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

S E N A T E

S. B. No. 2645

(In substitution of S.B. Nos. 1652 and 2520, and taking into consideration H.B. No. 3293)

Prepared jointly by the Committees on Health and Demography and Finance with Senators Legarda, Villar and Cayetano, (P.) as authors thereof

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, CONVERTING IT INTO THE FOOD, DRUGS, COSMETICS AND DEVICES ADMINISTRATION (FDCDA), 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. This Act shall be known as the Food, Drugs, Cosmetics and Devices Administration (FDCDA) Act of 2008.

SEC. 2. Section 2 of Republic Act 3720, as amended, *is hereby amended* to read *as follows:*

"SECTION 2. The State policies as embodied in Article II, Section 15 of the 1987 Constitution, that: 'The State shall protect and promote the right to health of the people and instill health consciousness among them' and in Section 12, Article XIII of the 1987 Constitution, that: 'The State shall 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 are iterated.'

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 HEALTH PRODUCT 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. 3. Section 4 of Republic Act 3720, as amended, is hereby amended to read as follows

"SECTION 4. To carry out the provisions of this Act, there is hereby created [an office to be called] the Food, [and] DrugS, COSMETICS AND DEVICES Administration (FCDA) 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 PRIMARY JURISDICTION IN the collection of samples of [food, drug and cosmetic] HEALTH PRODUCTS.

(c). To analyze and inspect [food, drug and cosmetic] 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 and cosmetic] 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 and cosmetic manufacturers and establishments.]

TO ISSUE AUTHORIZATIONS AND SPOT-CHECK FOR COMPLIANCE WITH REGULATIONS ESTABLISHMENTS OF MANUFACTURERS, IMPORTERS, EXPORTERS, DISTRIBUTORS, WHOLESALERS, AND RETAILERS OF HEALTH PRODUCTS, ESTABLISHMENTS OPERATING OR HANDLING RADIATION DEVICES, AND OTHER ESTABLISHMENTS AS DETERMINED BY THE FDCDA.

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(*H*) TO REQUIRE ALL MANUFACTURERS, DISTRIBUTORS, IMPORTERS, EXPORTERS, WHOLESALERS, TRADERS/RETAILERS AND CONSUMERS/USERS OF HEALTH PRODUCTS TO REPORT TO FDCDA ANY INCIDENT THAT REASONABLY INDICATES THAT SAID PRODUCT HAS

CAUSED OR CONTRIBUTED TO THE DEATH, SERIOUS ILLNESS OR SERIOUS INJURY TO A CONSUMER, A PATIENT, OR A MEMBER OF THE PUBLIC;

(I) TO ISSUE CEASE AND DESIST ORDERS *MOTU PROPIO* OR UPON VERIFIED COMPLAINT;

(J) TO ORDER THE BAN, RECALL, AND/OR WITHDRAWAL OF ANY HEALTH PRODUCT AS RECOMMENDED BY THE DIRECTOR-GENERAL AND UPON APPROVAL OF THE SECRETARY, AND TO REQUIRE ALL CONCERNED TO SUBMIT A *PRODUCT RECALL PLAN BEFORE ISSUANCE* OF A LICENSE TO OPERATE;

(K) TO STRENGTHEN THE POST MARKET SURVEILLANCE SYSTEM IN MONITORING PRODUCTS UNDER THE FDCDA'S JURISDICTION AND INCIDENTS OF ADVERSE EVENTS INVOLVING SUCH PRODUCTS;

(L) TO DEVELOP AND ISSUE STANDARDS AND APPROPRIATE AUTHORIZATIONS THAT WOULD COVER ESTABLISHMENTS AND PRODUCTS AND SHALL REFER SUCH STANDARDS TO THE BUREAU OF PRODUCT STANDARDS OF THE DEPARTMENT OF TRADE AND INDUSTRY FOR PROMULGATION, AS MAY BE APPLICABLE;

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

(*N*) TO PRESCRIBE STANDARDS AND REGULATIONS WITH RESPECT TO INFORMATION, ADVERTISEMENTS AND OTHER MARKETING INSTRUMENTS AND PROMOTION, SPONSORSHIP, AND OTHER MARKETING ACTIVITIES ABOUT THE HEALTH PRODUCTS AS COVERED IN THIS ACT.

(O) TO MAINTAIN BONDED WAREHOUSES AND/OR ESTABLISH THE SAME, WHENEVER NECESSARY OR APPROPRIATE, AS DETERMINED BY THE DIRECTOR-GENERAL FOR CONFISCATED GOODS IN STRATEGIC AREAS OF THE COUNTRY ESPECIALLY AT MAJOR PORTS OF ENTRY; AND

(P) 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. 4. Section 5 of Republic Act No. 3720, as amended, is hereby amended and new subsections are added to read as follows:

"SEC. 5. The FDCDA 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/URBAN HAZARDOUS SUBSTANCES); AND

(4) CENTER FOR DEVICE REGULATION AND RADIATION HEALTH.

THESE CENTERS SHALL REGULATE THE MANUFACTURE, IMPORTATION, EXPORTATION, DISTRIBUTION, SALE, OFFER FOR SALE, TRANSFER, PROMOTION, ADVERTISEMENT, SPONSORSHIP OF, AND/OR, WHERE APPROPRIATE, THE USE AND TESTING OF HEALTH PRODUCTS. THE CENTERS SHALL LIKEWISE CONDUCT RESEARCH IN THE SAFETY, EFFICACY, AND QUALITY OF HEALTH PRODUCTS, AND TO INSTITUTE STANDARDS FOR THE SAME.

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

(1). LICENSING AND REGISTRATION DIVISION, WHICH SHALL BE RESPONSIBLE FOR EVALUATING PRODUCTS AND ESTABLISHMENTS AS COVERED BY THIS ACT FOR THE PURPOSE OF ISSUANCE OF AUTHORIZATIONS AND CONDITIONS TO BE OBSERVED;

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

(3). LABORATORY SUPPORT DIVISION, WHICH SHALL BE RESPONSIBLE FOR THE CONDUCT OF APPROPRIATE TESTS AND

CALIBRATION, 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 AND DEPARTMENT OF HEALTH FACILITIES WHICH SHALL BE SEPARATE AND DISTINCT PER MAJOR PRODUCT CATEGORY THAT IS REGULATED.

(C) THE ADMINISTRATION AND FINANCE OFFICE HEADED BY THE DEPUTY DIRECTOR-GENERAL FOR ADMINISTRATION AND FINANCE 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.

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

(E) THE FIELD REGULATORY OPERATIONS OFFICE HEADED BY THE DEPUTY DIRECTOR-GENERAL FOR FIELD REGULATORY OPERATIONS SHALL INCLUDE, AMONG OTHERS, ALL THE FIELD OFFICES, FIELD OR SATELLITE LABORATORIES.

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

SEC. 5. Section 6 of RA 3720, as amended, is hereby amended, to read as follows:

[The Food and Drug Administration shall have a Food and Drug Administrator who shall be appointed by the Secretary of Health subject to the Civil Service rules and regulations. The compensation of said official shall be determined by the Secretary of Health.]

"(A) THE FDCDA SHALL BE HEADED BY A DIRECTOR-GENERAL, WITH THE RANK OF UNDERSECRETARY, WHO SHALL BE TASKED, AMONG OTHERS, TO DETERMINE THE NEEDED PERSONNEL AND, TO

APPOINT PERSONNEL, BELOW THE ASSISTANT DIRECTOR LEVEL IN COORDINATION WITH THE SECRETARY OF HEALTH.

(B) THE DIRECTOR-GENERAL SHALL BE ASSISTED BY TWO (2) DEPUTY DIRECTORS-GENERAL, FOR ADMINISTRATION AND FINANCE AND FOR FIELD REGULATORY OPERATIONS.

(C) THE DIRECTOR-GENERAL AND DEPUTY DIRECTORS-GENERAL SHALL BE APPOINTED BY THE PRESIDENT OF THE REPUBLIC.

(D) EACH CENTER AND FIELD OFFICE SHALL BE HEADED BY A DIRECTOR WHO SHALL BE ASSISTED BY AN ASSISTANT DIRECTOR. THESE DIRECTORS SHALL BE APPOINTED BY THE SECRETARY OF HEALTH.

(E) THE APPOINTMENT OF THE DIRECTOR-GENERAL, DEPUTY DIRECTORS-GENERAL, DIRECTORS AND ASSISTANT DIRECTORS OF THE FDCDA SHALL BE BASED ON THE FITNESS AND MERIT PRINCIPLE IN ACCORDANCE WITH THE ESTABLISHED CIVIL SERVICE COMMISSION LAW, RULES, AND REGULATIONS. THE DIRECTOR-GENERAL AND THE DEPUTY DIRECTORS-GENERAL MUST ALSO HAVE MANAGEMENT EXPERIENCE IN A POSITION RELATED TO HIS/HER FIELD OF DISCIPLINE OR PROFESSION.

(F) THE EXISTING DIRECTORS AND DIVISION CHIEFS OF THE BUREAU OF FOOD AND DRUGS AND OF THE BUREAU OF HEALTH DEVICES AND TECHNOLOGY, IF QUALIFIED, SHALL BE GIVEN UTMOST PREFERENCE FOR APPOINTMENT AS DIRECTORS AND ASSISTANT DIRECTORS OF THEIR RESPECTIVE CENTERS."

Sec. 6. Section 7 of RA 3720, as amended, is hereby amended to read as follows:

[The Secretary of Health shall provide for the additional personnel needed to carry out the functions and duties of the Food and Drug Administration.] THE FDCDA SHALL REVIEW ITS STAFFING PATTERN AND POSITION TITLES SUBJECT TO THE APPROVAL OF THE SECRETARY OF HEALTH.

SEC. 7. Section 10, subsections (a), (e), (f), (g), (h), (i), (q), (r) and (v) of RA 3720, as amended, are hereby further amended, and new subsections are added, to read as follows:

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

(a). ["Bureau" means the Bureau of Food and Drugs.] ***"FDCDA"*** MEANS THE FOOD, DRUGS, COSMETICS AND DEVICE ADMINISTRATION.

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.] 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 Pharmacopoeia-National Formulary (USP-NF), official Homeopathic Pharmacopoeia of the United States, official National Drug Formulary, or any supplement to any of them:] OFFICIAL PHARMACOPEIAS AND FORMULARIES, INCLUDING OFFICIAL HOMEOPATHIC PHARMACOPEIAS, OR ANY SUPPLEMENT TO ANY OF THEM, WHICH IS RECOGNIZED AND ADOPTED BY THE FDCDA; [and] (2) articles WHETHER OF PLANT, ANIMAL OR HUMAN ORIGIN intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; [and] (3) articles (other than food) WHETHER OF PLANT, ANIMAL OR HUMAN ORIGIN intended to affect the structure of any function of [the body of man or animals] HUMANS; [and] OR (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.

(1) "***MEDICAL DEVICE***" MEANS ANY INSTRUMENT, APPARATUS, IMPLEMENT, MACHINE, APPLIANCE, IMPLANT, IN-VITRO REAGENT OR CALIBRATOR, SOFTWARE, MATERIAL, OR OTHER SIMILAR OR RELATED ARTICLE INTENDED BY THE MANUFACTURER TO BE USED ALONE, OR IN COMBINATION, FOR HUMAN BEINGS FOR ONE OR MORE OF THE SPECIFIC PURPOSE(S) OF: DIAGNOSIS, PREVENTION, MONITORING, TREATMENT OR ALLEVIATION OF DISEASE; DIAGNOSIS, MONITORING, TREATMENT, ALLEVIATION OF, OR COMPENSATION FOR AN INJURY; INVESTIGATION, REPLACEMENT, MODIFICATION, OR SUPPORT OF THE ANATOMY OR OF A PHYSIOLOGICAL PROCESS; SUPPORTING OR SUSTAINING LIFE; PREVENTING INFECTION; CONTROL OF CONCEPTION; DISINFECTION OF MEDICAL DEVICES; AND PROVIDING INFORMATION

FOR MEDICAL OR DIAGNOSTIC PURPOSES BY MEANS OF IN-VITRO EXAMINATION OF SPECIMENS DERIVED FROM THE HUMAN BODY.

THIS DEVICE DOES NOT ACHIEVE ITS PRIMARY INTENDED ACTION IN OR ON THE HUMAN BODY BY PHARMACOLOGICAL, IMMUNOLOGICAL OR METABOLIC MEANS BUT WHICH MAY BE ASSISTED IN ITS INTENDED FUNCTION BY SUCH MEANS.

(2) "***RADIATION DEVICE***" MEANS AN ELECTRICAL OR ELECTRONIC APPARATUS EMITTING ANY IONIZING OR NON-IONIZING ELECTROMAGNETIC OR PARTICULATE RADIATION; OR ANY SONIC, INFRASONIC, OR ULTRASONIC WAVE. IT INCLUDES IONIZING RADIATION-*EMITTING EQUIPMENT WHICH IS NOT INTENTIONALLY DESIGNED TO* PRODUCE RADIOACTIVE MATERIALS.

(3) "***HEALTH-RELATED DEVICE***" MEANS ANY DEVICE NOT USED IN HEALTH CARE BUT HAS BEEN DETERMINED BY THE FDCDA TO ADVERSELY AFFECT THE HEALTH OF THE PEOPLE.

(h). ***"Cosmetics"*** means [(1) articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and (2) articles intended for use as a component of any such articles.] ANY SUBSTANCE OR PREPARATION INTENDED TO BE PLACED IN CONTACT WITH THE VARIOUS EXTERNAL PARTS OF THE HUMAN BODY OR WITH THE TEETH AND THE MUCOUS MEMBRANES OF THE ORAL CAVITY, WITH A VIEW EXCLUSIVELY OR MAINLY TO CLEANING THEM, PERFUMING THEM, CHANGING THEIR APPEARANCE AND/OR CORRECTING BODY ODOR, AND/OR PROTECTING THE BODY OR KEEPING THE SAME IN GOOD CONDITION.

(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 easily legible through the outside container or wrapper.

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

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

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(*v*) "***ManufactureR***", in relation to a HEALTH PRODUCT means AN ESTABLISHMENT ENGAGED IN any and all operations involved in the production of [a drug or device] HEALTH PRODUCTS 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.

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

(Y) "***AUTHORIZATION***" MEANS A PERMISSION EMBODIED IN A DOCUMENT GRANTED BY THE FDCDA TO A NATURAL OR JURIDICAL PERSON WHO HAS SUBMITTED AN APPLICATION TO CARRY OUT THE MANUFACTURE, IMPORTATION, EXPORTATION, SALE, OFFER FOR SALE, DISTRIBUTION, TRANSFER, AND/OR WHERE APPROPRIATE THE USE, TESTING, PROMOTION, ADVERTISING , OR SPONSORSHIP OF HEALTH PRODUCTS. THE AUTHORIZATION CAN TAKE THE FORM OF A PERMIT, A LICENSE, A CERTIFICATE OF REGISTRATION, OF ACCREDITATION, OF COMPLIANCE, OR OF EXEMPTION, OR ANY SIMILAR DOCUMENT.

(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 DOSES. 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) "***DISTRIBUTOR/IMPORTER/EXPORTER***" MEANS ANY ESTABLISHMENT THAT IMPORTS OR EXPORTS RAW MATERIALS, ACTIVE INGREDIENTS AND/OR FINISHED PRODUCTS FOR ITS OWN USE OR FOR WHOLESALE OR RETAIL DISTRIBUTION TO OTHER ESTABLISHMENTS OR OUTLETS. IF THE DISTRIBUTOR/IMPORTER/EXPORTER SELLS TO THE GENERAL PUBLIC, IT SHALL BE CONSIDERED A TRADER/RETAILER.

(CC) "***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.

(DD) "***ESTABLISHMENT***" MEANS A SOLE PROPRIETORSHIP, A PARTNERSHIP, A CORPORATION, AN INSTITUTION, AN ASSOCIATION, OR AN ORGANIZATION ENGAGED IN THE MANUFACTURE, IMPORTATION, EXPORTATION, SALE, OFFER FOR SALE, DISTRIBUTION, TRANSFER, USE, TESTING, PROMOTION, ADVERTISING, OR SPONSORSHIP OF HEALTH PRODUCTS INCLUDING THE FACILITIES AND INSTALLATIONS NEEDED FOR ITS ACTIVITIES.

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

(FF) "***HOUSEHOLD/URBAN HAZARDOUS SUBSTANCE***" IS:

(1) ANY SUBSTANCE OR MIXTURE OF SUBSTANCES INTENDED FOR INDIVIDUAL OR LIMITED PURPOSES AND 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 AGRICULTURAL FERTILIZER AND PESTICIDE, INSECTICIDE AND OTHER ECONOMIC POISONS, RADIOACTIVE SUBSTANCE, OR

SUBSTANCES INTENDED FOR USE AS FUELS, COOLANTS, REFRIGERANTS AND THE LIKE.

(2) ANY SUBSTANCE WHICH THE FDCDA FINDS TO BE UNDER THE CATEGORIES ENUMERATED IN CLAUSE (1) OF THIS PARAGRAPH;

(3) ANY TOY OR OTHER ARTICLES INTENDED FOR USE BY CHILDREN WHICH THE FDCDA MAY DETERMINE TO POSE AN ELECTRICAL, CHEMICAL, PHYSICAL, OR THERMAL HAZARD.

(4) THIS TERM SHALL NOT APPLY TO FOOD, DRUGS, COSMETICS, DEVICES, OR TO SUBSTANCES INTENDED FOR USE AS FUELS WHEN STORED IN CONTAINERS AND USED IN THE HEATING, COOKING OR REFRIGERATION SYSTEM OF A HOUSE, BUT SUCH TERM SHALL APPLY TO ANY ARTICLE WHICH IS NOT IN ITSELF AN AGRICULTURAL PESTICIDE BUT WHICH IS A HAZARDOUS SUBSTANCE, AS CONSTRUED IN PARAGRAPH (1) OF THIS SECTION, BY REASON OF BEARING OR CONTAINING SUCH HARMFUL SUBSTANCES DESCRIBED THEREIN.

(GG) "***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.

(HH) "***LICENSING***" MEANS THE PROCESS OF APPROVAL OF AN APPLICATION TO OPERATE OR ESTABLISH AN ESTABLISHMENT PRIOR TO ENGAGING IN THE MANUFACTURE, IMPORTATION, EXPORTATION, SALE, OFFER FOR SALE, DISTRIBUTION, TRANSFER, AND WHERE APPLICABLE THE USE, TESTING, PROMOTION, ADVERTISEMENT, AND/OR SPONSORSHIP OF HEALTH PRODUCTS.

(II) "***MISBRANDING***" MEANS MISINFORMATION OR MISLEADING INFORMATION ON THE LABEL OR OTHER INFORMATION MATERIALS AUTHORIZED BY THE FDCDA. IT SHALL NOT REFER TO COPYRIGHT, TRADEMARK, OR OTHER INTELLECTUAL PROPERTY–LIKE INSTRUMENTS.

(JJ) "***REGISTRATION***" MEANS THE PROCESS OF APPROVAL PRIOR TO ENGAGING IN THE MANUFACTURE, IMPORTATION, EXPORTATION, SALE, OFFER FOR SALE, DISTRIBUTION, TRANSFER, AND WHERE APPLICABLE THE USE, TESTING, PROMOTION, ADVERTISEMENT, AND/OR SPONSORSHIP OF HEALTH PRODUCTS.

(KK) "***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.

(MM) "***TRADER/RETAILER***" MEANS ANY ESTABLISHMENT WHICH SELLS OR OFFERS TO SELL ANY HEALTH PRODUCT TO THE GENERAL PUBLIC

SEC. 8. Sec. 11, subsections (a), (b), (d), (g), (j), (k) and (l) of R. A. 3720, as amended, is 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, USE, PROMOTION, ADVERTISING, OR SPONSORSHIP of any [food, drug, device, or cosmetic] HEALTH PRODUCT that is adulterated, UNREGISTERED, or misbranded.

(b) The adulteration or misbranding of any [food, drug, device, or cosmetics,] HEALTH PRODUCT.

x x x

(d) 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] OR ENTITY from whom he received in good faith the [food, drug, device, or cosmetic] HEALTH PRODUCTS or the giving of a guaranty or undertaking referred to in Section twelve (b) 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, or cosmetics,] HEALTH PRODUCTS 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, USE, PROMOTION, ADVERTISEMENT, OR SPONSORSHIP of any [drug, or device,] HEALTH PRODUCT which,

ALTHOUGH REQUIRING REGISTRATION, is not registered with the [Bureau] FDCDA 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; THE MANUFACTURE, IMPORTATION, EXPORTATION, TRANSFER OR DISTRIBUTION OF ANY FOOD, COSMETIC OR HOUSEHOLD/URBAN HAZARDOUS SUBSTANCE; OR THE OPERATION OF A RADIATION ESTABLISHMENT by any NATURAL OR JURIDICAL person without the license TO OPERATE from the [Bureau] FDCDA required under this Act.

(l) The sale, [or] offering for sale, IMPORTATION, EXPORTATION DISTRIBUTION OR TRANSFER of any [drug, or device] HEALTH PRODUCT beyond its expiration or expiry date, IF APPLICABLE.

x x x.

THE PROHIBITED ACTS MENTIONED HEREIN SHALL COVER ALL APPLICABLE HEALTH PRODUCTS."

SEC. 9. 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 HEALTH PRODUCT 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. *PROVIDED, FINALLY,* THAT THE HEALTH PRODUCTS FOUND IN VIOLATION OF THE PROVISIONS OF THIS ACT AND

OTHER RELEVANT LAWS, RULES AND REGULATIONS MAY BE SEIZED AND HELD IN CUSTODY PENDING PROCEEDINGS PURSUANT TO SECTION 26 (D) OF RA 3720, AS AMENDED IN SECTION 10 HEREOF, WITHOUT HEARING OR COURT ORDER, WHEN THE DIRECTOR GENERAL HAS REASONABLE CAUSE TO BELIEVE FROM FACTS FOUND BY HIM/HER OR AN AUTHORIZED OFFICER OR EMPLOYEE OF THE FDCDA THAT THE HEALTH PRODUCTS MAY CAUSE INJURY OR PREJUDICE TO THE CONSUMING PUBLIC OR IS IN VIOLATION OF THE PROVISIONS OF REPUBLIC ACT 3720, AS AMENDED, AND OTHER RELEVANT LAWS, RULES AND REGULATIONS IMPLEMENTED BY THE FDCDA."

x x x

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. 10. Section 26, subsections (c) and (d) of Republic Act No. 3720, as amended, are hereby further amended and subsection (g) is hereby added thereto to read as follows:

"x x x

(c) Hearings authorized or required by this Act shall be conducted by the [Bureau which shall submit its recommendation to the Secretary] FDCDA.

(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 FDCDA.

x x x.

(g) BOTH CRIMINAL AND ADMINISTRATIVE ACTIONS MAY BE INSTITUTED SEPARATELY AND INDEPENDENT OF ONE ANOTHER."

SEC. 11. Section 29-A of Republic Act No. 3720, as amended, is hereby further amended, and new subsections are added to read as follows:

"SEC. 29-A. Administrative Sanctions. [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.]

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:

(1) CANCELLATION OF ANY AUTHORIZATION WHICH MAY HAVE BEEN GRANTED BY THE FDCDA 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;

(2) A FINE OF NOT LESS THAN FIFTY THOUSAND PESOS (P50,000.00) BUT NOT MORE THAN FIVE HUNDRED THOUSAND PESOS (P500,000.00). AN ADDITIONAL FINE OF NOT MORE THAN ONE THOUSAND PESOS (P1,000.00) SHALL BE IMPOSED FOR EACH DAY OF CONTINUING VIOLATION;

(3) DESTRUCTION AND/OR APPROPRIATE DISPOSITION OF THE SUBJECT HEALTH PRODUCT, AND/OR CLOSURE OF THE ESTABLISHMENT AS DETERMINED BY THE DIRECTOR-GENERAL; AND

(4) IN THE CASE OF ESTABLISHMENTS OPERATING RADIATION DEVICES, CLOSURE OF THE NON-COMPLYING ESTABLISHMENT AS DETERMINED BY THE DIRECTOR-GENERAL."

SEC. 12. A new Section 30 and a new headnote "ADDITIONAL POWERS AND FUNCTIONS OF THE DIRECTOR-GENERAL" are hereby added to Republic Act 3720, which shall read as follows:

"SEC. 30. THE DIRECTOR-GENERAL SHALL ALSO EXERCISE THE FOLLOWING POWERS:

(1) TO HOLD IN DIRECT OR INDIRECT CONTEMPT ANY PERSON WHO DISREGARDS ORDERS OR WRITS HE OR SHE ISSUES AND TO IMPOSE THE APPROPRIATE PENALTIES THEREOF;

(2) 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 FDCDA;

(3) TO OBTAIN INFORMATION FROM ANY OFFICER OR OFFICE OF THE NATIONAL OR LOCAL GOVERNMENTS, GOVERNMENT AGENCIES AND ITS INSTRUMENTALITIES;

(4) TO ISSUE ORDERS OF SEIZURE, TO SEIZE AND HOLD IN CUSTODY ANY HEALTH PRODUCT THAT IS ADULTERATED, COUNTERFEITED, MISBRANDED OR UNREGISTERED;

(5) 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; AND

(6) TO EXERCISE SUCH POWERS AND FUNCTIONS AS MAY BE NECESSARY FOR THE EFFECTIVE IMPLEMENTATION OF THIS ACT."

Sec. 13. Two new sections shall be added, which shall be the new Sections 31 and 32 of RA 3720, as amended, which shall read as follows:

SEC. 31. THE ORDER, RULING OR DECISION OF THE DIRECTOR-GENERAL OF THE FDCDA SHALL BE IMMEDIATELY EXECUTORY UNLESS A MOTION FOR RECONSIDERATION IS REASONABLY FILED.

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. 32. THE ORDERS, RULINGS OR DECISIONS OF THE DIRECTOR-GENERAL OF THE FDCDA 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. 14. Section 30 of Republic Act No. 3720, as amended, shall be renumbered as Section 33, and the subsequent sections shall also be renumbered accordingly.

SEC. 15. *Section 31, Chapter XIII of Republic Act No. 3720, as amended,* is hereby further amended to read as follows:

"SEC. [31] 34. [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 AUTHORIZATION FEES SHALL* ANNUALLY BE DETERMINED AND REVIEWED BY THE FDCDA 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 FDCDA, 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. 16. *All income that the FDCDA 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 acquisition of office and laboratory space, human resource development and expansion, purchase of laboratory equipment and motor vehicles, the upgrading of its current facilities and equipment and maintenance and other operating expenses of the central office laboratory *divisions 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 FDCDA on its own initiative or through an order or directive by any higher office.

The FDCDA shall submit to the Secretary of Health, the Secretary of Budget and Management and the Congressional Oversight Committee, created under Section 20 of this Act, a report on how the funds were utilized, including its accomplishments.

SEC. 17. A new chapter XIV and three new sections, Sections 35, 36, and 37 shall be introduced, which shall read as follows:

"CHAPTER XIV – TESTING LABORATORIES AND FIELD OFFICES

SEC. 35. THE FDCDA IS HEREBY MANDATED TO IMPROVE, UPGRADE AND INCREASE THE CAPABILITY OF THE AGENCY, TO TEST, CALIBRATE, ASSAY AND EXAMINE SAMPLES OF 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 LABORATORIES 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.

SEC. 36. THE FDCDA 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 FDCDA'S SOLE CONTROL AND SUPERVISION. THE REGIONAL FIELD OFFICE SHALL ALSO ASSUME 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 33(A) OF REPUBLIC ACT NO. 3720, AS AMENDED, WITHOUT PREJUDICE TO THE EXERCISE OF THE POWERS OF THE DIRECTOR-GENERAL PROVIDED UNDER SECTION 12 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. 37. THE FDCDA, 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 FDCDA CENTRAL OFFICE AND ITS FIELD OFFICES, SUBJECT TO EXISTING RULES AND REGULATIONS."

SEC. 18. *Appropriations.* – The appropriations for the Bureau of Food and Drugs and the Bureau of Health Devices and Technology 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 this Act. Thereafter, such sums as may be necessary for its continued implementation shall be included in the annual General Appropriations Act.

SEC. 19. *Implementing Rules and Regulations.* – The Department of Health shall promulgate, in consultation with the FDCDA, the implementing rules and regulations of this Act within sixty (60) days after the passage of this Act.

SEC. 20. *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 FDCDA.

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

SEC. 21. *Transitory Provisions.* - The BFAD Director and Deputy Director shall serve on a temporary basis as FDCDA Director-General and Deputy Director-General for Field Regulatory Operations, respectively, until such time when the President of the Republic shall have appointed the permanent Director-General and the two Deputy Directors-General. The current officials and employees of the BFAD shall be transferred as far as practicable to the appropriate unit in the FDCDA as determined by the Director-General. The current officials and employees of the Bureau of Health Devices and Technology shall be transferred to the Center for Device Regulation and Radiation Health. The current regional Food and Drug Regulatory Officers and regional health physicists under the Centers for Health Development of the DOH shall be transferred as far as practicable to the appropriate unit in the FDCDA as determined by the Director-General. There shall be no demotion in ranks and positions and no diminution in salaries, benefits, allowances and emoluments of all BFAD, BHDT and indicated CHD personnel transferred to the FDCDA. All positions, powers, functions and duties together with the facilities, equipment, supplies, records, files, appropriations, and funds for these bureaus and the indicated CHD personnel shall be transferred to the FDCDA.

SEC. 22. *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. 23. *Repealing Clause.* – Laws or part of laws, executive orders, circulars, regulations and memoranda inconsistent with this Act are hereby repealed or amended accordingly.

SEC. 24. *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,