- (g) To certify batches of antibiotics and antibiotics preparations in compliance with the provisions of this Act."

"Section 12. (a) Any person who violates any of the provisions of the Section Eleven hereof shall, upon conviction, be subject to imprisonment of not less than One (1) year but not more than Ten (10) years, or a fine of not less than Twenty-Five Thousand Pesos (P25,000.00) but not more than Fifty Thousand Pesos

(₱50,000.00), or both such fine and imprisonment, in the discretion of the Court;

PROVIDED, THAT, IF THE VIOLATION RESULTS IN DEATH, DEFORMITY OR INJURY TO ANY PERSON, THE PENALTIES PROVIDED FOR UNDER THE REVISED PENAL CODE SHALL APPLY, WHENEVER IT IS HIGHER, PROVIDED FURTHER, THAT IN THE CASE OF RECIDIVISTS, THE FINE IMPOSABLE SHALL BE FIFTY THOUSAND PESOS (₱50,000.00). Should the offense be committed by a juridical person, the Chairman of the Board of Directors, the President, General Manager, or the partners and/or the persons directly responsible therefor shall be penalized.

AFTER FINAL JUDGEMENT OF CONVICTION, THE COURT UPON PETITION OF THE PROSECUTING ATTORNEY IN THE SAME PROCEEDINGS, AND AFTER DUE HEARINGS, MAY, WHEN THE PUBLIC INTEREST SO REQUIRES, ORDER THE SUSPENSION OR DISSOLUTION OF SUCH CORPORATION, TRUST, FIRM PARTNERSHIP, ASSOCIATION OR JURIDICAL PERSON."

SECTION 26. (C). THE BUREAU OF FOOD AND DRUGS SHALL HAVE THE POWER AND AUTHORITY:

- (1) TO INIATE AND CONDUCT INSPECTION AND INVESTIGATON AS MAY BE NECESSARY IN ORDER TO ACCOMPLISH AND CARRY OUT THE PURPOSE OF R.A. 3720 AS AMENDED AND OTHER LAWS UNDER ITS JURISDICTION;

- (2) TO CONDUCT HEARINGS ON COMPLAINTS INVOLVING VIOLATIONS OF R.A. 3720 AS AMENDED AND OTHER LAWS UNDER ITS JURISDICTION AS WELL AS THE RULES AND REGULATIONS ISSUED PURSUANT THERETO TO DETERMINE AND DECIDE APPROPRIATE ADMINISTRATIVE SANCTIONS;
- (3) TO ADMINISTER OATHS AND AFFIRMATIONS, AND ISSUE SUBPOENA AD TESTIFICANDUM AND SUBPOENA DUCES TECUM REQUIRING THE ATTENDANCE AND TESTIMONY OF PARTIES, WITNESSES AND/OR THE PRODUCTION OF SUCH BOOKS, CONTRACTS, CORRESPONDENCE, RECORDS, STATEMENT OF ACCOUNTS AND OTHER DOCUMENTS AS MAY BE MATERIAL TO THE INVESTIGATION CONDUCTED BY THE BUREAU;
- (4) TO OBTAIN INFORMATION FROM ANY OFFICER OR OFFICE OF THE NATIONAL AND LOCAL GOVERNMENTS, GOVERNMENT AGENCIES OR ITS INSTRUMENTALITIES;
- (5) TO SEIZE AND HOLD IN CUSTODY ANY ARTICLE OR ARTICLES OF FOOD, DRUG, DEVICE OR COSMETIC THAT IS ADULTERATED, COUNTERFEITED, MISBRANDED OR UNREGISTERED INTRODUCED, INTO DOMESTIC COMMERCE AND ITS ESTABLISHMENT CLOSED, PENDING THE AUTHORIZED HEARING UNDER R.A. 3720 AS AMENDED, WHEN THE DIRECTOR HAS A PROBABLE CAUSE TO BELIEVE THAT THE FOOD, DRUG, DEVICE OR COSMETIC OR THE OPERATION OF THE ESTABLISHMENT ENDANGERS THE HEALTH OR SAFETY OF THE PUBLIC OR THE CONSUMERS;

- (6) TO CALL ON THE ASSISTANCE OF ANY DEPARTMENT, OFFICE OR AGENCY FOR THE EFFECTIVE IMPLEMENTATION OF THE PROVISIONS OF THIS ACT;
- (7) TO HOLD ANY PERSON IN DIRECT OR INDIRECT CONTEMPT AND IMPOSE THE APPROPRIATE PENALTIES FOLLOWING THE SAME PROCEDURES AND PENALTIES PROVIDED IN THE RULES OF COURT."

"ARTICLES 29-A THE BUREAU OF FOOD AND DRUGS IS HEREBY AUTHORIZED TO IMPOSE, AFTER NOTICE AND HEARINGS, ANY OR ALL OF THE FOLLOWING:

- (a) SEIZURE AND/OR CONDEMNATION OF ANY ARTICLE OR ARTICLES OF FOOD, DRUG, DEVICE OR COSMETIC INTRODUCED, OR SOUGHT TO BE INTRODUCED INTO DOMESTIC COMMERCE THAT IS ADULTERATED, COUNTERFEITED, MISBRANDED, BANNED OR UNREGISTERED;
- (b) CLOSURE AND/OR CANCELLATION OR REVOCATION OF THE LICENSE TO OPERATE ANY FOOD, DRUG, DEVICE AND COSMETIC ESTABLISHMENT FOUND TO HAVE VIOLATED THE PROVISIONS OF R.A. 3720 AS AMENDED BY R.A. 7394, OR ANY LAW ADMINISTERED AND IMPLEMENTED BY THE BUREAU AS WELL AS ITS IMPLEMENTING RULES AND REGULATIONS;
- (c) SUSPENSION, CANCELLATION OR REVOCATION OF REGISTRATION OF ANY FOOD, DRUG, DEVICE OR COSMETIC FOUND ADULTERATED, MISBRANDED, OTHERWISE UNSAFE;

(d) IMPOSE ADMINISTRATIVE FINES OF NOT LESS THAN FIVE HUNDRED PESOS NOR MORE THAN THREE HUNDRED THOUSAND PESOS (P300,000.00)."

SECTION 2. In all its administrative proceedings, the Bureau shall not be bound by the technical rules of evidence;

SECTION 3. The orders, ruling, decision of the Director of the Bureau shall be appealable to the Secretary of Health within fifteen (15) days from the notice of such order, ruling or decision;

SECTION 4. The order, ruling decision of the Director of the Bureau shall be immediately executory unless an order from the Secretary of Health is issued to stay the execution thereof;

SECTION 5. Any order, ruling or decision of the Secretary may be reviewed by the Supreme Court on certiorari in appropriate cases, or petition for review by any person affected thereby. The appeal by certiorari or petition for review shall be filed within thirty (30) days from the notice of the denial of a motion for reconsideration from said order, ruling or decision, in cases when motion for reconsideration from said order, ruling or decision, in cases when motion for reconsideration had been filed;

SECTION 6. The institution of a Writ of Certiorari or other special remedies in the Supreme Court shall in no case supercede or stay any order, ruling or decision of the Secretary, unless the Supreme Court shall so direct and the appellant may be required by the Supreme Court to give bond in such form and of such amount as may be deemed proper;

SECTION 7. The Secretary of Health shall expand the organizational structure of the Bureau of Food and Drugs (BFAD) and create additional positions thereat for the said Bureau to effectively exercise the additional powers and accomplish the functions mandated under this Act;

SECTION 8. The BFAD is authorized to retain all its income, including those derived from administrative fines imposed for violations of the laws it administer as well as their implementing rules and regulations, subject to the accounting and auditing rules and regulations;

SECTION 9. All existing laws, orders and other issuance inconsistent with this Act are hereby repealed and/or modified accordingly.

SECTION 10. This Act shall take effect fifteen (15) days from publication in at least two (2) newspapers of general circulation or in the Official Gazette.

Approved,