

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

8 SEP 30 13:32

RECEIVED BY: 

SENATE

COMMITTEE REPORT NO. 104

Submitted jointly by the Committees on Health and Demography, and Finance
on SEP 30 2008

RE : S. No. 2645

Recommending its approval in substitution of S. B. Nos. 1652 and 2520, and
taking into consideration H.B. No. 3293

Sponsor : Senator Pia S. Cayetano

Mr. President:

The Committees on Health and Demography, and Finance, to which
were referred S. B. No. 1652, introduced by Senator Legarda, *entitled*:

**"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"**

S.B. No. 2520, introduced by Senator Villar, *entitled*:

**"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"**

and H.B. No. 3293, introduced by Representatives Pingoy, Biron, Lagman, et al., *entitled*:

**“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) AND
AMENDING CERTAIN SECTIONS OF REPUBLIC ACT 3720,
AS AMENDED AND APPROPRIATING FUNDS THEREOF”**

have considered the same and have the honor to report back to the Senate with the recommendation that the attached **S. B. No. 2645**, prepared by the Committees, *entitled*:

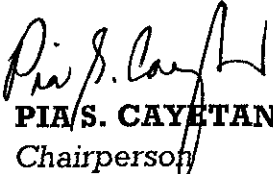
**“AN ACT
STRENGTHENING THE REGULATORY CAPACITY OF THE
BUREAU OF FOOD AND DRUGS (BFAD) BY ESTABLISHING
ADEQUATE TESTING LABORATORIES AND FIELD OFFICES,
UPGRADING ITS EQUIPMENT, AUGMENTING ITS HUMAN
RESOURCE COMPLEMENT, GIVING AUTHORITY TO RETAIN ITS
INCOME, CONVERTING IT INTO THE FOOD, DRUGS,
COSMETICS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

be approved in substitution of **S. B. Nos. 1652 and 2520**, taking into consideration **H.B. No. 3293**, with Senators Legarda, Villar and Cayetano (P.) as authors thereof.

RESPECTFULLY SUBMITTED:




JUAN PONCE ENRILE
Chairperson
Committee on Finance




PIA S. CAYETANO
Chairperson
Committee on Health and Demography
Member, *Committee on Finance*

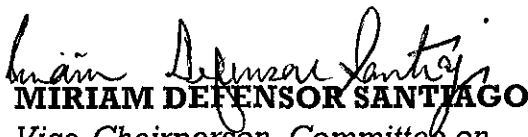
VICE-CHAIRPERSONS:




RODOLFO G. BIAZON
Vice-Chairperson
Committee on Health and Demography
Member, *Committee on Finance*



EDGARDO J. ANGARA *of auditors*
Vice-Chairperson
Committees on Health and Demography,
and Finance



MIRIAM DEFENSOR SANTIAGO
Vice-Chairperson, *Committee on Finance*



LOREN B. LEGARDA
Vice-Chairperson, *Committee on Health and Demography*
Member, *Committee on Finance*



JOKER P. ARROYO
Vice-Chairperson, *Committee on Finance*

MEMBERS:

may amend
FRANCIS "CHIZ" G. ESCUDERO
with legislation
Committees on Health and Demography, and Finance

ALAN PETER "COMPAÑERO" S. CAYETANO
Committee on Health and Demography

MANUEL "LITO" M. LAPID
Committees on Health and Demography, and Finance

GREGORIO B. HONASAN II
Committees on Health and Demography, and Finance

may amend
M. A. MADRIGAL
Committees on Health and Demography, and Finance

RAMON "PONG" REVILLA JR.
Committees on Health and Demography, and Finance

may amend
RICHARD "DICK" J. GORDON
Committee on Finance

may amend
MAR ROXAS
Committees on Health and Demography, and Finance

PANFILO M. LACSON
Committee on Finance

JUAN MIGUEL F. ZUBIRI
Committee on Finance

ANTONIO "SONNY" F. TRILLANES IV
Committee on Finance

EX- OFFICIO MEMBERS

may amend
AQUILINO Q. PIMENTEL JR.
Minority Leader

FRANCIS N. PANGILINAN
Majority Leader

may amend
JINGGOY EJERCITO ESTRADA
Senate President Pro-Tempore

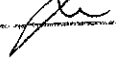
MANNY VILLAR
Senate President
Pasay City

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SENATE

S. B. No. 2645

RECEIVED BY: 

(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:*

1 **SECTION 1.** This Act shall be known as the Food, Drugs, Cosmetics and
2 Devices Administration (FDCDA) Act of 2008.

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

5 "SECTION 2. The State policies as embodied in Article II, Section 15 of the
6 1987 Constitution, that: 'The State shall protect and promote the right to health
7 of the people and instill health consciousness among them' and in Section 12,
8 Article XIII of the 1987 Constitution, that: 'The State shall establish and maintain
9 an effective food and drug regulatory system and undertake appropriate health
10 manpower development and research, responsive to the country's health needs
11 and problems are iterated.'

12 IT IS HEREBY DECLARED A POLICY OF THE STATE TO ADOPT,
13 SUPPORT, ESTABLISH, INSTITUTIONALIZE, IMPROVE AND MAINTAIN
14 STRUCTURES, PROCESSES, MECHANISMS AND INITIATIVES THAT ARE
15 AIMED, DIRECTED AND DESIGNED TO: (A) PROTECT AND PROMOTE THE
16 RIGHT TO HEALTH OF THE FILIPINO PEOPLE; AND (B) HELP ESTABLISH
17 AND MAINTAIN AN EFFECTIVE HEALTH PRODUCT REGULATORY SYSTEM
18 AND UNDERTAKE APPROPRIATE HEALTH MANPOWER DEVELOPMENT

1 AND RESEARCH, RESPONSIVE TO THE COUNTRY'S HEALTH NEEDS AND
2 PROBLEMS. PURSUANT TO THIS POLICY, THE STATE MUST ENHANCE
3 ITS REGULATORY CAPACITY AND STRENGTHEN ITS CAPABILITY WITH
4 REGARD TO THE INSPECTION, LICENSING AND MONITORING OF
5 ESTABLISHMENTS, AND THE REGISTRATION AND MONITORING OF
6 FOOD, DRUGS, DEVICES, IN-VITRO DIAGNOSTIC REAGENTS, COSMETICS
7 AND HOUSEHOLD HAZARDOUS SUBSTANCES."

8 **SEC. 3.** Section 4 of Republic Act 3720, as amended, is hereby amended
9 to read as follows

10 "SECTION 4. To carry out the provisions of this Act, there is hereby
11 created [an office to be called] the Food, [and] DrugS, COSMETICS AND
12 DEVICES Administration (FCDA) in the Department of Health. Said
13 Administration shall be under the Office of the Secretary and shall have the
14 following functions, powers and duties:

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

17 (b). To [provide for] ASSUME PRIMARY JURISDICTION IN the collection
18 of samples of [food, drug and cosmetic] HEALTH PRODUCTS.

19 (c). To analyze and inspect [food, drug and cosmetic] HEALTH
20 PRODUCTS in connection with the implementation of this Act.

21 (d). To establish analytical data to serve as basis for the preparation of
22 [food, drug and cosmetic] HEALTH PRODUCTS standards, and to recommend
23 standards of identity, purity, SAFETY, EFFICACY, quality and fill of container.

24 (e). [To issue certificate of compliance with technical requirements to
25 serve as basis for the issuance of license and spot-check for compliance with
26 regulations regarding operation of food, drug and cosmetic manufacturers and
27 establishments.]

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

34 x x x

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

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

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

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

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

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

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

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

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

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

36 **SEC. 4.** Section 5 of Republic Act No. 3720, as amended, is hereby
37 amended and new subsections are added to read as follows:

1 "SEC. 5. The FDCA shall have the following [Divisions] CENTERS AND
2 OFFICES:

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

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

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

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

12 (2) CENTER FOR FOOD REGULATION AND RESEARCH;

13 (3) CENTER FOR COSMETICS REGULATION AND RESEARCH (TO
14 INCLUDE HOUSEHOLD/URBAN HAZARDOUS SUBSTANCES); AND

15 (4) CENTER FOR DEVICE REGULATION AND RADIATION HEALTH.

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

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

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

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

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

1 CALIBRATION, ANALYSES AND TRIALS OF PRODUCTS INCLUDING, BUT
2 NOT LIMITED TO, ASSAYS, AND THE CONDUCT OF OVERSIGHT AND/OR
3 AUDIT OF BIOAVAILABILITY AND BIOEQUIVALENCE TESTS AND OTHER
4 TESTS AS COVERED BY THIS ACT. IT SHALL LIKEWISE PROVIDE DIRECT
5 LINE SUPPORT TO THE CENTERS AND DEPARTMENT OF HEALTH
6 FACILITIES WHICH SHALL BE SEPARATE AND DISTINCT PER MAJOR
7 PRODUCT CATEGORY THAT IS REGULATED.

8 (C) THE ADMINISTRATION AND FINANCE OFFICE HEADED BY THE
9 DEPUTY DIRECTOR-GENERAL FOR ADMINISTRATION AND FINANCE
10 SHALL HAVE, AT LEAST, THE FOLLOWING DIVISIONS: THE HUMAN
11 RESOURCE DEVELOPMENT DIVISION; PROPERTY AND LOGISTICS
12 MANAGEMENT DIVISION; HUMAN RESOURCE MANAGEMENT DIVISION;
13 ASSETS AND FINANCIAL MANAGEMENT DIVISION; AND THE
14 INFORMATION AND COMMUNICATION TECHNOLOGY MANAGEMENT
15 DIVISION.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

31 **SEC. 7.** Section 10, subsections (a), (e), (f), (g), (h), (i), (q), (r) and (v) of RA
32 3720, as amended, are hereby further amended, and new subsections are
33 added, to read as follows:

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

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

37 x x x

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

8 (f) "**Drugs**" means: (1) articles recognized in [the current official United
9 States Pharmacopoeia-National Formulary (USP-NF), official Homeopathic
10 Pharmacopoeia of the United States, official National Drug Formulary, or any
11 supplement to any of them:] OFFICIAL PHARMACOPEIAS AND
12 FORMULARIES, INCLUDING OFFICIAL HOMEOPATHIC PHARMACOPEIAS,
13 OR ANY SUPPLEMENT TO ANY OF THEM, WHICH IS RECOGNIZED AND
14 ADOPTED BY THE FDCDA; [and] (2) articles WHETHER OF PLANT, ANIMAL
15 OR HUMAN ORIGIN intended for use in the diagnosis, cure, mitigation,
16 treatment, or prevention of disease in man or other animals; [and] (3) articles
17 (other than food) WHETHER OF PLANT, ANIMAL OR HUMAN ORIGIN
18 intended to affect the structure of any function of [the body of man or animals]
19 HUMANS; [and] OR (4) articles intended for use as a component of any articles
20 specified in clauses (1), (2), or (3) but do not include devices or their
21 components, parts or accessories.

22 (g) "**Device**" means [instruments, apparatus, or contrivances, including
23 their components, parts, and accessories, intended (1) for use in the diagnosis,
24 cure, mitigation, treatment, or prevention of disease in man or animals; or (2) to
25 affect the structure or any function of the body of man or animals] MEDICAL
26 DEVICES, RADIATION DEVICES AND HEALTH-RELATED DEVICES.

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

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

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

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

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

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

27 (i). "**Label**" means a display of written, printed, or graphic matter upon the
28 immediate container of any article and a requirement made by or under authority
29 of this Act that any word, statement, or other information appearing on the label
30 shall not be considered to be complied with unless such word, statement, OR
31 OTHER INFORMATION ALSO APPEARS ON THE OUTSIDE CONTAINER or
32 wrapper, if any there be, of the retail package of such article, or easily legible
33 through the outside container or wrapper.

34 X X X

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

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

4 X X X

5 (v) "**ManufactureR**", in relation to a HEALTH PRODUCT means AN
6 ESTABLISHMENT ENGAGED IN any and all operations involved in the
7 production of [a drug or device] HEALTH PRODUCTS including
8 [propagation] PREPARATION, processing, compounding, formulating, filling,
9 packing, repacking, altering, ornamenting, finishing and labeling with the
10 end[s] in view of its storage, sale or distribution: *Provided*, That the term shall
11 not apply to the compounding and filling of prescriptions in drugstores and
12 hospital pharmacies IN THE CASE OF DRUGS. A TRADER SHALL BE
13 CATEGORIZED AS A MANUFACTURER.

14 X X X

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

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

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

31 (AA) "**BIOEQUIVALENCE**" MEANS THE RATE AND EXTENT OF
32 ABSORPTION TO WHICH THE DRUGS DO NOT SHOW A SIGNIFICANT
33 DIFFERENCE FROM THE RATE AND EXTENT OF THE LISTED DRUG WHEN
34 ADMINISTERED AT THE SAME MOLAR DOSE OF THE THERAPEUTIC
35 INGREDIENT UNDER SIMILAR EXPERIMENTAL CONDITIONS IN EITHER A
36 SINGLE DOSE OR MULTIPLE DOSES. BIOEQUIVALENCE SHALL ALSO
37 REFER TO THE ABSENCE OF A SIGNIFICANT DIFFERENCE ON THE RATE
38 AND EXTENT TO WHICH THE ACTIVE INGREDIENT(S) OF THE SAMPLE

1 AND REFERENCE DRUG BECOMES AVAILABLE AT THE SITE OF DRUG
2 ACTION WHEN ADMINISTERED UNDER THE SAME MOLAR DOSE AND
3 UNDER SIMILAR CONDITIONS.

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

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

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

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

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

29 (1) ANY SUBSTANCE OR MIXTURE OF SUBSTANCES INTENDED
30 FOR INDIVIDUAL OR LIMITED PURPOSES AND WHICH IS TOXIC,
31 CORROSIVE, AN IRRITANT, A STRONG SENSITIZER, IS FLAMMABLE OR
32 COMBUSTIBLE, OR GENERATES PRESSURE THROUGH DECOMPOSITION,
33 HEAT OR OTHER MEANS, IF SUCH SUBSTANCE OR MIXTURE OF
34 SUBSTANCES MAY CAUSE SUBSTANTIAL INJURY OR SUBSTANTIAL
35 ILLNESS DURING OR AS A PROXIMATE RESULT OF ANY CUSTOMARY OR
36 REASONABLY FORESEEABLE INGESTION BY CHILDREN, BUT SHALL NOT
37 INCLUDE AGRICULTURAL FERTILIZER AND PESTICIDE, INSECTICIDE AND
38 OTHER ECONOMIC POISONS, RADIOACTIVE SUBSTANCE, OR

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

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

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

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

16 (GG) "**IN-VITRO DIAGNOSIS REAGENTS**" ARE REAGENTS AND
17 SYSTEMS INTENDED FOR USE IN THE DIAGNOSIS OF DISEASE OR
18 OTHER CONDITIONS, INCLUDING A DETERMINATION OF THE STATE OF
19 HEALTH, IN ORDER TO CURE, MITIGATE, TREAT OR PREVENT DISEASE
20 OR ITS SEQUELAE.

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

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

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

37 (KK) "**TRADER**" MEANS ANY ESTABLISHMENT WHICH IS A
38 REGISTERED OWNER OF A FOOD, DRUG, DEVICE, VACCINE, IN-VITRO

1 DIAGNOSTIC REAGENT, HOUSEHOLD HAZARDOUS SUBSTANCES AND
2 HEALTH PRODUCTS AND PROCURES THE RAW MATERIALS AND
3 PACKING COMPONENTS AND PROVIDES THE PRODUCTION
4 MONOGRAPHS, QUALITY CONTROL STANDARDS AND PROCEDURES,
5 BUT SUBCONTRACT THE MANUFACTURE OF SUCH PRODUCT TO A
6 LICENSED MANUFACTURER. IN ADDITION, A TRADER MAY ALSO
7 ENGAGE IN THE DISTRIBUTION AND/OR MARKETING OF ITS PRODUCTS.

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

11 **SEC. 8.** Sec. 11, subsections (a), (b), (d), (g), (j), (k) and (l) of R. A.
12 3720, as amended, is hereby further amended to read as follows:

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

15 (a) The manufacture, importation, exportation, sale, offering for sale,
16 distribution, [or] transfer, USE, PROMOTION, ADVERTISING, OR
17 SPONSORSHIP of any [food, drug, device, or cosmetic] HEALTH PRODUCT
18 that is adulterated, UNREGISTERED, or misbranded.

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

21 x x x

22 (d) The giving of a guaranty or undertaking referred to in Section
23 twelve (b) hereof which guaranty or undertaking is false, except by a person who
24 relied upon a guaranty or undertaking to the same effect, signed by, and
25 containing the name and address of[,] the person [residing in the Philippines] OR
26 ENTITY from whom he received in good faith the [food, drug, device, or
27 cosmetic] HEALTH PRODUCTS or the giving of a guaranty or undertaking
28 referred to in Section twelve (b) which guaranty or undertaking is false.

29 x x x

30 (g) The alteration, mutilation, destruction, obliteration, or removal of
31 *the whole or any part of the labeling of, or the doing of any other act with respect*
32 *to [a food, drug, device, or cosmetics,] HEALTH PRODUCTS if such act is done*
33 *while such article is held for sale (whether or not the first sale) and results in*
34 *such article being adulterated or misbranded.*

35 x x x

36 (j) The manufacture, importation, exportation, sale, offering for sale,
37 distribution, [or] transfer, USE, PROMOTION, ADVERTISEMENT, OR
38 SPONSORSHIP of any [drug, or device,] HEALTH PRODUCT which,

1 ALTHOUGH REQUIRING REGISTRATION, is not registered with the [Bureau]
2 FDCDA pursuant to this Act.

3 (k) The manufacture; importation, exportation, sale, offering for sale,
4 distribution, [or] transfer, OR RETAIL of any drug, [or] device OR IN-VITRO
5 DIAGNOSTIC REAGENT; THE MANUFACTURE, IMPORTATION,
6 EXPORTATION, TRANSFER OR DISTRIBUTION OF ANY FOOD, COSMETIC
7 OR HOUSEHOLD/URBAN HAZARDOUS SUBSTANCE; OR THE OPERATION
8 OF A RADIATION ESTABLISHMENT by any NATURAL OR JURIDICAL person
9 without the license TO OPERATE from the [Bureau] FDCDA required under this
10 Act.

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

14 X X X.

15 THE PROHIBITED ACTS MENTIONED HEREIN SHALL COVER ALL
16 APPLICABLE HEALTH PRODUCTS.”

17 **SEC. 9.** Section 12, subsection (a) of Republic Act No. 3720, as amended,
18 is hereby further amended to read as follows:

19 “SEC. 12. (a) Any person who violates any of the provisions of Section
20 eleven hereof shall, upon conviction, [be subject to imprisonment of not less than
21 one year but not more than five years, or a fine of not less than five thousand
22 pesos but not more than ten thousand pesos, or both such imprisonment and
23 fine, in the discretion of the Court.] SUFFER THE PENALTY OF
24 IMPRISONMENT RANGING FROM ONE (1) YEAR BUT NOT MORE THAN
25 TEN (10) YEARS OR A FINE OF NOT LESS THAN FIFTY THOUSAND PESOS
26 (P50,000.00) BUT NOT MORE THAN FIVE HUNDRED THOUSAND PESOS
27 (P500,000.00), OR BOTH, AT THE DISCRETION OF THE COURT: *PROVIDED,*
28 THAT IF THE OFFENDER IS A MANUFACTURER, IMPORTER OR
29 DISTRIBUTOR OF ANY HEALTH PRODUCT THE PENALTY OF AT LEAST
30 FIVE (5) YEARS IMPRISONMENT BUT NOT MORE THAN TEN (10) YEARS
31 AND A FINE OF AT LEAST FIVE HUNDRED THOUSAND PESOS
32 (P500,000.00) BUT NOT MORE THAN FIVE MILLION PESOS (P5,000,000.00)
33 SHALL BE IMPOSED; *PROVIDED, FURTHER,* THAT AN ADDITIONAL FINE
34 OF ONE PERCENT (1%) OF THE ECONOMIC VALUE/COST OF THE
35 VIOLATIVE PRODUCT OR VIOLATION, OR ONE THOUSAND PESOS
36 (P1,000.00), WHICHEVER IS HIGHER, SHALL BE IMPOSED FOR EACH DAY
37 OF CONTINUING VIOLATION. *PROVIDED, FINALLY,* THAT THE HEALTH
38 PRODUCTS FOUND IN VIOLATION OF THE PROVISIONS OF THIS ACT AND

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

11 X X X

12 SHOULD THE OFFENSE BE COMMITTED BY A FOREIGN NATIONAL,
13 HE SHALL, IN ADDITION TO THE PENALTIES PRESCRIBED, BE DEPORTED
14 WITHOUT FURTHER PROCEEDINGS AFTER SERVICE OF SENTENCE.

15 X X X.

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

19 “ X X X

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

22 (d) [When it appears to the Director that the report of the Bureau that any
23 article of food or any drug, device, or cosmetic secured pursuant to Section
24 twenty-eight of this Act is adulterated, misbranded, or not registered, he shall
25 cause notice thereof to be given to the person or persons concerned and such
26 person or persons shall be given an opportunity to be heard before the Bureau
27 and to submit evidence impeaching the correctness of the finding or charge in
28 question.]

29 UPON PRELIMINARY FINDINGS OF THE CONDUCT OF PROHIBITED
30 ACT/S, THE DIRECTOR-GENERAL SHALL ISSUE THE PROPER NOTICES
31 OR ORDERS TO THE PERSON OR PERSONS CONCERNED AND SUCH
32 PERSON OR PERSONS SHALL BE GIVEN AN OPPORTUNITY TO BE HEARD
33 BEFORE THE FDCDA.

34 X X X.

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

37

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

3 “SEC. 29-A. Administrative Sanctions. [In addition to the administrative
4 sanctions provided for under Letter of Instructions No. 1223, the Secretary is
5 hereby authorized to impose, after notice and hearing, administrative fines of not
6 less than one thousand pesos nor more than five thousand pesos for any
7 violation of this Act.]

8 WHERE THERE IS FINDING OF PROHIBITED ACTIONS AND
9 DETERMINATION OF THE PERSONS LIABLE THERETO, AFTER NOTICE
10 AND HEARING, THE DIRECTOR-GENERAL IS EMPOWERED TO IMPOSE
11 ONE OR MORE OF THE FOLLOWING ADMINISTRATIVE PENALTIES:

12 (1) CANCELLATION OF ANY AUTHORIZATION WHICH MAY
13 HAVE BEEN GRANTED BY THE FDCDA IN CONNECTION WITH THE
14 PARTICULAR PRODUCT SUBJECT OF THE VIOLATION, OR SUSPENSION
15 OF THE VALIDITY THEREOF FOR SUCH PERIOD OF TIME AS THE
16 DIRECTOR-GENERAL MAY DEEM REASONABLE WHICH SHALL NOT
17 EXCEED ONE (1) YEAR;

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

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

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

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

32 “SEC. 30. THE DIRECTOR-GENERAL SHALL ALSO EXERCISE THE
33 FOLLOWING POWERS:

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

37 (2) TO ADMINISTER OATHS AND AFFIRMATIONS AND ISSUE
38 *SUBPOENA DUCES TECUM* AND *SUBPOENA AD TESTIFICANDUM*

1 REQUIRING THE ATTENDANCE AND TESTIMONY OF PARTIES,
2 WITNESSES AND/OR THE PRODUCTION OF SUCH BOOKS, CONTRACTS,
3 CORRESPONDENCE, RECORDS, STATEMENT OF ACCOUNTS AND OTHER
4 DOCUMENTS AS MAY BE MATERIAL TO THE INVESTIGATION
5 CONDUCTED BY THE FDCDA;

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

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

12 (5) TO CALL ON THE ASSISTANCE OF ANY DEPARTMENT, OFFICE
13 OR AGENCY AND DEPUTIZE MEMBERS OF THE PHILIPPINE NATIONAL
14 POLICE OR ANY LAW ENFORCEMENT AGENCY FOR THE EFFECTIVE
15 IMPLEMENTATION OF THIS ACT; AND

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

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

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

23 THE INSTITUTION OF A PETITION FOR *CERTIORARI* OR OTHER
24 SPECIAL REMEDIES IN THE PROPER COURT SHALL, IN NO CASE,
25 SUPERSEDE OR STAY ANY ORDER, RULING OR DECISION OF THE
26 SECRETARY, UNLESS THE PROPER COURT SHALL SO DIRECT AND THE
27 APPELLANT MAY BE REQUIRED BY THE PROPER COURTS TO GIVE BOND
28 IN SUCH FORM AND SUCH AMOUNT AS MAY BE DEEMED PROPER.

29 SEC. 32. THE ORDERS, RULINGS OR DECISIONS OF THE
30 DIRECTOR-GENERAL OF THE FDCDA SHALL BE APPEALABLE TO THE
31 SECRETARY OF HEALTH WITHIN FIFTEEN (15) DAYS FROM NOTICE OF
32 SUCH ORDER, RULING OR DECISION. AN APPEAL SHALL BE DEEMED
33 PERFECTED UPON FILING OF THE NOTICE OF APPEAL AND POSTING OF
34 THE CORRESPONDING APPEAL BOND.

35 **SEC. 14.** Section 30 of Republic Act No. 3720, as amended, shall be
36 renumbered as Section 33, and the subsequent sections shall also be
37 renumbered accordingly.

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

3 “SEC. [31] 34. [The amount of one million pesos is hereby appropriated
4 from any funds in the National Treasury not otherwise appropriated to augment
5 the funds transferred to this Office under Section eight for the implementation of
6 this Act. All income derived from fees authorized in Section Four of this Act shall
7 accrue to the General Fund.] *FEES AND OTHER INCOME.* – (A) UPON
8 APPROVAL OF THE SECRETARY, THE AUTHORIZATION FEES SHALL
9 ANNUALLY BE DETERMINED AND REVIEWED BY THE FDCDA AND ANY
10 PROPOSED INCREASE SHALL BE PUBLISHED IN TWO (2) LEADING
11 NEWSPAPERS OF GENERAL CIRCULATION.

12 (B) THERE SHALL BE DETERMINED AND CONSTITUTED ADDITIONAL
13 FEES SUCH AS SALE OF PUBLICATIONS AND SERVICES, ASSESSMENT
14 FEES, FINES, PENALTIES, AND OTHER FEES AND CHARGES OUTSIDE
15 THE USUAL LICENSING AND REGISTRATION FEES, TO BE KNOWN AS
16 ‘OTHER RELATED REGULATORY FEES’.

17 (C) THE DIRECTOR-GENERAL OF THE FDCDA, UPON APPROVAL OF
18 THE SECRETARY, SHALL BE AUTHORIZED TO PROMULGATE RULES AND
19 REGULATIONS GOVERNING THE COLLECTION OF THE ‘OTHER RELATED
20 REGULATORY FEES’. UPON APPROVAL OF THE SECRETARY, THESE
21 FEES SHALL LIKEWISE BE REVIEWED PERIODICALLY AND ANY
22 PROPOSED INCREASE SHALL BE PUBLISHED IN TWO (2) LEADING
23 NEWSPAPERS OF GENERAL CIRCULATION.”

24 **SEC. 16.** All income that the FDCDA is allowed to retain under section 31
25 of the Universally Accessible Cheaper and Quality Medicines Act of 2008 shall,
26 any provision of law to the contrary notwithstanding, be deposited in an
27 authorized government depository bank as a special regulatory fund. Such fund
28 shall be used primarily for the acquisition of office and laboratory space, human
29 resource development and expansion, purchase of laboratory equipment and
30 motor vehicles, the upgrading of its current facilities and equipment and
31 maintenance and other operating expenses of the central office laboratory
32 divisions and satellite laboratories in Davao, Cebu and other testing laboratories,
33 in case the above laboratories will be increased.

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

37 The retention, use and application of this fund shall not be delayed,
38 amended, altered or modified, or affected in any way by an order or directive

1 from any executive office, but will be subject only to the general accounting rules
2 and guidelines by the Commission on Audit (COA). The primary purpose of the
3 fund as herein stated shall prevail over any other purpose that may be pursued
4 by the FDCDA on its own initiative or through an order or directive by any higher
5 office.

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

10 **SEC. 17.** A new chapter XIV and three new sections, Sections 35, 36, and
11 37 shall be introduced, which shall read as follows:

12 "CHAPTER XIV – TESTING LABORATORIES AND FIELD OFFICES

13 SEC. 35. THE FDCDA IS HEREBY MANDATED TO IMPROVE,
14 UPGRADE AND INCREASE THE CAPABILITY OF THE AGENCY, TO TEST,
15 CALIBRATE, ASSAY AND EXAMINE SAMPLES OF HEALTH PRODUCTS.

16 FOR THE PURPOSE OF ACHIEVING THE ABOVE MANDATE, THERE
17 SHALL BE ESTABLISHED AT LEAST ONE (1) TESTING LABORATORY EACH
18 IN LUZON, VISAYAS AND MINDANAO, WHICH SHALL HAVE THE
19 NECESSARY AND APPROPRIATE STATE-OF-THE-ART LABORATORY
20 EQUIPMENT AND PERSONNEL COMPLEMENT. THE MAIN TESTING
21 LABORATORIES AT THE CENTRAL OFFICE SHALL BE MAINTAINED AND
22 SHALL SERVE AS A SUPPORT UNIT TO THE CENTERS FOR PRODUCT
23 RESEARCH AND EVALUATION AND STANDARDS DEVELOPMENT AND
24 SHALL SERVE AS TESTING CENTERS THAT WOULD INCLUDE ASSAY AND
25 THE CONDUCT, SUPERVISION, OVERSIGHT AND/OR AUDIT OF
26 BIOEQUIVALENCE AND BIOAVAILABILITY TEST/RESEARCHES, AMONG
27 OTHERS. THE EXISTING LABORATORY IN CEBU AND DAVAO WILL BE
28 UPGRADED AND TRANSFORMED AS QUALITY ASSURANCE
29 LABORATORIES, WHILE ANOTHER ONE WILL BE ESTABLISHED IN SUBIC,
30 ZAMBALES. THE TESTING LABORATORIES MAY BE INCREASED BY THE
31 DIRECTOR-GENERAL, UPON APPROVAL OF THE SECRETARY.

32 SEC. 36. THE FDCDA SHALL ESTABLISH FIELD OFFICES IN ALL
33 REGIONS OF THE COUNTRY TO EFFECTIVELY IMPLEMENT ITS
34 REGULATORY FUNCTIONS. THE CURRENT REGIONAL FOOD AND DRUG
35 REGULATORY OFFICERS IN EVERY REGIONAL OFFICE OF THE
36 DEPARTMENT OF HEALTH SHALL NOW BE PUT UNDER THE FDCDA'S
37 SOLE CONTROL AND SUPERVISION. THE REGIONAL FIELD OFFICE
38 SHALL ALSO ASSUME PRIMARY JURISDICTION IN THE COLLECTION OF

1 SAMPLES OF FOOD, DRUGS, DEVICES AND COSMETICS BEING
2 IMPORTED OR OFFERED FOR IMPORT AT A PORT OF ENTRY OTHER
3 THAN MANILA IN HIS ASSIGNED REGION AND WHERE IT APPEARS THAT
4 SAID ITEMS OR PRODUCTS SATISFY ANY OF THE CONDITIONS AS
5 PROVIDED FOR IN SECTION 33(A) OF REPUBLIC ACT NO. 3720, AS
6 AMENDED, WITHOUT PREJUDICE TO THE EXERCISE OF THE POWERS OF
7 THE DIRECTOR-GENERAL PROVIDED UNDER SECTION 12 OF THIS ACT IN
8 THE EXERCISE OF THE AGENCY'S REGULATORY FUNCTIONS. THE FIELD
9 OFFICES SHALL BE COMPRISED OF THE FOLLOWING: (A) INSPECTION
10 AND COMPLIANCE DIVISION, WHICH SHALL HAVE CHARGE OF THE
11 INSPECTION OF FOOD, DRUGS AND COSMETIC ESTABLISHMENTS
12 ENGAGED IN THEIR MANUFACTURE, IMPORTATION, DISTRIBUTION, AND
13 SALE; (B) SATELLITE LABORATORY DIVISION; AND (C) ADMINISTRATIVE
14 DIVISION.

15 SEC. 37. THE FDCDA, WITH THE APPROVAL OF THE SECRETARY,
16 SHALL CREATE ORGANIZATIONAL UNITS WHICH ARE DEEMED
17 NECESSARY TO ADDRESS EMERGING CONCERNS AND TO BE ABREAST
18 WITH INTERNATIONALLY ACCEPTABLE STANDARDS AND SHALL SEEK
19 THE CREATION OF ADDITIONAL PLANTILLA POSITIONS TO AUGMENT
20 THE HUMAN RESOURCE COMPLEMENT OF THE FDCDA CENTRAL OFFICE
21 AND ITS FIELD OFFICES, SUBJECT TO EXISTING RULES AND
22 REGULATIONS."

23 **SEC. 18. Appropriations.** – The appropriations for the Bureau of Food and
24 Drugs and the Bureau of Health Devices and Technology included in the budget
25 of the Department of Health under the current General Appropriations Act shall
26 be used to carry out the implementation of this Act. The appropriation may be
27 augmented by the income which the agency is authorized to use under this Act.
28 Thereafter, such sums as may be necessary for its continued implementation
29 shall be included in the annual General Appropriations Act.

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

33 **SEC. 20. Congressional Oversight Committee.** – A Congressional
34 Oversight Committee (COC) is hereby created composed of the Chairpersons of
35 the Committees on Health and Appropriations of the House of Representatives
36 and two (2) Members to be appointed by the Speaker, the Chairpersons of the
37 Committees on Health and Finance of the Senate and two (2) Members to be
38 appointed by the President of the Senate, to oversee the implementation of this

1 Act for a period of five (5) years and to review the accomplishments and the
2 utilization of income of the FDCDA.

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

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

23 **SEC. 22. *Separability Clause.*** - If any part, section or provision of this
24 Act shall be declared invalid or unconstitutional, other provisions or parts thereof
25 which are not affected thereby shall remain in full force and effect.

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

29 **SEC. 24. *Effectivity.*** - This Act shall take effect fifteen (15) days after
30 its publication in the *Official Gazette* or in two (2) newspapers of general
31 circulation.

32 Approved,

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