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

SENATE
S.B. No. 1652

Introduced by Senator Loren Legarda

EXPLANATORY NOTE

This bill seeks to address the lack of technical capability, manpower and resources of the Bureau of Food and Drugs (BFAD) which are hindrances in the effective performance of its duties as a drug regulatory, licensing and monitoring agency by amending certain provisions of Republic Act (R.A.) No. 3720, otherwise known as the "Food, Drug and Cosmetic Act."

Under Article XIII, Section 12 of the Constitution, the establishment and maintenance of an effective food and drug regulatory system and appropriate health, manpower development and research, responsive to the country's health needs and problems shall be undertaken by the State. Consonant to this Constitutional policy, R.A. 3720 was enacted on June 22, 1963, which created the defunct Food and Drug Administration (FDA). Through Executive Order No. 851, the FDA was abolished and BFAD was created to replace it.

BFAD is tasked with the same responsibility as the FDA, which is to ensure the quality of medicines and pharmaceuticals, among other products, that are made available to the public. In 1992, R.A. 7394 (Consumer Act of the Philippines) was passed in order to reaffirm BFAD's duty "to protect consumers from adulterated or unsafe product with false, deceptive and misleading information".

Amidst these laws and other legislations set to protect the consumers against the proliferation of unregulated, tampered or expired drugs, doubts on BFAD's effectiveness have arisen due to BFAD's financial, technological and manpower constraints. According to BFAD Director Joshua Ramos' study entitled "Pharmaceutical Policies for Affordable Access," BFAD is incapable of absorbing the huge demand for product testing as exhibited by the number of pending applications. His paper also suggests that there is a disproportionate ratio between Food and Drug Regulation Officers (FDROs) and the number of drug establishments. A Senate Committee on Health and Demography report in 2004, confirmed that BFAD only has one 150 FDROs (40 in Metro Manila and 114 spread in the other 15 regions of the country).

This bill hopes to strengthen BFAD by updating the regulations and prohibitions on the manufacture, tampering, labeling, importation, exportation, sale, distribution and transfer of food, drugs, devices, in-vitro diagnostic reagents, cosmetics and household hazardous substances.

This proposed measure likewise gives additional powers to the BFAD Director and revised the penalties imposed by R.A. 3720.

Under this bill, BFAD is given the authority to retain its income and is tasked to establish a Health Regulatory Fund which will be used by BFAD for its operations and upgrading.

Finally, this bill mandates the Department of Health to improve, upgrade and increase the technical and regulatory capability of BFAD, establish adequate testing laboratories and field offices all over the country, upgrading its equipment and augmenting its human resource complement.

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

LOREN LEGARDA
Senator

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

SENATE
S.B. No. 1652

Introduced by Senator Loren Legarda

AN ACT
STRENGTHENING THE REGULATORY CAPACITY OF THE BUREAU OF FOOD AND DRUGS (BFAD) BY ESTABLISHING ADEQUATE TESTING LABORATORIES AND FIELD OFFICES, UPGRADING ITS EQUIPMENT, AUGMENTING ITS HUMAN RESOURCE COMPLEMENT, GIVING AUTHORITY TO RETAIN ITS INCOME AND FOR OTHER PURPOSES AMENDING CERTAIN SECTIONS OF REPUBLIC ACT 3720, AS AMENDED AND APPROPRIATING FUNDS THEREOF.

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

SECTION 1. *Short Title* - This Act shall be known as the **"Bureau of Food and Drugs Empowerment Act of 2007".**

SECTION 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 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 inspection, licensing and monitoring of establishments and the registration and monitoring of food, drugs, devices, in-vitro diagnostic reagents cosmetics and household hazardous substances.

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

(a) To enhance and strengthen the administrative and technical capacity of the Bureau of Food and Drugs in the regulation of establishments and products under its jurisdiction;

(b) To ensure the Bureau of Food and Drugs' monitoring and regulatory coverage over establishments and products under its jurisdiction; and

(c) To provide coherence in the Bureau of Food and Drugs' regulatory system for establishments and products under its jurisdiction.

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

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(H) TO REQUIRE ALL:

1. MANUFACTURERS, IMPORTERS, DISTRIBUTORS AND RETAILERS OF DRUGS OR DEVICES, OR

2. MANUFACTURERS, IMPORTERS AND DISTRIBUTORS OF FOOD, IN-VITRO DIAGNOSTIC REAGENTS, COSMETICS, AND HOUSEHOLD HAZARDOUS SUBSTANCES

TO REPORT TO THE BUREAU OF FOOD AND DRUGS ANY INCIDENT THAT REASONABLY INDICATES THAT A FOOD, DRUG, DEVICE, IN-VITRO DIAGNOSTIC REAGENT, COSMETIC OR HOUSEHOLD HAZARDOUS SUBSTANCE HAS CAUSED OR CONTRIBUTED TO THE DEATH, SERIOUS ILLNESS OR SERIOUS INJURY TO A CONSUMER OR A PATIENT;

(I) TO ORDER, *MOTU PROPIO* 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 IS IN VIOLATION OF THE PROVISIONS OF REPUBLIC ACT NO. 3720 AS AMENDED AND OTHER RELEVANT LAWS, RULES AND REGULATIONS IMPLEMENTED BY THE BUREAU:

1. MANUFACTURERS, IMPORTERS, DISTRIBUTORS AND/OR RETAILERS OF DRUGS OR DEVICES, OR

2. MANUFACTURERS, IMPORTERS AND DISTRIBUTORS OF FOOD, IN-VITRO DIAGNOSTIC REAGENTS, COSMETICS, AND/OR HOUSEHOLD HAZARDOUS SUBSTANCES,

TO CEASE AND DESIST FROM MANUFACTURING, IMPORTING, EXPORTING, SELLING, AND OFFERING FOR SALE, DISTRIBUTING, OR TRANSFERRING ANY DRUGS, DEVICES, IN-VITRO DIAGNOSTIC REAGENTS, FOOD, COSMETICS, OR HOUSEHOLD HAZARDOUS SUBSTANCES.

(J) TO BAN, RECALL, STOP FURTHER DISTRIBUTION OR CAUSE THE WITHDRAWAL OF ANY FOOD, DRUGS, DEVICES, IN-VITRO DIAGNOSTIC REAGENTS, COSMETICS, OR 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 DIRECTOR SHALL ISSUE REGULATIONS,

UPON APPROVAL OF THE SECRETARY, REQUIRING 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 STRENGTHEN THE POST MARKET SURVEILLANCE SYSTEM IN MONITORING INCIDENTS OF ADVERSE EVENTS INVOLVING PRODUCTS UNDER THE BUREAU'S JURISDICTION.

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

"**Section 5.** [The Food and Drug Administration shall have the following Divisions:] EFFECTIVE FOOD, DRUG, DEVICE, COSMETIC, AND HOUSEHOLD HAZARDOUS SUBSTANCES REGULATION - THERE SHALL BE ESTABLISHED A SEPARATE FOOD REGULATION OFFICE AND DRUG, DEVICE, COSMETIC, AND HOUSEHOLD HAZARDOUS SUBSTANCES REGULATION OFFICE IN THE BUREAU. THE OPERATION OF THE TWO OFFICES SHALL BE UNDERTAKEN BY TWO SEPARATE MANAGEMENT GROUPS EACH CONSISTING OF TWO (2) SEPARATE DIVISIONS NAMELY THE LICENSING AND COMPLIANCE DIVISION, AND THE REGISTRATION DIVISION.

EACH MANAGEMENT GROUP SHALL BE HEADED BY A DEPUTY DIRECTOR, NAMELY THE DEPUTY DIRECTOR FOR FOOD AND THE DEPUTY DIRECTOR FOR DRUGS, DEVICES, COSMETICS, AND HOUSEHOLD HAZARDOUS SUBSTANCES, RESPECTIVELY.

[(a) Inspection and Licensing Division, which shall have charge of the inspection of food, drug, and cosmetic establishments engaged in their manufacture and sale.]

[(b) Laboratory Division, which shall conduct all the tests, analyses and trials of products covered by this Act.]"

SECTION 6. Subsection (e) of Section 10 of Republic Act No. 3720 as amended is hereby amended and subsections (x), (y) and (z) are hereby added thereto to read as follows:

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(e) "Food" means [(1) articles used for food or drink for man, (2) chewing gum, and (3) articles used for components of any such article.] ANY PROCESSED SUBSTANCE WHICH IS INTENDED FOR HUMAN CONSUMPTION AND INCLUDES DRINK FOR MAN, BEVERAGES, CHEWING GUM AND ANY SUBSTANCES WHICH HAVE BEEN USED AS AN INGREDIENT IN THE MANUFACTURE, PREPARATION OR TREATMENT OF FOOD."

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(x) "FOOD-DRUG REGULATION OFFICERS (FDRO)" SHALL REFER TO THE BUREAU OF FOOD AND DRUGS' PERSONNEL TASKED TO IMPLEMENT THE REGULATORY FUNCTIONS OF THE BUREAU.

(Y) "*HOUSEHOLD HAZARDOUS SUBSTANCE*" IS ANY SUBSTANCE OR MIXTURE OF SUBSTANCE WHICH IS TOXIC, CORROSIVE, AN IRRITANT, A STRONG SENSITIZER, IS FLAMMABLE OR COMBUSTIBLE, OR 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, COSMETICS, RADIOACTIVE SUBSTANCE, OR SUBSTANCES INTENDED FOR USE AS FUELS WHEN STORED IN CONTAINERS AND USED IN HEATING, COOKING OR REFRIGERATION SYSTEM OF A HOUSE;]

(Z) "IN-VITRO DIAGNOSTIC REAGENTS" ARE REAGENTS AND SYSTEMS INTENDED FOR USE IN THE DIAGNOSIS OF DISEASE OR OTHER CONDITIONS, INCLUDING A DETERMINATION OF THE STATE OF HEALTH, IN ORDER TO CURE, MITIGATE, TREAT OR PREVENT DISEASE OR ITS *SEQUELAE* (PATHOLOGICAL CONDITIONS RESULTING FROM A PRIOR DISEASE, INJURY, OR ATTACK).

SECTION 7. Subsections (a), (b), (c), (g), (j), (k), and (l) of Section 11 of Republic Act No. 3720 as amended, are hereby amended to read as follows:

(a) The manufacture, IMPORTATION, EXPORTATION, sale, offering for sale, DISTRIBUTION, transfer of any food, device, IN-VITRO DIAGNOSTIC REAGENTS, cosmetic OR HOUSEHOLD HAZARDOUS SUBSTANCES that is adulterated, [or] misbranded OR COUNTERFEITED, OR OF ADULTERATED OR MISBRANDED DRUG.

(b) The adulteration or misbranding of any food, drug, device, [or cosmetic], IN-VITRO DIAGNOSTIC REAGENTS, COSMETICS, OR HOUSEHOLD HAZARDOUS SUBSTANCES.

(c) [The refusal to permit entry or inspection as authorized by Section twenty-seven hereof or to allow samples to be collected.] THE GIVING OF A GUARANTY OR UNDERTAKING REFERRED TO IN SECTION TWELVE (B) HEREOF WHICH GUARANTY OR UNDERTAKING IS FALSE, EXCEPT BY A PERSON WHO RELIED UPON A GUARANTY OR UNDERTAKING TO THE SAME EFFECT SIGNED BY, AND CONTAINING THE NAME AND ADDRESS OF THE PERSON RESIDING IN THE PHILIPPINES FROM WHOM HE RECEIVED IN GOOD FAITH THE FOOD, DRUG, DEVICE, IN-VITRO

DIAGNOSTIC REAGENTS, COSMETIC OR HOUSEHOLD HAZARDOUS SUBSTANCES OR THE GIVING OF A GUARANTY OR UNDERTAKING REFERRED TO IN SECTION TWELVE (B) *WHICH GUARANTY OR UNDERTAKING IS FALSE.*

(g) The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to food, drug, device, **IN-VITRO-DIAGNOSTIC REAGENTS, [or] cosmetic, OR HOUSEHOLD HAZARDOUS SUBSTANCE,** if such act is done while such article is held for sale (whether or not the first sale) and results in such article being adulterated or misbranded."

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(J) THE MANUFACTURE, IMPORTATION, EXPORTATION, SALE, OFFERING FOR SALE, DISTRIBUTION, TRANSFER OR ADVERTISEMENT OF ANY FOOD, DRUG, DEVICE, IN-VITRO DIAGNOSTIC REAGENT, COSMETIC OR HOUSEHOLD HAZARDOUS SUBSTANCES WHICH IS NOT REGISTERED WITH THE BUREAU PURSUANT TO THIS ACT: *PROVIDED* THAT PRODUCT REGISTRATION SHALL MEAN COMPLIANCE WITH THE REQUIREMENTS AS SPECIFIED IN REGULATIONS TO BE ISSUED BY THE BUREAU AFTER CONSULTATION UPON APPROVAL OF THE SECRETARY. *PROVIDED FURTHER,* THAT THE BUREAU UPON THE APPROVAL OF THE SECRETARY MAY LIKEWISE ISSUE SUCH REGISTRATION REGULATIONS IT DEEMS NECESSARY TO COMPLY WITH INTERNATIONAL AGREEMENTS.

(K) THE MANUFACTURE, IMPORTATION, EXPORTATION, DISTRIBUTION, OR RETAIL OF ANY DRUG, DEVICE OR IN-VITRO DIAGNOSTIC REAGENTS, OR THE MANUFACTURE, IMPORTATION, EXPORTATION, OR DISTRIBUTION OF ANY FOOD, 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, IN-VITRO DIAGNOSTIC REAGENTS, OR COSMETIC BEYOND ITS EXPIRATION OR EXPIRY DATE.

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SECTION 8. Subsection (a) of Section 12 of Republic Act No. 3720 as amended is hereby amended to read as follows:

Section 12.

(A) Any person who **[**violates**]** **SHALL VIOLATE** any of the provisions of Section 11 hereof shall, upon conviction, **[**be subject to**]** **SUFFER THE PENALTY OF** imprisonment **[**of not less than six (6) months and one day**]** **RANGING FROM ONE (1) YEAR** but not more than **[**five years**]**

TEN (10) YEARS, or a fine of not less than [one thousand pesos] FIFTY THOUSAND PESOS (P50,000.00), BUT NOT MORE THAN FIVE HUNDRED THOUSAND PESOS (P500,000.00) or both [such imprisonment or fine, in the] AT THE discretion of the court: *PROVIDED* THAT IF THE OFFENDER IS A MANUFACTURER, IMPORTER OR DISTRIBUTOR OF ANY COUNTERFEIT FOOD, DEVICE, IN-VITRO DIAGNOSTIC REAGENTS, COSMETIC OR HOUSEHOLD HAZARDOUS SUBSTANCES THE PENALTY OF AT LEAST FIVE (5) YEARS AND A FINE OF AT LEAST FIVE HUNDRED THOUSAND PESOS (P500,000.00) SHALL BE IMPOSED.

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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.

AFTER FINAL JUDGMENT 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.*

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

(d) [When it appears to the Food and Drug Administrator from the report of the Food and Drug Laboratory that any article of food or any drug, or cosmetic secured pursuant to Section twenty-eight of this Act is adulterated or misbranded, he shall cause notice thereof to be given to the person or persons concerned and such person or persons shall be given an opportunity to be heard before the Board of Food and Drug Inspection and to submit evidence impeaching the correctness of the finding or charge *in question.*] UPON PRELIMINARY FINDINGS OF THE CONDUCT OF PROHIBITED ACT/S, THE DIRECTOR SHALL ISSUE THE PROPER NOTICES OR ORDERS 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 amended to read as follows:

(a) [The Secretary may cause to be disseminated information regarding food, drugs, devices, or cosmetics in situations involving, in the opinion of the Secretary, imminent danger to health, or gross deception of the consumer. Nothing in this Section shall be construed to prohibit the Secretary from collecting, reporting, and illustrating the results of the investigations of the Department.] IN CASE WHERE THERE IS FINDING OF PROHIBITED ACTIONS AND DETERMINATION OF THE PERSONS LIABLE THERETO, AFTER NOTICE AND HEARING, THE DIRECTOR IS EMPOWERED TO IMPOSE ONE OR MORE OF THE FOLLOWING ADMINISTRATIVE PENALTIES:

I) CANCELLATION OF ANY LICENSE, AUTHORITY, OR REGISTRATION WHICH MAY HAVE BEEN GRANTED BY THE BUREAU, OR SUSPENSION OF THE VALIDITY THEREOF FOR SUCH PERIOD OF TIME AS THE DIRECTOR MAY DEEM REASONABLE WHICH SHALL NOT EXCEED ONE (1) YEAR;

II) THE WITHHOLDING OF ANY LICENSE, AUTHORITY, OR REGISTRATION WHICH IS BEING SECURED BY THE RESPONDENT FROM THE BUREAU;

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 REMAINING ITEMS SHALL BE SUBJECT T DESTRUCTION;

IV) A FINE OF NOT LESS THAN FIFTY THOUSAND PESOS (50,000.00) BUT NOT MORE THAN FIVE HUNDRED THOUSAND PESOS (P500, 000.00). IN ADDITION, AN ADDITIONAL FINE OF NOT MORE THAN ONE THOUSAND PESOS (P1,000.00) SHALL BE IMPOSED FOR EACH DAY OF CONTINUING VIOLATION;

V) CLOSURE OF MANUFACTURING SITE, DISTRIBUTION OFFICES, AND ANY OTHER FACILITY USED FOR PRODUCTION, LABELING, SELLING, 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;

(b) THE DIRECTOR IS ALSO EMPOWERED TO HOLD IN DIRECT OR INDIRECT CONTEMPT ANY PERSON WHO DISREGARDS ORDERS OR WRITS HE OR SHE ISSUES AND IMPOSE THE APPROPRIATE PENALTIES FOLLOWING THE SAME PROCEDURES AND PENALTIES PROVIDED IN THE RULES OF COURT.

(c) THE ORDERS, RULINGS, DECISIONS OF THE DIRECTOR OF THE BUREAU SHALL BE APPEALABLE TO THE SECRETARY OF HEALTH WITHIN FIFTEEN (15) DAYS FROM NOTICE OF SUCH ORDER, RULING OR DECISION. AN APPEAL SHALL BE DEEMED PERFECTED UPON FILING OF THE NOTICE OF APPEAL AND POSTING OF THE CORRESPONDING APPEAL BOND.

(d) THE ORDER, RULING OR 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.

(e) 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 HAD BEEN FILED.

(f) THE INSTITUTION OF A WRIT OF CERTIORARI OR OTHER SPECIAL REMEDIES IN THE SUPREME COURT SHALL IN NO CASE SUPERSEDE 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 SUCH AMOUNT AS MAY BE DEEMED PROPER.

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

Section 31. "[The amount of one million pesos is hereby appropriated from any funds in the National Treasury not otherwise appropriated to augment the funds transferred to this Office under Section eight for the implementation of this Act. All income derived from fees authorized in Section Four of this Act shall

accrue to the General Fund.]" **FEES AND AUTHORITY TO RETAIN INCOME.**

(A) THE REGISTRATION AND/OR LICENSE FEES SHALL ANNUALLY BE DETERMINED AND REVIEWED BY THE BUREAU FOR ANY PROPOSED INCREASE AND TO BE PUBLISHED IN TWO (2) LEADING NEWSPAPERS OF GENERAL CIRCULATION UPON APPROVAL OF THE SECRETARY;

(B) THERE SHALL BE DETERMINED AND CONSTITUTED ADDITIONAL FEES SUCH AS SALE OF PUBLICATIONS AND SERVICES, ASSESSMENT FEES, FINES, PENALTIES, AND OTHER FEES AND CHARGES OUTSIDE THE USUAL LICENSING AND REGISTRATION FEES, TO BE KNOWN "OTHER RELATED REGULATORY FEES"

(C) THE DIRECTOR OF THE BUREAU, UPON APPROVAL OF THE SECRETARY, SHALL BE AUTHORIZED TO PROMULGATE RULES AND REGULATIONS GOVERNING THE COLLECTION OF THE "OTHER RELATED 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 APPROVAL OF THE SECRETARY.

(D) THE BUREAU OF FOOD AND DRUGS SHALL BE AUTHORIZED TO RETAIN AND USE ALL ITS INCOME GENERATED INCLUDING THOSE DERIVED FROM ADMINISTRATIVE FINES IMPOSED AND OTHER CHARGES COLLECTED BY THE BUREAU UNDER THIS ACT AND OTHER LAWS THAT THE BUREAU ADMINISTER AND WILL BE MANDATED TO ADMINISTER, SUBJECT TO THE USUAL ACCOUNTING AND AUDITING RULES AND REGULATIONS.

SECTION 12. The head note of Chapter XIV of Republic Act No. 3720 is hereby amended to read as follows:

"[CHAPTER XIV-- REPEALING CLAUSE AND EFFECTIVITY]"

"CHAPTER XIV – REGULATORY STRENGTHENING"

SECTION 13. Section 32 of Republic Act No. 3720 is hereby amended to read as follows:

Section 32. "**[** If any provision of this Act or the application of such provision to any person or circumstance is held invalid, the remainder of this Act or the application of such provision to other persons of circumstances should not be affected thereby]" **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 SEPARATED TO THE BUREAU'S ANNUAL BUDGET.

(B) THE FUND SHALL BE ALLOWED TO ACCEPT DONATIONS AND ALL OTHER ENDOWMENTS IN ACCORDANCE WITH PERTINENT LAWS, RULES AND REGULATIONS.

(C) THE FUND SHALL BE DEPOSITED AND MAINTAINED IN A SEPARATE ACCOUNT OR FUND, WHICH MAY BE USED OR DISBURSED DIRECTLY BY THE DIRECTOR SUBJECT TO *EXISTING ACCOUNTING AND AUDITING RULES* AND REGULATIONS. THE FUND SHALL BE USED FOR THE BUREAU'S OPERATIONS, LIKE UPGRADING OF ITS FACILITIES INCLUDING MAINTENANCE AND OTHER OPERATING EXPENSES FOR THE CENTRAL OFFICE LABORATORY AND THE SATELLITE LABORATORIES IN DAVAO, CEBU AND OTHER TESTING LABORATORIES IN CASE THE ABOVE *LABORATORIES WILL BE* INCREASED, EQUIPMENT OUTLAY, PURCHASE OF MOTOR VEHICLES, AND HUMAN RESOURCE DEVELOPMENT, AMONG OTHERS, TO IMPROVE THE DELIVERY OF ITS SERVICES TO THE PUBLIC. 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 14. Sections 33 and 34 of Republic Act No. 3720 are hereby amended and a new section to be known as Section 35 is hereby added to read as follows:

Section 33. "[Section eleven hundred and nine to Section eleven hundred twenty-nine of the Administrative Code, and such other laws, executive orders, rules and regulations inconsistent with the provisions of this Act are repealed.

Section 34. This Act shall take effect upon its approval.]"

BUREAU OF FOOD AND DRUGS' QUALITY ASSURANCE LABORATORIES - THE DEPARTMENT OF HEALTH (DOH) IS HEREBY MANDATED TO IMPROVE, UPGRADE AND INCREASE THE CAPABILITY OF THE BUREAU OF FOOD AND DRUGS, TO TEST, ASSAY AND EXAMINE SAMPLES OF FOOD, DRUGS,

DEVICES, COSMETICS, AND HOUSEHOLD HAZARDOUS SUBSTANCES.

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 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. THE TESTING LABORATORIES MAY BE INCREASED WHICH THE DIRECTOR OF THE BUREAU SHALL DETERMINE THE TOTAL NUMBER AND LOCATION OF ADDITIONAL TESTING LABORATORIES UPON APPROVAL OF THE SECRETARY.

SECTION 34. BUREAU OF FOOD AND DRUGS' FIELD OFFICES. - THE BFAD SHALL ESTABLISH FIELD OFFICES IN ALL REGIONS OF THE COUNTRY TO EFFECTIVELY IMPLEMENT ITS REGULATORY FUNCTIONS. THE PRESENT REGIONAL FOOD AND DRUG REGULATORY OFFICERS IN EVERY REGIONAL OFFICE OF THE DEPARTMENT OF HEALTH SHALL NOW BE PUT UNDER THE BFAD'S SOLE CONTROL AND SUPERVISION. THE BUREAU, WITH APPROVAL OF THE SECRETARY, SHALL SEEK THE CREATION OF ADDITIONAL PLANTILLA POSITIONS AS MAY BE NECESSARY TO AUGMENT THE HUMAN RESOURCE COMPLEMENT OF THE BFAD CENTRAL OFFICE AND ITS FIELD OFFICES, SUBJECT TO THE RULES AND REGULATIONS OF THE CIVIL SERVICE COMMISSION.

SECTION 35. 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 OF NOT EXCEEDING FIVE (5) YEARS FROM THE DATE OF EFFECTIVITY OF THIS ACT.

SECTION 15. Appropriations - The appropriations for the Bureau of Food and Drugs included in the Department of Health under the current General Appropriations Act and the income retained in Subsection (d) of Section 31 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 Appropriations Act.

SECTION 16. 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 one hundred eighty (180) days after the passage of the Act.

SECTION 17. 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 18. Repealing Clause - Laws of part of laws, executive orders, circulars, regulations and memoranda inconsistent with this Act are hereby repealed or amended accordingly.

SECTION 19. Effectivity - This Act shall take effect fifteen (15) days after publication in the Official Gazette or in two (2) newspapers of general circulation.

Approved,