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

SENATE

S. No. 2520

Introduced by Senator Manny Villar

EXPLANATORY NOTE

The promotion and protection of right to health of the Filipino people is a policy of the State. In pursuit of this policy, Republic Act 3720 otherwise known as the Food, Drug and Cosmetic Act was enacted into law in 1963. It aims to ensure the supply of safe, pure, and quality food, drugs, cosmetics and other health products to the public, Thus, in order to carry out effectively the policies and objectives of this Act, the Food and Drug Administration (FDA) was created.

In 1982, by virtue of Executive Order 851, FDA was abolished and replaced by the now Bureau of Food and Drugs (BFAD). It absorbed all the functions of the former and expanded its operations. State of the art analytical instruments and modern experimental animal laboratory were acquired to strengthen its capabilities in research, analysis and inspection of food and health products.

Since then, there were no material changes in BFAD's technical and regulatory capacity to cope up with new challenges and thus, this bill is being proposed. It aims to amend RA 3720 to strengthen the agency's technical and regulatory capacity by establishing adequate testing laboratories and field offices, upgrade the agency's equipment, augment its human resource component and, foremost, gives it the authority to retain its income to carry out its vital mandate.

The enactment of this bill will ensure a more effective implementation of its mandate to administer and enforce the laws pertaining to safety and quality of food, drugs, health products and cosmetics.

Based on the foregoing, the immediate enactment of this bill is earnestly sought.

MANNY VILLAR

FOURTEENTH CONGRESS OF THE)
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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, RENAMING IT AS THE FOOD AND DRUGS ADMINISTRATION (FDA), AMENDING CERTAIN SECTIONS OF REPUBLIC ACT NO. 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. The Bureau of Food and Drugs (BFAD) is hereby renamed the Food and Drugs Administration (FDA).

SEC. 2. This Act shall be known as the Food and Drugs Administration (FDA) Act of 2008.

SEC. 3. 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 drugs 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.

SEC. 4. This Act has the following objectives:

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

(b) To ensure the FDA's monitoring and regulatory coverage over establishments and products under its jurisdiction; and

(c) To provide coherence in the FDA's regulatory system for establishments and products under its jurisdiction.

SEC. 5. Section 4(a), (b), (c), (d) and (e) of Republic Act No. 3720, as amended, is hereby amended and other subsections are added thereto to read as follows:

"SEC. 4. To carry out the provisions of this Act, there is hereby created an office to be called the Food and Drug**S** Administration **(FDA)** in the Department of Health. Said Administration shall be under the Office of the Secretary and shall have the following functions, powers and duties:

"(*a*) To administer **[**and supervise**]** the **EFFECTIVE** implementation of this Act and of the rules and regulations issued pursuant to the same.

"(*b*) To **[**provide for**]** **ASSUME SOLE AND PRIMARY JURISDICTION IN** the collection of samples of food, drug**S, [**and cosmetic**]** **DEVICES, IN-VITRO DIAGNOSTIC REAGENTS, BIOLOGICALS, VACCINES, COSMETICS AND HEALTH PRODUCTS.**

"(*c*) To analyze and inspect food, drug**S, [**and cosmetic**]** **DEVICES, IN-VITRO DIAGNOSTIC REAGENTS, BIOLOGICALS, VACCINES, COSMETICS AND HEALTH PRODUCTS** in connection with the implementation of this Act.

"(*d*) To establish analytical data to serve as basis for the preparation of food, drug**S, [**and cosmetic**]** **DEVICES, IN-VITRO DIAGNOSTIC REAGENTS, BIOLOGICALS, VACCINES, COSMETICS AND HEALTH PRODUCTS** standards, and to recommend standards of identity, purity, **SAFETY, EFFICACY,** quality and fill of container.

"(*e*) To issue certificate of compliance with technical requirements to serve as basis for the issuance of license and spot-check for compliance with regulations regarding operation of food, drug**S, [**and cosmetic**]** **DEVICES, IN-VITRO DIAGNOSTIC REAGENTS, BIOLOGICALS, VACCINES, COSMETICS AND HEALTH PRODUCTS** manufacturers, importers, **EXPORTERS,** distributors, **[**retailers and sales establishments.**]** **WHOLESALERS, DRUG OUTLETS, AND OTHER ESTABLISHMENTS AS DETERMINED BY THE FDA.** "x x x

"(*H*) TO REQUIRE ALL MANUFACTURERS, TRADERS, DISTRIBUTOR/IMPORTER, DISTRIBUTOR/EXPORTER, DISTRIBUTOR/WHOLESALER/RETAILER AND CONSUMERS/USERS OF FOOD, DRUGS, DEVICES, IN-VITRO DIAGNOSTIC REAGENTS, BIOLOGICALS, VACCINES, COSMETICS, HOUSEHOLD HAZARDOUS SUBSTANCES AND HEALTH PRODUCTS TO REPORT TO THE FDA ANY INCIDENT THAT REASONABLY INDICATES THAT SAID PRODUCT HAS CAUSED OR CONTRIBUTED TO THE DEATH, SERIOUS ILLNESS OR SERIOUS INJURY TO A CONSUMER OR A PATIENT.

"(*I*) TO STRENGTHEN THE POST MARKET SURVEILLANCE SYSTEM IN MONITORING PRODUCTS UNDER THE FDA'S JURISDICTION AND INCIDENTS OF ADVERSE EVENTS INVOLVING SUCH PRODUCTS.

"(*J*) TO DEVELOP AND ISSUE STANDARDS AND APPROPRIATE AUTHORIZATIONS THAT WOULD COVER ESTABLISHMENTS, FACILITIES AND PRODUCTS.

"*(K)* TO CONDUCT, SUPERVISE, MONITOR AND AUDIT RESEARCH STUDIES ON HEALTH AND SAFETY ISSUES OF PRODUCTS UNDERTAKEN BY ENTITIES DULY APPROVED BY THE FDA.

"*(L)* TO PRESCRIBE STANDARDS AND GUIDELINES WITH RESPECT TO INFORMATION AND ADVERTISEMENTS AND OTHER MARKETING INSTRUMENTS AND ACTIVITIES ABOUT THE HEALTH PRODUCTS AS COVERED IN THIS ACT.

"*(M)* TO EXERCISE SUCH OTHER POWERS AND PERFORM SUCH OTHER FUNCTIONS AS MAY BE NECESSARY TO CARRY OUT ITS DUTIES AND RESPONSIBILITIES UNDER THIS ACT."

SEC. 6. Section 5 of Republic Act No. 3720, as amended, is hereby amended and new subsections are added to read as follows:

"SEC. 5. The Food and Drug**S** Administration shall have the following **[***Divisions***]** **CENTERS AND OFFICES**:

"**[**(*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.**]**

(*A*) THE CENTERS SHALL BE ESTABLISHED PER MAJOR PRODUCT CATEGORY THAT IS REGULATED, NAMELY:

"(1) CENTER FOR DRUGS REGULATION AND RESEARCH (TO INCLUDE VETERINARY MEDICINE, VACCINES AND BIOLOGICALS);

"(2) CENTER FOR FOOD REGULATION AND RESEARCH;

"(3) CENTER FOR COSMETICS REGULATION AND RESEARCH (TO INCLUDE HOUSEHOLD HAZARDOUS SUBSTANCES); AND

"(4) CENTER FOR DEVICES REGULATION AND RESEARCH.

"THESE CENTERS SHALL REGULATE THE MANUFACTURE, IMPORTATION, EXPORTATION, DISTRIBUTION, SALE, OFFER FOR SALE, TRANSFER OF, AND USE OF, HEALTH PRODUCTS AND SHALL INCLUDE THE CONDUCT OF CONTINUING STUDIES IN THE SAFETY, EFFICACY AND QUALITY OF FOOD, DRUGS, COSMETICS, DEVICES AND HEALTH PRODUCTS AND TO INSTITUTE STANDARDS FOR THE SAME.

"EACH CENTER SHALL BE HEADED BY A DIRECTOR. THE CENTERS SHALL BE SO ORGANIZED SUCH THAT EACH WILL HAVE, AT LEAST, THE FOLLOWING DIVISIONS:

"(i) LICENSING AND REGISTRATION DIVISION, WHICH SHALL BE RESPONSIBLE FOR EVALUATING PRODUCTS AND ESTABLISHMENTS AS COVERED BY THIS ACT FOR PURPOSES OF

ISSUANCE OF MARKET AUTHORIZATIONS AND CONDITIONS TO BE OBSERVED;

"(ii) PRODUCT RESEARCH AND STANDARDS DEVELOPMENT DIVISION, WHICH SHALL BE RESPONSIBLE FOR THE DEVELOPMENT OF STANDARDS, CONDUCT MONITORING, OVERSIGHT AND AUDIT OF RELATED RESEARCHES THAT WOULD ENSURE SAFETY, QUALITY, PURITY AND EFFICACY OF HEALTH PRODUCTS AS COVERED IN THIS ACT; AND

"(iii) LABORATORY SUPPORT DIVISION, WHICH SHALL BE RESPONSIBLE FOR THE CONDUCT OF ALL THE TESTS, ANALYSES AND TRIALS OF PRODUCTS INCLUDING, BUT NOT LIMITED TO, ASSAYS, AND THE CONDUCT OF OVERSIGHT AND/OR AUDIT OF BIOAVAILABILITY AND BIOEQUIVALENCE TESTS AND OTHER TESTS AS COVERED BY THIS ACT. IT SHALL LIKEWISE PROVIDE DIRECT LINE SUPPORT TO THE CENTERS WHICH SHALL BE SEPARATE AND DISTINCT PER MAJOR PRODUCT CATEGORY THAT IS REGULATED.

"(*B*) THE ADMINISTRATION AND FINANCE OFFICE SHALL HAVE, AT LEAST, THE FOLLOWING DIVISIONS: THE HUMAN RESOURCE DEVELOPMENT DIVISION; PROPERTY AND LOGISTICS MANAGEMENT DIVISION; HUMAN RESOURCE MANAGEMENT DIVISION; ASSETS AND FINANCIAL MANAGEMENT DIVISION; AND THE INFORMATION AND COMMUNICATION TECHNOLOGY MANAGEMENT DIVISION.

"(*C*) THE POLICY AND PLANNING OFFICE WHICH SHALL BE UNDER THE OFFICE OF THE DIRECTOR-GENERAL SHALL HAVE, AT LEAST, THE TRAINING, ADVOCACY AND COMMUNICATIONS DIVISION AND SHALL MONITOR THE PERFORMANCE OF THE *CENTERS FOR PRODUCT RESEARCH AND EVALUATION* AND STANDARDS DEVELOPMENT.

"(*D*) THE FOOD, DRUGS AND HEALTH PRODUCTS REGULATORY AND ENFORCEMENT OFFICE SHALL INCLUDE, AMONG OTHERS, ALL THE FIELD OFFICES, FIELD OR SATELLITE LABORATORIES AND THE REGULATORY ENFORCEMENT UNITS.

"(*E*) THE LEGAL SERVICES SUPPORT CENTER SHALL PROVIDE LEGAL SERVICES TO THE ENTIRE FDA AND SHALL BE DIRECTLY UNDER THE OFFICE OF THE DIRECTOR-GENERAL."

SEC. 7. The FDA shall have a Director-General, with the rank of undersecretary, who shall be tasked, among others, to determine and appoint the needed personnel, in coordination with the Secretary of Health. The Director-General shall be assisted by two (2) Deputy Director-Generals, for administration and finance and for regulatory operations.

The Director-General who shall be appointed by the President shall, preferably, possess either a university degree in medicine or at least the relevant master's degree in pharmaceutical sciences or allied sciences, or equivalent executive course in any regulatory management. In addition, he/she shall have management experience in his field of discipline or profession and in any development, manufacturing, regulatory work or quality assurance of products as covered in this Act.

The Deputy Director-General for Operations of the FDA shall, preferably, possess the relevant master's degree in pharmaceutical sciences, relevant aster's degree in pharmaceutical sciences or allied sciences, or equivalent executive course in any regulatory management. In addition, he/she shall have management experience in his field of discipline or profession and in any development, manufacturing, regulatory work or quality assurance of products as covered in this Act.

The Deputy Director-General for Administration and Finance of the FDA shall be a certified public accountant or shall possess a master's degree in accounting, management, economics or any business course, and must have management experience in a position related to his field of discipline or profession.

The Centers and the field offices will be headed by a Director who shall be assisted by Assistant Directors. The officials and employees of the old Bureau of Food and Drugs shall be transferred to the appropriate centers. The officials and employees of the Bureau of Health Devices and Technology shall be transferred to the Center for Devices, Regulation and Research.

The existing Division Chiefs in the Bureau of Food and Drugs shall be given utmost preference for appointments as Center Directors.

The current Food and Drug Regulatory Officers (FDROs) under the Centers for Health Development in the Department of Health shall accordingly be transferred to the FDA.

There shall be no diminution of salaries, allowances and emoluments of all personnel transferred to the FDA. Thereafter, all positions, powers, functions and duties together with the facilities, equipment, supplies, records, files, appropriations and funds of the former bureaus shall be transferred to the FDA.

SEC. 8. Section 10, subsections (a), (e), (f), (g), (i), (q), (r), (v), and (w) of Republic Act No. 3720, as amended, are hereby further amended, and new subsections (x), (y), (z), (aa), (bb), (cc), (dd), (ee), (ff), (gg), and (hh) are hereby added to read as follows:

"SEC. 10. For the purposes of this Act, the term:

"(*a*) **[**"Bureau" means the Bureau of Food and Drugs.**]** **"FDA" MEANS THE FOOD AND DRUGS ADMINSTRATION.** "x x x

"(*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.**]** **"FOOD" MEANS 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.**

"(*f*) "Drugs" means (1) articles recognized **[**in the current official United States Pharmacopeia-National Formulary (USPNF), official Homeopathic Pharmacopeia of the United States, official National Drug Formulary, or any supplement to any of them;**]** **BY THE FDA FROM ACCEPTABLE AND OFFICIAL PHARMACOPEIAS AND FORMULARIES, WHICH INCLUDE OFFICIAL HOMEOPATHIC**

PHARMACOPEIAS, OR ANY SUPPLEMENT TO ANY OF THEM; [and] (2) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; [and] (3) articles (other than food) intended to affect the structure or any function of the body of man or animals; and (4) articles intended for use as a component of any articles specified in clauses (1), (2), or (3), but do not include devices or their components, parts, or accessories.

"(*g*) "Device" means [instruments, apparatus, or contrivances, including their components, parts, and accessories, intended (1) for use in the diagnosis, 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] **MEDICAL DEVICES, RADIATION DEVICES AND HEALTH-RELATED DEVICES**.

"(*g.1.*) "MEDICAL DEVICES" SHALL REFER TO AN APPARATUS OR CONTRIVANCES, INCLUDING THEIR COMPONENTS, PARTS, ACCESSORIES, SYSTEMS AND SOFTWARE INTENDED (1) FOR USE IN THE DIAGNOSIS, CURE, MITIGATION/ ALLEVIATION, TREATMENT, MONITORING, OR PREVENTION OF DISEASE, INJURIES/HANDICAP IN MAN OR ANIMALS; OR (2) TO AFFECT THE STRUCTURE OR ANY FUNCTION OF THE BODY OF MAN OR ANIMALS.

"(*g.2.*) "RADIATION DEVICES" SHALL REFER TO AN ELECTRICAL OR ELECTRONIC APPARATUS EMITTING ANY IONIZING OR NON-IONIZING ELECTROMAGNETIC OR PARTICULATE RADIATION; OR ANY SONIC, INFRASONIC, OR ULTRASONIC WAVE.

"(*g.3.*) "HEALTH-RELATED DEVICES" SHALL REFER TO ANY DEVICE NOT USED IN HEALTH CARE BUT HAS BEEN DETERMINED BY THE FDA TO ADVERSELY AFFECT THE HEALTH OF THE PEOPLE. "

x x x

"(*i*) "Label" means a display of written, printed, or graphic matter upon the immediate container of any article and a requirement made by or under authority of this Act that any word, statement, or other information appearing on the label shall not be considered to be complied with unless such word, statement, or [other information also appears on the outside container or] wrapper, if any there be, of the retail package of such article, or is easily legible through the outside container or wrapper."

x x x

"(*q*) "Director-**GENERAL**" means [Director of the Bureau of Food and Drugs] **THE HEAD** of the Food and Drugs Administration.

"(*r*) "*Distribute*" *means the delivery or sale of any* **FOOD,** drug, **COSMETIC** or device for purposes of distribution in commerce, except that such term does not include a manufacturer or retailer of such product."

x x x

"(*v*) "ManufactureR", in relation to a **FOOD,** drug, device, **BIOLOGICALS, VACCINES, IN-VITRO DIAGNOSTIC REAGENTS, HOUSEHOLD HAZARDOUS SUBSTANCES AND HEALTH PRODUCTS** where applicable, means **AN ESTABLISHMENT ENGAGED IN** any and all operations involved in the production of **[**a drug or device**]** **SAID PRODUCT** including **[**propagation**]** **PREPARATION**, processing, compounding, formulating, filling, packing, repacking, altering, ornamenting, finishing and labeling with the end**[**s**]** in view of its storage, sale or distribution: *Provided,* That the term shall not apply to the compounding and filling of prescriptions in drugstores and hospital pharmacies **IN THE CASE OF DRUGS. A TRADER SHALL BE CATEGORIZED AS A MANUFACTURER.**

"(*w*) "**[**New v**]**Veterinary drugs" means drugs intended for use for animals including any drug intended for use in animal feeds but not including animal feeds within the contemplation of the implementing rules and regulations.

"(*X*) "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 SHALL 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.

"(*Y*) "IN-VITRO DIAGNOSIS 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.

"(*Z*) "BIOAVAILABILITY" MEANS THE RATE AND EXTENT TO WHICH THE ACTIVE INGREDIENT OR THERAPEUTIC INGREDIENT IS ABSORBED FROM A DRUG AND BECOMES AVAILABLE AT THE SITE OF DRUG ACTION.

"(*AA*) "BIOEQUIVALENCE" MEANS THE RATE AND EXTENT OF ABSORPTION TO WHICH THE DRUGS DO NOT SHOW A SIGNIFICANT DIFFERENCE FROM THE RATE AND EXTENT OF THE LISTED DRUG WHEN ADMINISTERED AT THE SAME MOLAR DOSE OF THE THERAPEUTIC INGREDIENT UNDER SIMILAR EXPERIMENTAL CONDITIONS IN EITHER A SINGLE DOSE OR MULTIPLE DOSE. BIOEQUIVALENCE SHALL ALSO REFER TO THE ABSENCE OF A SIGNIFICANT DIFFERENCE ON THE RATE AND EXTENT TO WHICH THE ACTIVE INGREDIENT(S) OF THE SAMPLE AND REFERENCE DRUG BECOMES AVAILABLE AT THE SITE OF DRUG ACTION WHEN ADMINISTERED UNDER THE SAME MOLAR DOSE AND UNDER SIMILAR CONDITIONS.

"(*BB*) "TRADER" MEANS ANY ESTABLISHMENT WHICH IS A REGISTERED OWNER OF A FOOD, DRUG, DEVICE, VACCINE, IN-VITRO DIAGNOSTIC REAGENT, HOUSEHOLD HAZARDOUS SUBSTANCES AND HEALTH PRODUCTS AND PROCURES THE RAW MATERIALS AND PACKING COMPONENTS AND PROVIDES THE PRODUCTION MONOGRAPHS, QUALITY CONTROL STANDARDS AND PROCEDURES, BUT SUBCONTRACT THE MANUFACTURE OF SUCH PRODUCT TO A LICENSED MANUFACTURER. IN ADDITION, A TRADER MAY ALSO ENGAGE IN THE DISTRIBUTION AND/OR MARKETING OF ITS PRODUCTS.

"(*CC*) "ASSAY" IS AN ANALYSIS TO DETERMINE THE (1) PRESENCE OF A SUSBTANCE AND THE AMOUNT OF THAT SUBSTANCE AND (2) THE BIOLOGICAL OR PHARMACOLOGICAL POTENCY OF A DRUG.

"(*DD*) "DISTRIBUTOR/IMPORTER/EXPORTER" MEANS ANY ESTABLISHMENT THAT IMPORTS OR EXPORTS RAW MATERIALS, ACTIVE INGREDIENTS AND/OR FINISHED PRODUCTS FOR ITS OWN USE OR FOR WHOLESOME DISTRIBUTION TO OTHER DRUG ESTABLISHMENTS OR OUTLETS.

"(*EE*) "DISTRIBUTOR/WHOLESALER/RETAILER" MEANS ANY DRUG ESTABLISHMENT THAT PROCURES RAW MATERIALS, ACTIVE INGREDIENTS AND/OR FINISHED PRODUCTS FROM LOCAL *ESTABLISHMENTS FOR LOCAL DISTRIBUTION ON WHOLESALE OR* RETAIL BASIS.

"(*FF*) "REGISTRATION" MEANS THE PROCESS OF APPROVAL FOR THE MANUFACTURE, IMPORTATION, EXPORTATION, SALE, OFFER FOR SALE, DISTRIBUTION OR TRANSFER OF FOOD, DRUGS, DEVICES, COSMETICS, BIOLOGICALS, VACCINES, IN-VITRO DIAGNOSTIC REAGENTS, HOUSEHOLD HAZARDOUS SUBSTANCES AND HEALTH PRODUCTS.

"(*GG*) "LICENSING" MEANS THE PROCESS OF APPROVAL OF AN APPLICATION OF A PERSON TO OPERATE OR ESTABLISH AN ESTABLISHMENT ENGAGED IN THE MANUFACTURE, IMPORTATION, EXPORTATION, SALE, OFFER FOR SALE, DISTRIBUTION OR TRANSFER OF FOOD, DRUGS, DEVICES, BIOLOGICALS, VACCINES, IN-VITRO DIAGNOSTIC REAGENTS, HOUSEHOLD HAZARDOUS SUBSTANCES AND HEALTH PRODUCTS.

"(*HH*) "HEALTH PRODUCTS" MEANS FOOD, DRUGS, DEVICES, COSMETICS, BIOLOGICALS, VACCINES, IN-VITRO DIAGNOSTIC REAGENTS AND HOUSEHOLD HAZARDOUS SUBSTANCES AND/OR A COMBINATION OF AND/OR A DERIVATIVE THEREOF. IT SHALL ALSO REFER TO PRODUCTS THAT MAY HAVE AN EFFECT TO HEALTH WHICH REQUIRE REGULATIONS AS DETERMINED BY THE FDA."

SEC. 9. Subsections (a), (b), (d), (g), (j), (k), and (l) of Section 11 of Republic Act No. 3720, as amended, are hereby further amended to read as *follows:*

"SEC. 11. The following acts and the causing thereof are hereby prohibited:

"(a) The manufacture, importation, exportation, sale, offering for sale, distribution, [or] transfer of any food, [drug,] device, [or cosmetic] **COSMETICS AND HOUSEHOLD HAZARDOUS SUBSTANCE** that is adulterated, [or] misbranded **OR COUNTERFEITED, OR DRUG, IN-VITRO DIAGNOSTIC REAGENT, BIOLOGICALS, AND VACCINE THAT IS ADULTERATED OR MISBRANDED**.

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

x x x

"(d) The giving of a guaranty or undertaking referred to in Section twelve **[**(b)**] (A)** 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] **OR ENTITY** from whom he received in good faith the food, drug**S**, device**S**, **IN-VITRO DIAGNOSTIC REAGENTS, [**or] cosmetic **OR HOUSEHOLD HAZARDOUS SUBSTANCES** or the giving of a guaranty or undertaking referred to in Section twelve **[**(b)**] (A)** which *guaranty or undertaking is false.*"

x x x

"(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**[**,**]** a food, drug, device, **IN-VITRO DIAGNOSTIC REAGENT**, [or] cosmetic[s], **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."

x x x

"(j) The manufacture, importation, exportation, sale, offering for sale, distribution, [or] transfer or advertisement of any food, drug, [or] device, **IN-VITRO DIAGNOSTIC REAGENT, COSMETIC OR HOUSEHOLD HAZARDOUS SUBSTANCE** which is not registered with the **[**Bureau**] FDA** pursuant to this Act.

"(k) The manufacture, importation, exportation, [sale, offering for sale,] distribution, [or transfer] **OR RETAIL** of any drug, [or] device **OR IN-VITRO DIAGNOSTIC REAGENT, OR THE MANUFACTURE, IMPORTATION, EXPORTATION, OR DISTRIBUTION OF ANY FOOD, COSMETIC OR HOUSEHOLD HAZARDOUS SUBSTANCE** by any person without the license **TO OPERATE** from the **[**Bureau**] FDA** required under this Act.

"(l) The **IMPORTATION, EXPORTATION,** sale, [or] offering for sale, **DISTRIBUTION OR TRANSFER** of any **FOOD,** drug, [or] device, **IN-VITRO DIAGNOSTIC REAGENT, OR COSMETIC** beyond its expiration or expiry date."

x x x

SEC. 10. The prohibited acts mentioned in Section 9 shall cover invitro diagnostic reagents, biologicals, vaccines, cosmetics, household hazardous substances and health products, other than food, drugs, devices and cosmetics.

SEC. 11. Section 12, subsection (a) of Republic Act No. 3720, as amended, is hereby further amended to read as follows:

"SEC. 12. (a) Any person who violates any of the provisions of Section eleven hereof shall, upon conviction, [be subject to imprisonment of not less than one year but not more than five years, or a fine of not less than five thousand pesos but not more than ten thousand pesos, or both such imprisonment and fine, in the discretion of the Court.] **SUFFER THE PENALTY OF IMPRISONMENT RANGING FROM ONE (1) YEAR BUT NOT MORE THAN TEN (10) 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: *PROVIDED,* THAT IF THE OFFENDER IS A MANUFACTURER, IMPORTER OR DISTRIBUTOR OF ANY COUNTERFEIT FOOD, DRUG, DEVICE, IN-VITRO DIAGNOSTIC REAGENT, COSMETIC OR HOUSEHOLD HAZARDOUS SUBSTANCES, AND HEALTH PRODUCTS THE PENALTY OF AT LEAST FIVE (5) YEARS IMPRISONMENT BUT NOT MORE THAN TEN (10) YEARS AND A FINE OF AT LEAST FIVE HUNDRED THOUSAND PESOS (P500,000.00) BUT NOT MORE THAN FIVE MILLION PESOS (P5,000,000.00) SHALL BE IMPOSED: *PROVIDED, FURTHER,* THAT AN ADDITIONAL FINE OF ONE PERCENT (1%) OF THE ECONOMIC VALUE/COST OF THE VIOLATIVE PRODUCT OR VIOLATION, OR ONE THOUSAND PESOS (P1,000.00), WHICHEVER IS HIGHER, SHALL BE IMPOSED FOR EACH DAY OF CONTINUING VIOLATION.**

"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 thereforE shall be penalized.

"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.

"x x x."

SEC. 12. Section 26, subsection (d) of Republic Act No. 3720, as amended, is hereby further amended to read as follows:

"(d) [When it appears to the Director that the report of the Bureau that any article of food or any drug, device, or cosmetic secured pursuant to Section twenty-eight of this Act is adulterated, misbranded, or not registered, 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 Bureau 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-GENERAL 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 FDA.**

"x x x."

SEC. 13. Section 29-A of Republic Act No 3720, as amended, is hereby further amended to read as follows:

"Section 29-A. [In addition to the administrative sanctions provided for under Letter of Instructions No. 1223, the Secretary is hereby authorized to impose, after notice and hearing, administrative fines of not less than one thousand pesos nor more than five thousand pesos for any violation of this Act.] **IN CASE WHERE THERE IS FINDING OF PROHIBITED ACTIONS AND DETERMINATION OF THE PERSONS LIABLE THERETO, AFTER NOTICE AND HEARING, THE DIRECTOR-GENERAL IS EMPOWERED TO IMPOSE ONE OR MORE OF THE FOLLOWING ADMINISTRATIVE PENALTIES:**

"I. CANCELLATION OF ANY AUTHORITY, OR REGISTRATION WHICH MAY HAVE BEEN GRANTED BY THE FDA IN CONNECTION WITH THE PARTICULAR PRODUCT SUBJECT OF THE VIOLATION, OR SUSPENSION OF THE VALIDITY THEREOF FOR SUCH PERIOD OF TIME AS THE DIRECTOR-GENERAL MAY DEEM REASONABLE WHICH SHALL NOT EXCEED ONE (1) YEAR; AND

"II. A FINE OF NOT LESS THAN FIFTY THOUSAND PESOS (*P50,000.00*) 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.

"THE DIRECTOR-GENERAL IS ALSO EMPOWERED TO:

"I. 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;

"II. TO ADMINISTER OATHS AND AFFIRMATIONS AND ISSUE *SUBPOENA DUCES TECUM* AND *SUBPOENA AD TESTIFICANDUM* 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 FDA;

"III. TO OBTAIN INFORMATION FROM ANY OFFICER OR OFFICE OF THE NATIONAL OR LOCAL GOVERNMENTS, GOVERNMENT AGENCIES AND ITS INSTRUMENTALITIES;

"IV. TO ISSUE ORDERS OF SEIZURE, TO SEIZE AND HOLD IN CUSTODY ANY ARTICLE OR ARTICLES OF FOOD, DEVICE, COSMETICS, HOUSEHOLD HAZARDOUS SUBSTANCES AND HEALTH PRODUCTS THAT IS ADULTERATED, COUNTERFEITED, MISBRANDED OR UNREGISTERED, OR DRUG, IN-VITRO DIAGNOSTIC REAGENT, BIOLOGICALS, AND VACCINE THAT IS ADULTERATED OR MISBRANDED, WHEN INTRODUCED INTO DOMESTIC COMMERCE PENDING THE AUTHORIZED HEARING

UNDER REPUBLIC ACT NO. 3720, AS AMENDED, EXECUTIVE ORDER NO. 175 (1987), AND REPUBLIC ACT NO. 7394, OTHERWISE KNOWN AS THE CONSUMERS ACT OF THE PHILIPPINES; AND

"V. TO CALL ON THE ASSISTANCE OF ANY DEPARTMENT, OFFICE OR AGENCY AND DEPUTIZE MEMBERS OF THE PHILIPPINE NATIONAL POLICE OR ANY LAW ENFORCEMENT AGENCY FOR THE EFFECTIVE IMPLEMENTATION OF THIS ACT."

SEC. 14. The orders, rulings or decisions of the Director-General of the FDA 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.

SEC. 15. The order, ruling or decision of the Director-General of the FDA shall be immediately executory unless an order from the Secretary of Health is issued to stay the execution thereof.

The institution of a petition for *certiorari* or other special remedies in the proper court shall, in no case, supersede or stay any order, ruling or decision of the Secretary, unless the proper court shall so direct and the appellant may be required by the proper courts to give bond in such form and such amount as may be deemed proper.

SEC. 16. Section 31, Chapter XIII of Republic Act No. 3720, as amended, is hereby further amended to read as follows:

"SEC. 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 OTHER INCOME.*** **– (A) UPON APPROVAL OF THE SECRETARY, THE REGISTRATION AND/OR LICENSE FEES SHALL ANNUALLY BE DETERMINED AND REVIEWED BY THE FDA AND ANY PROPOSED INCREASE SHALL BE PUBLISHED IN TWO (2) LEADING NEWSPAPERS OF GENERAL CIRCULATION.**

"(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 AS 'OTHER RELATED REGULATORY FEES'.

"(C) THE DIRECTOR-GENERAL OF THE FDA, UPON APPROVAL OF THE SECRETARY, SHALL BE AUTHORIZED TO PROMULGATE RULES AND REGULATIONS GOVERNING THE COLLECTION OF THE 'OTHER RELATED REGULATORY FEES'. UPON APPROVAL OF THE SECRETARY, THESE FEES SHALL LIKEWISE BE REVIEWED PERIODICALLY AND ANY PROPOSED INCREASE SHALL BE PUBLISHED IN TWO (2) LEADING NEWSPAPERS OF GENERAL CIRCULATION."

SEC. 17. All income that the FDA is allowed to retain under Section 31 of the Universally Accessible Cheaper and Quality Medicines Act of 2008 shall, any provision of law to the contrary notwithstanding, be deposited in an authorized

government depository bank as a special regulatory fund. Such fund shall be used primarily for the purchase of laboratory equipment and motor vehicles, the upgrading of its current facilities and equipment including maintenance and other operating expenses for the Central Office Laboratory Division and satellite laboratories in Davao, Cebu and other testing laboratories, in case the above laboratories will be increased.

The fund shall be allowed to accept grants, donations and all other endowments from local and external sources in accordance with pertinent laws, rules and regulations.

The retention, use and application of this fund shall not be delayed, amended, altered or modified, or affected in any way by an order or directive from any executive office, but will be subject only to the general accounting rules and guidelines by the Commission on Audit (COA). The primary purpose of the fund as herein stated shall prevail over any other purpose that may be pursued by the FDA on its own initiative or through an order or directive by any higher office.

The FDA shall submit to the Secretary of Health, the Secretary of Budget and Management and the Congressional Oversight Committee, created under Section 24 of this Act, a report on how the funds were utilized, including its accomplishments.

SEC. 18. The FDA is hereby mandated to improve, upgrade and increase the capability of the agency, to test, assay and examine samples of food, drugs, devices, cosmetics, biologicals, vaccines, and household hazardous substances and health products.

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 central office shall be maintained and shall serve as a support unit to the centers for product research and evaluation and standards development and shall serve as testing centers that would include assay and the conduct, supervision, oversight and/or audit of bioequivalence and bioavailability test/researches, among others. The existing laboratory in Cebu and Davao will be upgraded and transformed as quality assurance laboratories, while another one will be established in Subic, Zambales. The testing laboratories may be increased by the Director-General, upon approval of the Secretary of Health.

SEC. 19. The FDA shall establish field offices in all regions of the country to effectively implement its regulatory functions. The current regional food and drug regulatory officers in every regional office of the Department of Health shall now be put under the FDA's sole control and supervision. The regional field office shall also assume sole and primary jurisdiction in the collection of samples of food, drugs, devices and cosmetics being imported or offered for import at a port of entry other than Manila in his assigned region and where it appears that said items or products satisfy any of the conditions as provided for in Section 30(a) of Republic Act No. 3720, as amended, without prejudice to the exercise of the powers of the Director-General under Section 13 of this Act in the exercise of the agency's regulatory functions. The field offices shall be comprised of the following: (a) Inspection and Compliance Division, which shall have charge of the inspection of food, drugs and cosmetic establishments engaged in their manufacture, importation, distribution, and sale; (b) Satellite Laboratory Division; and (c) Administrative Division.

SEC. 20. The FDA shall establish a regulatory enforcement unit (REU) which shall be composed of at least five (5) qualified personnel in every region who shall be directly under the control and supervision of the Deputy Director-General for Regulatory Operations and shall be administratively supported by the field offices. They shall:

(a) bear arms, wear official uniforms and insignias and shall be classified as law enforcement agents; and

(b) execute and serve search warrants and arrest warrants issued by the courts in connection with violations under this Act and related laws concerning the regulation of food, drugs, devices, cosmetics, biologicals, vaccines, in-vitro diagnostic reagents, household hazardous substances and health products. Their authority and functions shall be strictly limited to the implementation of the FDA's regulatory functions.

All regional regulatory enforcement units shall be headed by a lawyer who is at least thirty (30) years old but not older than fifty (50); an Integrated Bar of the Philippines (IBP) member of good standing,and shall have a rank of a Division Director; and an assistant who must be at the very least an LLB graduate who shall have a rank of an Assistant Division Director.

SEC. 21. The FDA, with the approval of the Secretary, shall create organizational units which are deemed necessary to address emerging concerns and to be abreast with internationally acceptable standards and shall seek the creation of additional plantilla positions to augment the human resource complement of the FDA Central Office and its field offices, subject to existing rules and regulations.

SEC. 22. *Appropriations.* – The appropriations for the FDA included in the budget of the Department of Health under the current General Appropriations Act shall be used to carry out the implementation of this Act. The appropriation may be augmented by the income which the agency is authorized to use under Section 20 of this Act. Thereafter, such sums as may be necessary for its continued implementation shall be included in the annual General Appropriations Act.

SEC. 23. *Implementing Rules and Regulations.* – The Department of Health shall promulgate, in consultation with the FDA, the implementing rules and regulations of this Act within sixty (60) days after the passage of this Act.

SEC. 24. *Congressional Oversight Committee.* – A Congressional Oversight Committee (COC) is hereby created composed of the Chairpersons of the Committees on Health and Appropriations of the House of Representatives and two (2) Members to be appointed by the Speaker, the Chairpersons of the Committees on Health and Finance of the Senate and two (2) Members to be appointed by the President of the Senate, to oversee the implementation of this Act for a period of five (5) years and to review the accomplishments and the utilization of income of the FDA.

The secretariat of the COC shall be drawn from the existing personnel of the committees comprising the COC.

SEC. 25. *Transitory Provisions.* – The FDA shall be headed by the current BFAD Director while the position of the Deputy Director-General for Regulatory Operations will be assumed by the current the BFAD Deputy Director, both in a permanent capacity. The current personnel of the BFAD shall be assigned to

their appropriate unit as far as practicable in the FDA and as determined by the Director-General. Priority shall be given to them in the filling of new positions, in accordance with civil service regulations.

SEC. 26. *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.

SEC. 27. *Repealing Clause.* – Laws or part of laws, executive orders, circulars, regulations and memoranda inconsistent with this Act are hereby repealed or amended accordingly.

SEC. 28. *Effectivity.* – This Act shall take effect fifteen (15) days after its publication in the *Official Gazette* or in two (2) newspapers of general circulation.

Approved,