



Republic of the Philippines  
Department of Health  
**OFFICE OF THE SECRETARY**

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**DEPARTMENT CIRCULAR**

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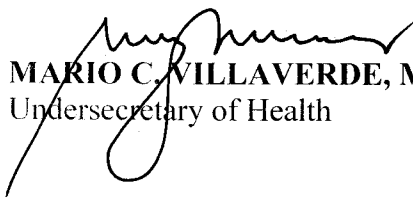
**FOR: ALL UNDERSECRETARIES, ASSISTANT SECRETARIES; DIRECTORS OF BUREAUS, CENTERS FOR HEALTH DEVELOPMENT, SERVICES AND SPECIALTY HOSPITALS; CHIEFS OF MEDICAL CENTERS & HOSPITALS, PRESIDENT OF THE PHIL. HEALTH INSURANCE CORPORATION AND EXECUTIVE DIRECTORS OF PHIL. NATIONAL AIDS COUNCIL, THE PHIL. INSTITUTE OF TRADITIONAL AND ALTERNATIVE HEALTH CARE, NATIONAL NUTRITION COUNCIL, POPULATION COMMISSION, LOCAL WATER UTILITIES ADMINISTRATION AND OTHERS CONCERNED**

**SUBJECT: The Rules and Regulations Implementing Republic Act No. 9711-The Food and Drug Administration Act of 2009**

Attached for your information and guidance is a copy of "The Rules and Regulations Implementing Republic Act No. 9711-The Food and Drug Administration Act of 2009"

Dissemination of the information to all concerned is required.

By Authority of the Secretary of Health

  
**MARIO C. VILLVERDE, MD, MPH, MPM, CESO I**  
Undersecretary of Health



Republic of the Philippines  
Department of Health  
**OFFICE OF THE SECRETARY**

**The Rules and Regulations  
Implementing Republic Act No. 9711 -  
The Food and Drug Administration Act of 2009**

**BOOK I**

**ARTICLE I**  
**PRELIMINARY PROVISIONS**

**Sec. 1. Title.** These Rules and Regulations shall be referred to as *"The Rules and Regulations Implementing Republic Act No. 9711 or The Food and Drug Administration (FDA) Act of 2009"*.

**Sec. 2. Declaration of Policy.** These Rules and Regulations are promulgated to adopt, support, establish, institutionalize, improve and maintain structures, processes, mechanisms, measures 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 human resource development and research, responsive to the country's health needs and problems.

Accordingly, the State shall enhance FDA's regulatory capacity and strengthen its capability with regard to the inspection, licensing and monitoring of establishments and the registration and monitoring of health products.

**Sec. 3. Objectives.** These Rules and Regulations are likewise promulgated to be consistent with the following expressed objectives of the FDA Act of 2009:

- 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. 4. Interpretation of the FDA Implementing Rules and Regulations.** Any doubt in the interpretation of these Rules and Regulations shall be resolved in a manner that would be consistent with the above-mentioned declared policy and objectives.

**Sec. 5. Definition of Terms.** All terms in Republic Act No. 3720, as amended, otherwise known as the "Foods, Drugs and Devices, and Cosmetics Act", and not amended or altered by the FDA Act of 2009 shall retain their respective meanings in these Rules and Regulations. In addition, the term:

- a. *"Accreditation"* means an attestation conveying formal demonstration of a laboratory's competence and capability to carry out specific scientific and technical tests or analytical service with respect to health products.
- b. *"Assay"* means an analysis to determine the (1) presence of a substance and the amount of that substance, or (2) the pharmaceutical potency of a drug.
- c. *"Assessment"* is a process undertaken by an accreditation body to determine the competence, capability and conformance of a laboratory, based on particular standard(s) and other normative documents for a defined scope of accreditation. It is also a process that systematically examines the short and long term consequences, in terms of health and resource use of the application of a health technology, a set of related technologies or a technology related issue.
- d. *"Authorization"* means a permission embodied in a document granted by the FDA to a natural or juridical person who has submitted an application to implement 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.
- e. *"Batch"* or *"Lot"* means a quantity of any health products produced during a given cycle of manufacture.
- f. *"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.



g. *"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.

h. *"Cosmetics"* means 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 them in good condition.

i. *"Device"* means 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 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 directly used in health care but has been determined by the FDA to adversely affect the health of the people.
- j. *"Director-General"* means the head of the FDA.
- k. *"Distribute"* means the delivery or sale of any health product for purposes of distribution in commerce, except that such term does not include the manufacture or retail of such product.
- l. *"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 distribution to other establishments or outlets. If the distributor/importer/exporter sells to the general public, it shall be considered a retailer.
- m. *"Distributor/Wholesaler"* means any establishment that procures raw materials, active ingredients and/or finished products from a local establishment for local distribution on wholesale basis.
- n. *"Drug"* means:
- (1) Articles recognized in official pharmacopoeias and formularies, including official homeopathic pharmacopoeias, or any documentary supplement to any of them, which are recognized and adopted by the FDA;
  - (2) Articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals;
  - (3) Articles (other than food) intended to affect the structure of any function of the body of human beings or animals; 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.
- o. *"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, donation, transfer, use, testing, promotion, advertising, or sponsorship of health products, including the facilities and installation needed for its activities.



p. “FDA” means the Food and Drug Administration created under Republic Act No. 9711.

q. “FDA Act of 2009” refers to Republic Act No. 9711, otherwise known as the Food and Drug Administration Act of 2009.

r. “Fees” means either the usual licensing, accreditation and registration charges, or other related regulatory fees such as fees from sale of publications and services (including but not limited to laboratory testing, training, and extension services), assessment fees, fines, penalties, and other fees and charges outside the usual licensing, accreditation and registration fees.

s. “Food” means any processed substance, which is intended for human consumption and includes drinks for human beings, beverages, chewing gum and any substances, which have been used as an ingredient in the manufacture, preparation or treatment of food.

t. “Food/Dietary Supplement” means a processed food product intended to supplement the diet that bears or contains one or more of the following dietary ingredients: vitamin, mineral, amino acid, herb, or other dietary substance of botanical, animal, artificial or natural origin to increase the total daily intake in amounts conforming to the latest Philippine recommended energy and nutrient intakes or internationally agreed minimum daily requirements. It is usually in the form of capsules, tablets, liquids, gels, powders or pills and is not represented for use as a conventional food or as the sole item of a meal or diet or a replacement for drugs and medicines.

u. “Foods, Drugs and Devices, and Cosmetics Act” refers to Republic Act No. 3720, as amended by Executive Order 175 s. 1987 and FDA Act of 2009.

v. “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 FDA.

w. “Health Product Vigilance” means the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other possible problems from health products.

x. “Household/Urban Hazardous Substance” means:



(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 fertilizers, agricultural pesticides, and agricultural insecticides and other economic poisons, radioactive substances, or substances intended for use as fuels, coolants, refrigerants and the like;

(2) Any substance which the FDA finds to be under the categories enumerated in paragraph (1) of this section;

(3) Any toy or other articles intended for use by children which the FDA may determine to pose an electrical, chemical, physical, or thermal hazard. For this purpose *"toys and other articles intended for use by children"* shall refer to those toys and articles specified to be for children less than fourteen (14) years of age; and

(4) The term '*Household/Urban Hazardous Substance*' shall not apply to food, drugs, cosmetics, devices, or to substances intended for use as fuel 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.

y. *"In-vitro diagnostic reagents"* means 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. *"Label"* means a display of written, printed, or graphic matter on the immediate container, or other materials affixed thereto, of any article. Any word, statement or other information appearing on the label required under authority of the FDA Act of 2009 or other relevant laws shall be deemed complied with if 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.



**aa.** “*Legal Fund*” means the interest earned from the total retained income, net of withholding tax, for use in case of any legal actions filed against the officials and employees of the FDA in the course of their lawful performance of official functions and duties.

**bb.** “*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.

**cc.** “*Manufacturer*”, in relation to a health product, means an establishment engaged in any and all operations involved in the production of health products including preparation, processing, compounding, formulating, filling, packaging, repackaging, altering, ornamenting, finishing and labeling with the end 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. A trader shall be categorized as a manufacturer.

**dd.** “*Misbranding*” means, in addition to definitions provided in the Foods, Drugs and Devices, and Cosmetics Act and in other relevant laws, giving unsubstantiated claims, misinformation or misleading information on the label or other information materials, including those contained in brand names or trademarks. It shall not refer to copyright, trademark, or other intellectual property-like instruments.

**ee.** “*Non-consumer users*” means personnel and workers who use radiation devices for medical and non-medical applications, and radioactive substances inside medical devices in the conduct of their profession or in the course of their work. It may also refer to users of other health products who are members of a certain class of profession or workers where the use of such health products may have an effect on health that requires regulations as determined by the FDA.

**ff.** “*Pharmacovigilance*” means the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other possible drug-related problems.

**gg.** “*Postmarketing Surveillance*” refers to activities involved in safety, efficacy, and quality monitoring of health products. This shall also include among others adverse events reporting, product safety update reporting, collection and testing of health products in the market.





**hh.** *"Private Testing Laboratory"* means a legal entity, other than a government testing laboratory, that engages in the business of conducting tests, calibration, assay, examination, measurements, or analytical services with respect to health products.

**ii.** *"Registration"* means the process of approval of an application to register health products 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.

**jj.** *"Retailer"* means any establishment which sells or offers to sell any health product directly to the general public.

**kk.** *"Retained Income"* means all fees, fines, royalties, and other charges collected by the FDA under existing laws including the interest earned thereon.

**ll.** *"Risk Management Plan"* means a set of health product vigilance activities and interventions designed to identify, characterize, prevent or minimize risks relating to health products, and the assessment of effectiveness of those interventions. The risk management plan is a requirement for the issuance of the appropriate authorization.

**mm.** *"Special Regulatory Fund"* means the retained income, including grants, donations and all other endowments from local and external sources, accepted by the FDA in accordance with pertinent laws, rules and regulations deposited in an authorized government depository bank.

**nn.** *"Trader"* means any establishment which is a registered owner of a health product and procures the raw materials and packing components, and provides the production monographs, quality control standards and procedures, but subcontracts 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.

**oo.** *"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 these Rules and Regulations.



## ARTICLE II

### **A. THE FOOD AND DRUG ADMINISTRATION**

**Sec. 1. Nature.** The FDA is an agency in the Department of Health (DOH) that shall be under the Office of the Secretary of Health.

**Sec. 2. General Powers and Functions.** The FDA shall have the following functions, powers and duties:

- a. To administer the effective implementation of the FDA Act of 2009, these Rules and Regulations, other relevant laws, and FDA-promulgated issuances;
- b. To assume primary jurisdiction in the collection of samples of health products;
- c. To analyze, test and/or inspect health products in connection with the implementation of the FDA Act of 2009, these Rules and Regulations, other relevant laws, and FDA-promulgated issuances;
- d. To establish analytical data to serve as basis for the preparation of health products standards, and to recommend standards of identity, purity, safety, efficacy, quality and fill of container;
- e. To issue certificates of compliance with technical requirements to serve as basis for the issuance of appropriate authorization and spot check for compliance with regulations regarding operation of manufacturers, importers, exporters, distributors, wholesalers, drug outlets, and other establishments and facilities of health products, as determined by the FDA;
- f. To levy, assess and collect appropriate fees in accordance with the FDA Act and other relevant laws as may be determined by the FDA;
- g. To certify batches of antibiotic and antibiotic preparation, where applicable, in compliance with the provisions of the FDA Act of 2009, these Rules and Regulations, other relevant laws, and FDA-promulgated issuances;
- h. To conduct appropriate tests on all applicable health products prior to the issuance of appropriate authorizations to ensure safety, efficacy, purity, and quality;



- i. To require all manufacturers, processors, traders, sellers, distributors, importers, exporters, wholesalers, retailers, non-consumer users, and encourage consumers, of 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, a patient, or any person;
- j. To issue cease and desist orders *motu proprio* or upon verified complaint in accordance with the FDA Act of 2009, relevant laws, and these Rules and Regulations;
- k. After due process, to order the ban, recall, withdrawal and/or destruction of any health product found to have caused the death, serious illness or serious injury to a consumer or patient, or is found to be imminently injurious, unsafe, dangerous, or grossly deceptive;
- l. To require all concerned to implement the risk management plan which is a requirement for the issuance of the appropriate authorization;
- m. To institute and strengthen the postmarketing surveillance system in monitoring health products as defined in the FDA Act of 2009, these Rules and Regulations, other relevant laws, and the FDA-promulgated issuances, and incidents of adverse events involving such products;
- n. To develop and issue policies, standards, regulations, and guidelines that would cover establishments, facilities and health products;
- o. To develop and issue appropriate authorizations that would cover establishments, facilities and health products;
- p. To conduct, supervise, monitor and audit research studies on health and safety issues of health products undertaken by entities duly approved by the FDA;
- q. To prescribe policies, standards, regulations, and guidelines with respect to information, advertisements, promotions, sponsorship, and other marketing instruments or activities about the health products as covered in the FDA Act of 2009, these Rules and Regulations, other relevant laws, and FDA-promulgated issuances;
- r. 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;

- s. To periodically review its fees and propose any increase and promulgate rules and regulations governing the collection of other related regulatory fees;
- t. To enter, at reasonable hours, any factory, warehouse, or establishment in which health products are manufactured, processed, packed, or held, for introduction into domestic commerce, or are held after such introduction, or to enter any vehicle used to transport or hold such health products in domestic commerce; and to inspect, in a reasonable manner, such factory, warehouse, establishment, or vehicle and all pertinent equipment, finished or unfinished materials, containers, and labeling therein;
- u. To create organizational units which are deemed necessary to address emerging concerns and to keep abreast with internationally acceptable standards;
- v. To provide technical assistance, consultative and advisory services to stakeholders and other government agencies in the implementation of laws, rules and regulations pertaining to health products;
- w. To impose administrative penalties/sanctions in accordance with the FDA Act of 2009 and other relevant laws;
- x. To accept grants, donations and other endowments from local and external sources in accordance with pertinent laws, rules and regulations;
- y. To review and recommend its staffing pattern and position titles subject to the approval of the Secretary of Health;
- z. To call upon other government and private testing laboratories, provided, that private testing laboratories are accredited by the Philippines Accreditation Office of the Department of Trade and Industry and the DOH through the FDA;
- aa. Subject to the approval of the Secretary of Health, to engage the services of private lawyers/firms to represent officials and employees of the FDA, regardless of their employment status, upon receipt by the FDA officials or employees of the court notice that a legal action, suit or proceeding is filed against them in connection



with the lawful exercise of their official functions, duties or responsibilities as FDA officials and employees. Any private lawyer/firm who/which is connected or related to any regulated establishment, including related foundations, shall be disqualified from representing FDA officials and employees to avoid impropriety and conflict of interest. The costs incurred in connection with such action, suit or proceeding, including attorney's fees, shall be paid from the Legal Fund; and

- bb. To exercise such other powers and perform such other functions as may be necessary to carry out its duties and responsibilities under the FDA Act of 2009, these Rules and Regulations, and other relevant laws or as may be required by the Secretary of Health.

## **B. RETENTION AND USE OF THE FDA INCOME**

**Sec. 3. Authority of the FDA to Retain and Utilize its Income.** The FDA is authorized to collect, retain, and utilize or apply all fees, fines, royalties and other charges collected by it under Section 31 of Republic Act No. 9502, otherwise known as the Universally Accessible Cheaper and Quality Medicines Act of 2008, and other laws that the FDA is mandated to administer or implement.

**Sec. 4. Special Regulatory Fund.** All income that the FDA is allowed to retain under Section 31 of the Universally Accessible Cheaper and Quality Medicines Act of 2008 and other laws that the FDA is mandated to administer or implement shall, any provision of law to the contrary notwithstanding, be deposited in an authorized government depository bank as a Special Regulatory Fund (SRF). Any interest earned by such fund shall form part of the retained income.

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, other operating expenses of the various laboratory support divisions of the respective Centers, the satellite laboratories in Davao, Cebu and Subic, and other activities or services of the FDA in the performance of its mandate.

**Sec. 5. Grants, Donations and All Other Endowments to the SRF.** The SRF shall be allowed to accept grants, donations and all other endowments from local and external sources in accordance with pertinent laws, rules and regulations.



**Sec. 6. SRF Depository.** Notwithstanding any provision of law to the contrary, the SRF shall be maintained and deposited:

- a. Directly by the FDA Cashier in any authorized government depository bank under a special fund account to be denominated as FDA (R.A. 9502 and R.A. 9711) Special Regulatory Fund account; and
- b. In any branch of the designated authorized government depository bank by the designated Collecting Officers of the Field Regulatory Operations Office through an Inter-branch Deposit to the FDA (R.A. 9502 and R.A. 9711) Special Regulatory Fund account.

The FDA shall maintain separate books of accounts to cover the collection, retention and utilization or application of all retained income, and lawfully accepted grants, donations and other endowments from local and external sources including interest earned by such income, grants, donations and other endowments.

**Sec. 7. Use and Accounting of the SRF.** The SRF shall be subject only to the general accounting and usual auditing rules and guidelines of the Commission on Audit. Its retention, use and application shall not be delayed, amended, altered or modified, or affected in any way by an order or directive from any executive office, other than the Office of the President or the Secretary of Health. .

The primary purpose of the SRF, 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.

**Sec. 8. Legal Fund.** There shall also be established a legal fund out of the interest earned from the retained income for use in case of legal actions against the officials and employees of the FDA in the course of the exercise of their official functions and duties.

The FDA is authorized to engage the services of private lawyers/firms to represent officials and/or employees of the FDA, regardless of their employment status, upon receipt of the court notice that an action, suit or proceeding is filed against said officials and/or employees in connection with the lawful exercise of their official functions, duties or responsibilities as FDA officials and/or employees subject to prohibitions, restrictions or limitations as may be provided by law or rules and regulations. Any private lawyer/firm who/which is connected or related to any regulated establishment, including related foundations, shall be disqualified from representing FDA officials and



employees to avoid impropriety and conflict of interest. For this purpose, the FDA shall establish rules in the use of the Legal Fund and the FDA shall, in coordination with the Office of the Solicitor General, establish mechanisms in engaging private legal assistance.

**Sec. 9. Reporting Requirement.** At the end of any fiscal year, the FDA shall submit to the Secretary of Health, the Secretary of Budget and Management, and the Congressional Oversight Committee, created under Section 23 of the FDA Act of 2009, a report on collections and retained income as well as how the funds were utilized, including its accomplishments.

### **C. COMMON PROVISIONS CONCERNING QUALIFICATIONS, DISQUALIFICATIONS, PRE-REQUISITES, APPOINTMENT OF FDA OFFICERS, PERSONNEL, STAFF AND EMPLOYEES**

**Sec. 10. Appointment of and Disciplinary Action Against All Personnel.** The appointment of, and disciplinary action against, all officials, personnel, staff and employees in the FDA shall be in accordance with the FDA Act of 2009, these Rules and Regulations, and relevant civil service laws, rules and regulations.

**Sec. 11. Authority to Appoint the Director-General and Deputy Director-Generals.** The Director-General and the two (2) Deputy Director-Generals shall be appointed by the President of the Republic of the Philippines.

**Sec. 12. Authority to Appoint Officials in Director and Assistant-Director Levels.** The Secretary of Health shall appoint all FDA directors and assistant directors.

**Sec. 13. Authority to Appoint Officials and Other Personnel and Employees Below the Assistant-Director Level.** The Director General shall appoint all other officials, personnel and employees, below the Assistant-Director level and in coordination with the Secretary of Health.

**Sec. 14. Inhibitions Against Officials and Employees of the FDA.** All prohibitions governing the conduct of national public officials and employees relating to prohibited business and pecuniary interests so provided in Republic Act 6713, otherwise known as the Code of Conduct and Ethical Standards for Public Officials and Employees, and other laws, rules and regulations shall also be applicable to the FDA officials and employees.



**Sec. 15. Director-General and Deputy Director-Generals: Prohibition Against Management and Supervisory Personnel Formerly Employed in Regulated Establishments.** Any person, who was previously employed in a regular full-time capacity, regardless of its consultative designation, at higher management supervisory levels in regulated establishments, including related foundations, shall be disqualified from appointment as Director-General and Deputy Director-General within three (3) years from termination of employment with the said establishment or foundation.

**Sec. 16. Director-General and Deputy Director-Generals: Declaration of any Conflict of Interest.** The Director-General and the two (2) Deputy Director-Generals shall, upon assumption into office, declare any conflict of interest with any establishment covered by the FDA, including their foundations.

**Sec. 17. Publication of Vacancies.** The FDA officer in charge of personnel, or his duly designated official, shall post in three (3) conspicuous places of the FDA offices, for a period of ten (10) days, and simultaneously publish in at least two (2) newspapers of general circulation or other media, a complete list of all existing vacant positions in the FDA which are authorized to be filled, and to transmit a copy of such list and the corresponding qualification standards to the Civil Service Commission not later than the tenth day of every month. Vacant positions shall not be filled until after publication: provided, however, the following vacant unfilled positions are not subject to the publication requirement:

- a. Primarily confidential;
- b. Policy-determining;
- c. Highly technical;
- d. Co-terminus with that of the appointing authority; or
- e. Limited to the duration of a particular project.

### **ARTICLE III**

#### **OFFICE OF THE DIRECTOR-GENERAL**

**Sec. 1. Qualifications of the Director-General.** The Director-General shall have the rank of an Undersecretary. In addition to the civil service eligibility requirements pertaining to the rank of Undersecretary, the Director General shall have the following qualifications:

- a. He/she 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 and





- b. He/she shall have management experience in his/her field of discipline or profession and in any development, manufacturing, regulatory work or quality assurance of products as covered in the FDA Act of 2009 and these Rules and Regulations.

Article II. C of these Rules and Regulations shall likewise apply.

**Sec. 2. Duties and Functions of the Director-General.** As head of the FDA, the Director-General shall exercise the following powers and perform the following duties and functions:

**a. Administrative Powers, Duties and Functions:**

- (1) To determine the needed personnel of the FDA and appoint personnel below the Assistant-Director level in accordance with the FDA Act of 2009, these Rules and Regulations, and the civil service rules and regulations;
- (2) Upon the recommendation of the Deputy Director-General for Field Regulatory Operations Office, to establish additional regional field/satellite laboratories in regions where the same is deemed necessary;
- (3) Upon approval of the Secretary of Health, to establish additional testing laboratories of the FDA as may be necessary;
- (4) To call upon other government and private testing laboratories, provided that private testing laboratories are accredited by the Philippine Accreditation Office (PAO) of the Department of Trade and Industry (DTI) and the DOH through the FDA;
- (5) To recommend for the approval of the Secretary of Health any proposed increase in licensing and registration fees and charges and to promulgate rules and regulations governing the collection of other related regulatory fees; and
- (6) To create, subject to the approval of the Secretary of Health, any organizational unit deemed necessary to address emerging concerns and/or to keep abreast with internationally acceptable standards;



b. Quasi-Judicial Powers, Duties and Functions:

- (1) To render decisions on actions or complaints before the FDA pursuant to the FDA Act of 2009, these Rules and Regulations, other existing laws, and FDA-promulgated issuances;
- (2) To hold in direct or indirect contempt any person who disregards orders or writs issued by the FDA and impose the appropriate penalties following the same procedures and penalties provided in the Rules of Court;
- (3) To administer oaths and affirmations and *issue subpoena duces tecum* and *subpoena ad testificandum* requiring the production of such books, contracts, correspondence, records, statement of accounts and other documents and/or the attendance and testimony of parties and witnesses as may be material to any investigation conducted by the FDA;
- (4) To obtain information from any officer or office of the national or local governments, government agencies and its instrumentalities;
- (5) 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 are adulterated, counterfeited, misbranded or unregistered; or any drug, in-vitro diagnostic reagents, biologicals, and vaccine that is adulterated or misbranded, when introduced into domestic commerce pending the authorized hearing under the FDA Act of 2009, these Rules and Regulations, and as far as applicable, other relevant laws; and
- (6) To impose the following administrative sanctions/penalties for violations of the provisions of the FDA Act of 2009, these Rules and Regulations, and where applicable, other relevant laws, after observance of and compliance with due process:
  - (i) Cancellation of any authorization which may have been granted by the FDA, or suspension of the validity thereof for such period of time as he/she may deem reasonable, which shall not exceed one (1) year;
  - (ii) A fine of not less than Fifty Thousand Pesos (PhP50,000.00), but not more than Five Hundred Thousand Pesos (PhP500,000.00). An additional fine of not more than One



Thousand Pesos(PhP1,000.00) shall be imposed for each day of continuing violation;

- (iii) Destruction and/or appropriate disposition of the subject health product and/or closure of the establishment for any violation of the FDA Act of 2009, these Rules and Regulations, other relevant laws, and FDA-promulgated issuances.

**c. Regulatory Powers, Duties and Functions:**

- (1) To issue appropriate authorizations that would cover establishments, facilities and health products;
  - (2) To determine the establishment and maintenance of bonded warehouses, including the lease or accreditation of bonded warehouses, whenever necessary or appropriate, for confiscated goods in the different regions of the country; and
  - (3) 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 the FDA Act of 2009, these Rules and Regulations, other relevant laws, and FDA-promulgated issuances.
- d. Such other powers and duties and functions as may be necessary for the effective implementation of the FDA Act of 2009, these Rules and Regulations, other relevant laws, FDA-promulgated issuances, and such other laws that the FDA is tasked to administer or implement.**

**Sec. 3. Offices Under the Director-General.** The following Offices and Centers in the FDA shall be directly under the control and supervision of the Director-General:

- a. Policy and Planning Office;
- b. Legal Services Support Center;
- c. Administration and Finance Office;
- d. Center for Drug Regulation and Research (to include veterinary medicines, vaccines and biologicals);
- e. Center for Food Regulation and Research;
- f. Center for Cosmetics Regulation and Research (to include household/urban hazardous substances);
- g. Center for Device Regulation, Radiation Health, and Research; and
- h. Field Regulatory Operations Office.



**ARTICLE IV**  
**OFFICE OF THE DEPUTY DIRECTOR-GENERAL**  
**FOR ADMINISTRATION AND FINANCE**

**Sec. 1. Qualifications of the Deputy Director-General for Administration and Finance.** In addition to the civil service eligibility requirements pertaining to the appropriate salary grade level, the Deputy Director-General for Administration and Finance shall have the following qualifications:

- a. He/she must be a certified public accountant or shall possess a master's degree in accounting, management, economics or any business course; and
- b. He/she must have management experience in a position related to his/her field of discipline or profession.

Article II. C of these Rules and Regulations shall likewise apply.

**Sec. 2. Powers and Functions of the Deputy Director-General for Administration and Finance.** The Deputy Director-General for Administration and Finance shall have the following powers and functions:

- a. To assist the Director General on all matters related to administration and finance;
- b. To develop plans and programs relative to finance and administrative management;
- c. To determine and evaluate administration and finance risk management in coordination with other offices within the agency;
- d. To coordinate with the Deputy Director General for Field Regulatory Offices on matters related to the Administration and Finance;
- e. To implement systems and procedures that will further enhance administration and financial management; and
- f. To exercise such other powers and perform such other functions as may be assigned or necessary to carry out its duties and responsibilities.

**Sec. 3. Offices under the Deputy Director-General for Administration and Finance.** The following divisions shall at least be the offices directly under the



control and supervision of the Deputy Director-General for Administration and Finance:

- a. Human Resource Development Division;
- b. Property and Logistics Management Division;
- c. Procurement Division;
- d. Human Resource Management Division;
- e. Assets and Financial Management Division;
- f. Information and Communication Technology Management Division.

**Sec. 4. Powers and Functions of the Offices under the Deputy Director General for Administration and Finance.** The following Offices under the Deputy Director General for Administrative and Finance shall have, but not limited to, the following powers and functions:

a. Human Resource Development Division

- (1) To formulate and assess training programs for specific categories of human resources;
- (2) To formulate and implement policies for employees merit and awards;
- (3) To establish career development systems; and
- (4) To exercise such other powers and perform such other functions as may be assigned or necessary to carry out its duties and responsibilities.

b. Property and Logistics Management Division

- (1) To formulate plans, policies, standards and guidelines related to property and logistics;
- (2) To conduct inventory of the property of the agency and prepare the necessary reports;
- (3) To maintain an inventory of all FDA properties;
- (4) To provide general services to the Centers and Offices of the FDA; and
- (5) To exercise such other powers and perform such other functions as may be assigned or necessary to carry out its duties and responsibilities.

c. Procurement Division

- (1) To procure, maintain and manage supplies, materials and services to support the logistical requirements of the agency;
- (2) To act as the FDA Bid and Awards Committee Secretariat; and



- (3) To exercise such other powers and perform such other functions as may be assigned or necessary to carry out its duties and responsibilities.

d. Human Resource Management Division

- (1) To develop and implement policies, standards, rules and regulations on selection, recruitment, deployment and utilization of human resources;
- (2) To formulate and implement benefits and compensation packages for human resources;
- (3) To establish an employee grievance procedure in accordance with existing rules and regulations;
- (4) To develop welfare program and packages for FDA personnel in accordance with existing laws, rules and regulations; and
- (5) To exercise such other powers and perform such other functions as may be assigned or necessary to carry out its duties and responsibilities.

e. Assets and Financial Management Division

- (1) To perform general accounting functions and advise management on financial matters;
- (2) To monitor and report the collection of fees from the different Centers and Offices of the FDA;
- (3) To allocate funds to different offices, in coordination with the Policy Planning Office (PPO), upon approval of the Director General, and monitor utilization of such funds;
- (4) To coordinate the preparation and implementation of the annual and long term budget, financial and work plans of the different Centers and offices of the FDA;
- (5) To collect fees and charges and disburse funds; and
- (6) To exercise such other powers and perform such other functions as may be assigned or necessary to carry out its duties and responsibilities.

f. Information and Communication Technology Management Division

- (1) To develop and manage the management information systems and information technology infrastructures including telecommunications services;
- (2) To develop and manage the information resources, library services and documents tracking, archiving and disposal services;



- (3) To provide technical assistance, consultancy and advisory services in information technology acquisition, operation and maintenance to the FDA;
- (4) To maintain a record of all duly registered health products and duly authorized and licensed establishments covered and under the jurisdiction of the FDA; and
- (5) To exercise such other powers and perform such other functions as may be assigned or necessary to carry out its duties and responsibilities.

## **ARTICLE V**

### **POLICY AND PLANNING OFFICE**

**Sec. 1. Policy and Planning Office.** There shall be a Policy and Planning Office (PPO) directly under the control and supervision of the Office of the Director-General.

The PPO shall be headed by a Director, to be assisted by an Assistant-Director, both of whom shall be appointed in accordance with the civil service eligibility requirements appropriate to the salary grade level.

**Sec. 2. Powers and Functions of the Policy and Planning Office.** The PPO shall have the following powers and functions:

- a. To provide services to the FDA on policy formulation, project development and evaluation, research development and analysis, and coordination and monitoring;
- b. To monitor the performance of the Product Research and Standards Development Division of each of the Centers;
- c. To formulate, update and conduct advocacy campaigns for appropriate legislation on any matter relating to health products. It shall (i) coordinate with the executive and legislative branches of the national government and other stakeholders on matters and issues pertaining to regulation of health products and health product establishments; (ii) manage the legislative, executive and other inter-governmental liaison service support to the FDA and its different units or offices; and (iii) monitor and review legislative and executive proposals on legislation of all health products and health product establishments' regulation. It shall coordinate with the Legal Support Services Center and other Centers on technical matters



pertaining to legislation and regulation of health products and health product establishments.

- d. To initiate, coordinate and implement the conduct of all relevant policy research and development work, pursuant to which it shall maintain a database of statistics related to health products and supervise the collection, monitoring and publication thereof;
- e. To formulate and conduct advocacy, training and communication programs in coordination with other government agencies, non-government and private entities and sectors in furtherance of the mandate of the FDA;
- f. To conduct integrated and performance-based planning and budgeting in consultation with other offices; and
- g. To exercise such other powers and perform such other functions as may be assigned or necessary to carry out its duties and responsibilities.

**Sec. 3. Offices under the PPO.** The PPO shall have at least the following divisions:

- a. Policy and Public Affairs Division;
- b. Training, Advocacy, and Communication Division;
- c. Planning and Monitoring Division

## **ARTICLE VI**

### **LEGAL SERVICES SUPPORT CENTER**

**Sec. 1. Legal Services Support Center.** There shall be a Legal Services Support Center (LSSC), which shall be directly under the control and supervision of the Office of the Director-General.

The LSSC shall be headed by a Director, to be assisted by an Assistant-Director, both of whom shall be appointed in accordance with the civil service eligibility requirements appropriate to the salary grade level.

**Sec. 2. Qualifications of the Director for Legal Services Support Center.** In addition to the civil service eligibility requirements appropriate to the salary grade level, the Director shall at least have the following qualifications:





- a. A lawyer, at least thirty (30) years of age, and who has been engaged in the practice of law in the Philippines for at least five (5) years and
- b. A member in good standing of the Integrated Bar of the Philippines.

**Sec. 3. Powers and Functions of the Legal Services Support Center.** The LSSC shall have the following powers, duties and functions:

- a. To assist and advise the Director-General in all official legal matters and quasi-judicial functions;
- b. To provide legal services to the entire FDA in the implementation of its mandate and objectives under the FDA Act of 2009, these Rules and Regulations, other relevant laws, and FDA-promulgated issuances;
- c. To assist in the promulgation of rules governing the activities relating to the operations of the FDA and rules to be issued in connection with the implementation of the FDA Act of 2009, these Rules and Regulations, and other relevant laws, and interpret laws and rules affecting health products, regulated establishments and facilities;
- d. To assist the Solicitor General and private lawyers/firms in actions/suits involving the FDA or its officials or employees or act as their principal counsel in all actions/suits taken in their official capacity before judicial or administrative bodies;
- e. To prepare or review contracts and instruments to which the FDA is a party;
- f. To coordinate with the PPO in providing technical assistance and advisory services on existing and proposed legislation and regulation on health products and health products establishment; and
- g. To exercise such other powers and perform such other functions as may be assigned or necessary to carry out its duties and responsibilities.

**Sec. 4. Offices under the LSSC.** The LSSC shall have at least the following divisions:

- a. Litigation and Enforcement Division;
- b. Documentation, Opinion and Contracts Review Division;
- c. Internal Affairs Division



## **ARTICLE VII**

### **THE CENTERS**

#### **A. COMMON PROVISIONS FOR THE CENTERS**

##### **POWER AND FUNCTIONS OF THE CENTERS**

**Sec. 1. The Four Centers.** There shall be, under the Office of the Director-General, four (4) Centers covering the four (4) major product categories that are regulated under FDA Act of 2009. These four (4) Centers are:

- a. Center for Drug Regulation and Research (to include veterinary medicines, vaccines and biologicals);
- b. Center for Food Regulation and Research;
- c. Center for Cosmetics Regulation and Research (to include household/urban hazardous substances); and
- d. Center for Device Regulation, Radiation Health, and Research.

Each Center shall be headed by a Director, to be assisted by an Assistant-Director, both of whom shall be appointed in accordance with the civil service eligibility requirements appropriate to the salary grade level.

The officer, staff and personnel complement of each of the Centers, including their respective Divisions, shall be based on the technical and skill requirements of the work, the volume of work, as well as any emerging concern, in each major product category covered by the Centers.

**Sec. 2. Powers and Functions of the Centers.** Each of these Centers, with respect to its major product category, shall have the following powers and functions:

- a. To 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;
- b. To conduct research on the safety, efficacy, and quality of health products;
- c. To institute standards for the safety, efficacy, and quality of health products;



- d. To operate the respective Center's testing and/or calibration laboratories;
- e. To inspect and evaluate establishments covered by the particular Center and issue appropriate licenses;
- f. To evaluate and issue appropriate authorizations for all health products and health product establishments regulated by each Center;
- g. To conduct audits of regional field offices in coordination with the Deputy Director General for Field Regulatory Operations Office;
- h. To conduct postmarketing surveillance on health products;
- i. To conduct technology assessment of health products that may have the potential to affect human health, whether or not in the market;
- j. To employ a consultative risk management approach to decision-making across all product classes;
- k. To provide PPO technical assistance and advisory services on matters pertaining to health products and health product establishments' legislation and regulations; and
- l. To levy, assess and collect fees;
- m. In coordination with PPO, to provide technical assistance, consultative and advisory services to stakeholders and other government agencies in the implementation of laws, rules and regulations pertaining to health products; and
- n. To exercise such other powers and perform such other functions as may be assigned or necessary to carry out its duties and responsibilities.

## DIVISIONS OF EACH CENTER

**Sec. 3. Division Composition of the Center.** Each of the Centers shall have, at least, the following divisions:

- a. Licensing and Registration Division;
- b. Product Research and Standards Development Division; and



c. Laboratory Support Division

The FDA, with the approval of the Secretary, shall create other organizational units which are deemed necessary to address emerging concerns and to be abreast with internationally acceptable standards.

**[II]. LICENSING AND REGISTRATION DIVISION**

**Sec. 4. Powers and Functions of the Licensing and Registration Division.**

The Licensing and Registration Division of each of the Centers shall have the following powers and functions, with respect to the major product category covered by the respective Centers:

- a. To regulate the manufacture, importation, exportation, distribution, sale, offer for sale, transfer, and use, if applicable, of all health products covered by their respective product category. This provision shall not include the use of radiation devices, which is provided for under Article VII E of these Rules;
- b. To evaluate, analyze and/or inspect the respective health products covered by the particular Center for purposes of issuance of authorizations, registrations and licenses and in connection with the implementation of this Act;
- c. To conduct, monitor, inspect, and evaluate health product establishments including spot checking when necessary, for the purpose of issuance of appropriate authorizations to manufacture, import, export, sale, offer for sale, distribute, and other activities as may be determined by FDA;
- d. To maintain a database of all registered health products and duly authorized and licensed establishments covered and under the jurisdiction of the FDA;
- e. To require appropriate tests on all applicable health products prior to the issuance of appropriate authorizations to ensure safety, efficacy, purity, and quality;
- f. To require all manufacturers, processors, traders, sellers, distributors, importers, exporters, wholesalers, retailers, or non-consumer users, and encourage consumers, of 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, a patient, or any person;



- g. After proper evaluation, to recommend the ban, recall, and/or withdrawal of any health product found to have caused the death, serious illness or serious injury to a consumer or patient, or is found to be imminently injurious, unsafe, dangerous, or grossly deceptive;
- h. To mandate, order, review, and implement a Risk Management Plan on any health product for conformance with the FDA standards;
- i. To require the collection and testing of samples of health products and/or the raw materials and/or packaging materials for testing and verification of compliance;
- j. To prescribe standards, guidelines and regulations with respect to information, advertisements and other marketing instruments and promotion, sponsorship, and other marketing activities as covered by the FDA Act of 2009, these Rules and Regulations, other relevant laws, and FDA-promulgated issuances; and
- k. To exercise such other powers and perform such other functions as may be assigned or necessary to carry out its duties and responsibilities.

### **[II] PRODUCT RESEARCH AND STANDARDS DEVELOPMENT DIVISION**

**Sec. 5. Powers and Functions of the Product Research and Standards Development Division.** The Product Research and Standards Development Division of each Center shall have the following powers, functions, and responsibilities with respect to the major product category covered by the respective Centers:

- a. In coordination with the PPO, to develop standards and regulations for health products and establishments;
- b. To establish and maintain the postmarketing surveillance system in monitoring health products and incidents of adverse events involving such products in coordination with the Licensing and Registration Division and the Regional Field Offices, including strategizing and developing post market surveillance programs, fact-finding activities or gathering and monitoring information on health product risks and actions, and procedures for inspections based on risk and/or other accepted systems;



- c. To undertake, when appropriate, oversight/audit of related researches that would ensure safety, efficacy and quality of health products;
- d. To conduct research and to establish analytical data to serve as basis for the development of health products standards; and
- e. To exercise such other powers and perform such other functions as may be assigned or necessary to carry out its duties and responsibilities.

### [III] LABORATORY SUPPORT DIVISION

**Sec. 6. Powers and Functions of the Laboratory Support Division.** The Laboratory Support Division of each Center shall serve as direct line support to the respective Center and shall have the following powers, functions and responsibilities with respect to the major product category covered by the respective Centers:

- a. To conduct research and appropriate tests and calibration, analyses and trials of products including, but not limited to, assays;
- b. To undertake oversight and/or audit of all satellite laboratories; provided that the Center for Drug Regulation and Research shall oversee and/or audit centers conducting bioavailability and bioequivalence tests;
- c. To conduct appropriate tests on all applicable health products as needed prior to the issuance of appropriate authorizations to ensure safety, efficacy and quality;
- d. To conduct tests, that are not routinely performed in the other FDA laboratories, for confirmatory and/or investigatory purposes and to resolve disputes in test results, when necessary;
- e. To analyze and/or and inspect health products in connection with the implementation of the FDA Act of 2009, these Rules and Regulations, other relevant laws, and FDA-promulgated issuances;
- f. To provide technical supervision and monitor the operations of the FDA Satellite Laboratories (Quality Assurance Laboratories) in Visayas (Cebu), Mindanao (Davao), and Luzon (Subic), as well as, satellite laboratories in the region;



- g. To establish analytical data to serve as basis for the preparation of health products standards, and to recommend standards of identity, purity, safety, efficacy and quality;
- h. To conduct health technology assessment, as necessary;
- i. To accredit private testing laboratories; and
- j. To exercise such other powers and perform such other functions as may be assigned or necessary to carry out its duties and responsibilities.

**Sec. 7. Other Government and Private Testing Laboratories.** Other government and duly qualified and accredited private testing laboratories may be called upon to provide support for testing, calibration, assay, examination, and measurements, or analytical services with respect to health products, especially in those regions where there are no existing FDA laboratories.

## **B. CENTER FOR DRUG REGULATION AND RESEARCH**

**Sec. 8. Product Jurisdiction.** The Center for Drug Regulation and Research 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 drugs (to include veterinary medicine, vaccines and biologicals) and, when appropriate, certify batches of antibiotic and antibiotic preparations.

The Center shall likewise conduct research on the safety, efficacy, and quality of drug products, and to institute standards for the same.

## **C. CENTER FOR FOOD REGULATION AND RESEARCH**

**Sec. 9. Product Jurisdiction.** The Center for Food Regulation and Research 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 food products and food/dietary supplements.

The Center shall likewise conduct research on the safety and quality of food products and food/dietary supplements, and institute standards for the same.



- g. To establish analytical data to serve as basis for the preparation of health products standards, and to recommend standards of identity, purity, safety, efficacy and quality;
- h. To conduct health technology assessment, as necessary;
- i. To accredit private testing laboratories; and
- j. To exercise such other powers and perform such other functions as may be assigned or necessary to carry out its duties and responsibilities.

**Sec. 7. Other Government and Private Testing Laboratories.** Other government and duly qualified and accredited private testing laboratories may be called upon to provide support for testing, calibration, assay, examination, and measurements, or analytical services with respect to health products, especially in those regions where there are no existing FDA laboratories.

## **B. CENTER FOR DRUG REGULATION AND RESEARCH**

**Sec. 8. Product Jurisdiction.** The Center for Drug Regulation and Research 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 drugs (to include veterinary medicine, vaccines and biologicals) and, when appropriate, certify batches of antibiotic and antibiotic preparations.

The Center shall likewise conduct research on the safety, efficacy, and quality of drug products, and to institute standards for the same.

## **C. CENTER FOR FOOD REGULATION AND RESEARCH**

**Sec. 9. Product Jurisdiction.** The Center for Food Regulation and Research 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 food products and food/dietary supplements.

The Center shall likewise conduct research on the safety and quality of food products and food/dietary supplements, and institute standards for the same.





#### **D. CENTER FOR COSMETICS REGULATION AND RESEARCH**

**Sec. 10. Product Jurisdiction.** The Center for Cosmetic Regulation and Research, which includes household/urban hazardous substances, 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 cosmetics and household/urban hazardous substances.

The Center shall likewise conduct research on the safety and quality of cosmetics and household/urban hazardous substances, and institute standards for the same.

#### **E. CENTER FOR DEVICE REGULATION, RADIATION HEALTH, AND RESEARCH**

**Sec. 11. Product Jurisdiction.** The Center for Device Regulation, Radiation Health, and Research 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 devices.

The Center shall likewise conduct research on the safety, efficacy, and quality of devices, and institute standards for the same.

**Sec. 12. The Radiation Regulation Division.** In addition to the three divisions as provided for in Sec. 3, Article VII of these Rules and Regulations, the Center for Device Regulation, Radiation Health, and Research shall have another Division, the Radiation Regulation Division, which shall have the following powers and functions over the use of radiation devices:

- a. To regulate the use of ionizing and non-ionizing radiation devices in medicine, dentistry, veterinary medicine, commerce and industry, education and training, research, anti-crime, security, household activities, and all other facilities/establishments and activities where radiation devices are used;
- b. In coordination with PPO, to develop policies, standards, regulations, and guidelines for the use of ionizing and non-ionizing radiation devices;



- c. To conduct radiation protection survey and evaluation of radiation facilities and the activities thereat;
- d. To issue appropriate authorizations for medical and non-medical radiation facilities;
- e. To issue certificates of compliance with technical requirements as basis for the issuance of appropriate authorization regarding the use of radiation devices and operation of radiation facilities;
- f. To conduct compliance monitoring of radiation facilities;
- g. In coordination with PPO, to provide technical assistance, consultative and advisory services to stakeholders and other government agencies in the implementation of laws, rules and regulations pertaining to radiation facilities; and
- h. To exercise such other powers and perform such other functions as may be assigned or necessary to carry out its duties and responsibilities.

## **ARTICLE VIII**

### **FIELD REGULATORY OPERATIONS OFFICE**

#### **A. OFFICE OF THE DEPUTY DIRECTOR-GENERAL FOR FIELD REGULATORY OPERATIONS**

**Sec. 1. Qualifications of the Deputy Director-General for Field Regulatory Operations.** In addition to the civil service eligibility requirements pertaining to the appropriate salary grade level, the Deputy Director General for Field Regulatory Operations shall have the following qualifications:

- a. He/she preferably possess the relevant master's degree in pharmaceutical sciences or allied sciences, or equivalent executive course in any regulatory management and
- b. He/she shall have management experience in his/her field of discipline or profession and in any development, manufacturing, regulatory work or quality assurance of products covered by the FDA Act of 2009, these Rules and Regulations, other relevant laws, and FDA-promulgated issuances.

Article II. C of these Rules and Regulations shall likewise apply.



**Sec. 2. Duties and Functions of the Deputy Director-General for Field Regulatory Operations Office.** The Deputy Director-General for Field Regulatory Operations shall have the following powers, functions and responsibilities:

- a. To assist the Director-General in all matters relating to the supervision and control of the Field Regulatory Operations Office;
- b. To have supervision of all Field Regulatory Operations Offices, that shall include, among others, all the Field Offices, Field or Satellite Laboratories and the Regulatory Enforcement Units;
- c. To recommend, to the Director-General, the officer, staff and personnel complement of each Regional Field Office, including the respective Divisions, based on the volume of work in each Regional Field Office as well as to address any emerging concern in each particular Regional Field Office;
- d. To monitor collection of fees by the regional field offices;
- e. To recommend to the Director-General, other government and private testing laboratories in the regions qualified and properly equipped to conduct testing, calibration, assay, and examination of samples and health products;
- f. To implement systems and procedures that will further enhance field operations management; and
- g. To exercise such other powers and perform such other functions as may be assigned or necessary to carry out its duties and responsibilities.

**Sec. 3. Offices under the Deputy Director-General for Field Regulatory Operations.** The following Offices shall be directly under the supervision and control of the Deputy Director-General for Field Regulatory Operations:

- a. Regional Field Offices;
- b. Testing and Quality Assurance Laboratories (Luzon, Visayas and Mindanao)
- c. Regulatory Enforcement Units



## **B. REGIONAL FIELD OFFICES**

### **OFFICE OF THE DIRECTOR AND ASSISTANT DIRECTOR**

**Sec. 4. Establishment of Regional Field Office.** There shall be established Field Offices in all of the regions of the country, including the National Capital Region and the autonomous regions.

A Regional Field Office shall be headed by a Director who shall be assisted by an Assistant-Director, and both shall be appointed in accordance with the civil service eligibility requirements appropriate to the salary grade level.

**Sec. 5. Powers and Functions of the Regional Field Offices.** Field Offices in all regions of the country shall have the following powers and functions in their respective assigned region:

- a. To implement laws, policies, plans, programs, rules and regulations of the FDA in the regional area;
- b. To oversee the operations of the divisions and units of the regional field offices;
- c. To prepare and submit budget proposals for the region to the Office of the Deputy Director General for Field Regulatory Office, administer the budget of the regional office, disburse funds pursuant to the approved work and financial programs, and administer budget control machinery in the region;
- d. To administratively support the Regional Regulatory Enforcement Units (REU) assigned in their respective region;
- e. To implement the established a postmarketing surveillance system in monitoring health products and incidents of adverse events involving such products in coordination with the Product Research and Standards Development Division of each Center;
- f. To operate field and/or satellite laboratories in their respective regions;
- g. To inspect and evaluate establishments and issue appropriate renewal licenses, and other appropriate authorizations as may be delegated and undertake compliance monitoring;



- h. To evaluate health products and issue appropriate authorizations, as may be delegated (except product registration) and undertake compliance monitoring;
- i. To levy, assess and collect appropriate fees;
- j. To coordinate with regional offices of other departments, bureaus and agencies in the area;
- k. To coordinate with local government units in the area; and
- l. To exercise such other powers and perform such other functions as may be assigned or necessary to carry out its duties and responsibilities.

## DIVISIONS

**Sec. 6. Divisions under the Regional Field Offices.** Each Regional Field Office shall be composed of the following divisions:

- a. Licensing, Inspection, and Compliance Division;
- b. Field and/or Satellite Laboratory Division;
- c. Administrative Division

### [I] LICENSING, INSPECTION, AND COMPLIANCE DIVISION

**Sec. 7. Powers and Functions of the Licensing, Inspection, and Compliance Division.** Each Regional Field Office's Licensing, Inspection, and Compliance Division shall have the following powers and functions in their respective assigned regions:

- a. To enter and inspect establishments and facilities engaged in the manufacture, importation, exportation, distribution, sale, offer for sale and transfer, and, where appropriate, use of health products;
- b. To monitor, inspect and evaluate health products and establishments covered by the FDA Act of 2009, these Rules and Regulations, and other relevant laws for the purpose of the issuance of the necessary authorizations;
- c. To review, evaluate and monitor implementation of Risk Management Plans for conformance with the FDA standards;



- d. To levy, assess and collect fees for inspection, analysis and testing of products and materials submitted in compliance with the provisions of the FDA Act of 2009, these Rules and Regulations, other relevant laws, and FDA-promulgated issuances;
- e. To issue certificates of compliance with technical requirements to serve as basis for the issuance of appropriate authorization including the use of radiation devices and operation of radiation facilities and spot check for compliance with regulations regarding operation of manufacturers, importers, exporters, distributors, wholesalers, drug outlets, and other establishments and facilities of health products, as determined by the FDA;
- f. To collect samples of health products being imported or offered for import at any port of entry in its assigned region and where it appears that said items or products satisfy any of the conditions as provided in Sec. 33(a) of Republic Act No. 3720 or the Foods, Drugs and Devices and Cosmetics Act as amended, without prejudice to the exercise of the powers of the Director-General under Sections 13 and 14 of the FDA Act of 2009;
- g. Upon finding, in the course of its evaluation, monitoring, inspection and spot checking, of any violation in the compliance and other requirements required by the FDA and its implemented laws, such as the FDA Act of 2009, these Rules and Regulations, and other relevant laws, to submit a report to serve as basis for the *motu proprio* action of the Director of the Regional Field Office;
- h. To monitor compliance with standards, guidelines, and regulations with respect to information, advertisements and other marketing instruments and promotion, sponsorship, and other marketing activities about the health products;
- i. To conduct postmarketing monitoring of all health products;
- j. As may be delegated, to conduct radiation protection survey and evaluation of radiation facilities and the activities thereat and compliance monitoring of radiation facilities; and
- k. To exercise such other powers and perform such other functions as may be assigned or necessary to carry out its duties and responsibilities.



### **[II] SATELLITE LABORATORY DIVISION**

**Sec. 8. Establishment of Satellite Laboratories.** In view of the objectives of the FDA Act of 2009 to strengthen the technical capacity of the FDA in the regulation of establishments and products under its jurisdiction, Satellite Laboratories shall be established in all the regional field offices.

**Sec. 9. Powers and Functions of the Satellite Laboratory Division.** The Satellite Laboratory Division of each Regional Field Office shall have the power and function to conduct appropriate tests on all applicable health products to ensure safety, efficacy, purity and quality. More specifically, these are:

- a. To analyze and inspect health products in connection with the implementation of the FDA Act of 2009, these Rules and Regulations, other relevant laws, and FDA-promulgated issuances;
- b. To establish analytical data to serve as basis for the preparation of health products standards, and to recommend standards of identity, purity, safety, efficacy, quality and fill of container;
- c. To conduct appropriate tests on all applicable health products prior to the issuance of appropriate authorizations;
- d. To audit centers conducting bioavailability and bioequivalence tests, as may be delegated;
- e. To accredit private testing laboratories; and
- f. To exercise such other powers and perform such other functions as may be necessary to carry out its duties and responsibilities under the FDA Act of 2009, these Rules and Regulations, other relevant laws, and FDA-promulgated issuances.

### **[III] ADMINISTRATIVE DIVISION**

**Sec. 10. Powers and Functions of the Administrative Division.** The Administrative Division of each Regional Field Office shall provide the administrative and office personnel complement in support of the Licensing, Inspection and Compliance and the Satellite Laboratory Divisions.



## **C. TESTING AND QUALITY ASSURANCE LABORATORIES**

**Sec. 11. Testing and Quality Assurance Laboratories.** 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 existing laboratories in Cebu and Davao shall be upgraded and transformed into quality assurance laboratories while another quality assurance laboratory shall be established in Subic, Zambales.

## **D. REGULATORY ENFORCEMENT UNITS (REUs)**

**Sec. 12. Regulatory Enforcement Units Personnel Composition.** There shall be established, in each region of the country, including the National Capital Region and the Autonomous Regions, a Regulatory Enforcement Unit (REU) composed of at least five (5) qualified personnel who shall be under the control and supervision of the Deputy Director-General for Field Regulatory Operations and shall be administratively supported by the field offices.

All REUs shall be headed by a lawyer who shall have the rank of a Division Director, and an assistant head who shall have the rank of an Assistant Division Director.

**Sec. 13. Qualifications of the Head and Assistant Head of REUs.** In addition to the civil service eligibility requirements pertaining to the salary grade level, the Head of an REU have the following qualifications:

- a. He/she shall be a lawyer;
- b. He/she must be at least thirty (30) years old but not older than fifty (50) years old at the time of appointment; and
- c. He/she must be a member in good standing of the Integrated Bar of the Philippines (IBP).

In addition to the civil service eligibility requirements appropriate to the salary grade level, the Assistant Head of an REU must, at the very least, be a law graduate.

**Sec. 14. Duties and Functions of the Personnel Assigned in the REUs.** The qualified personnel in each REU shall have the following authority and





functions, the exercise of which shall be strictly limited to the implementation of the FDA's regulatory functions:

- a. Bear arms, wear official uniforms and insignias and shall be classified as law enforcement agents;
- b. Serve and execute rulings, orders, and decisions of the Regional Field Director or the Director-General;
- c. Execute and serve search warrants and arrest warrants issued by the courts in connection with violations under the FDA Act of 2009, these Rules and Regulations, and related laws concerning the regulation of health products; and
- d. To exercise such other powers and perform such other functions as may be assigned or necessary to carry out its duties and responsibilities in support of the objectives of the Law and this IRR.

**Sec. 15. Necessary Training.** All law enforcement agents of the REUs shall undergo the appropriate training to equip them with the necessary skills needed in the performance of their authority and functions. For this purpose, the FDA may seek the assistance of other governmental agencies and offices, including the Philippine National Police (PNP) and the National Bureau of Investigation (NBI), to conduct the appropriate training.

**Sec. 16. Administrative Support to the REUs.** The FDA's Regional Field Office shall administratively support the REUs in their respective regions.

**Sec. 17. Term for Establishment of the REUs.** The FDA shall establish the REUs for a period not exceeding five (5) years from the effectivity of the FDA Act of 2009.

## BOOK II

### ARTICLE I

#### LICENSING OF ESTABLISHMENTS AND REGISTRATION OF HEALTH PRODUCTS

##### **Sec. 1. General Provisions.**

- a. The manufacture, importation, exportation, sale, offering for sale, distribution, transfer, non-consumer use, promotion, advertising, or sponsorship of any health product without the proper authorization from the FDA is prohibited.
- b. The manufacture, importation, exportation, sale, offering for sale, distribution, transfer, or retail of any drug or device; the manufacture, importation, exportation, transfer or distribution of any food, cosmetics, household hazardous substances or urban pesticides; or the operation of a radiation facility or pest control establishment without the appropriate authorization from the FDA is prohibited.

**Sec. 2. Rules and Regulations on Licensing of Establishments and Registration of Health Products.** Unless subsequently amended or superseded, the existing rules on licensing of establishments and registration of health products shall remain in effect.

##### **Sec. 3. Approval of License of Establishments and Registration of Health Products.**

###### **A. License to Operate.**

- (1) *Initial License.* An approved application for a license shall be issued a corresponding License to Operate (LTO).

An LTO covering a particular establishment shall be *prima facie* evidence of the licensee's authority to engage in the activity/ies specified in the LTO.

- (2) *Renewal of License.* No application for renewal shall be accepted unless the prescribed renewal fee is paid.

There shall be automatic renewal of the LTO when the following conditions are satisfied:



- i. The application is filed before the expiration date of the license;
- ii. The prescribed renewal fee is paid upon filing of the application; and
- iii. A sworn statement indicating no change or variation whatsoever in the establishment is attached to the application.

An application for renewal of an LTO received after its date of expiration shall be subject to a surcharge or penalty equivalent to twice the renewal licensing fee and an additional 10% per month or a fraction thereof of continuing non-submission of such application up to a maximum of one hundred twenty (120) days. Any application for renewal of license filed thereafter shall be considered expired and the application shall be subject to a fee equivalent to the total surcharge or penalty plus the initial filing fee and the application shall undergo the initial filing and evaluation procedure.

For applications for renewal filed within one hundred twenty (120) days from its original expiry, the LTO shall be considered valid and existing until a decision or resolution by the FDA is rendered on the application for renewal.

- (3) *Assignment and Transfer of Pending Applications, Existing Licenses.* Assignment or transfer of a valid and unexpired LTO, or pending application for renewal thereof without any change or variation whatsoever in the establishment shall be a mere amendment, otherwise, considered initial.

## **B. Authorization/Certificate of Product Registration.**

- (1) *Initial Registration.* An approved application for a health product registration shall be issued a proper authorization or a corresponding Certificate of Product Registration (CPR).

An authorization or CPR covering a particular health product shall be prima facie evidence of the registrant's marketing authority for said health product in connection with the activity/ies permitted pursuant to the LTO.

Only establishments with a valid License to Operate from the FDA may apply for registration.



- (2) *Renewal of Registration.* No application for renewal shall be accepted unless the prescribed renewal fee is paid.

There shall be automatic renewal of the CPR when the following conditions are satisfied:

- i. The application is filed before the expiration date of the registration;
- ii. The prescribed renewal fee is paid upon filing of the application; and
- iii. A sworn statement indicating no change or variation whatsoever in the product is attached to the application.

An application for renewal of a registration received after its date of expiration shall be subject to a surcharge or penalty equivalent to twice the renewal registration fee and an additional 10% per month or a fraction thereof of continuing non-submission of such application up to a maximum of one hundred twenty (120) days. Any application for renewal of registration filed thereafter shall be considered expired and the application shall be subject to a fee equivalent to the total surcharge or penalty plus the initial filing fee and the application shall undergo the initial filing and evaluation procedure.

For applications for renewal filed from within one hundred twenty (120) days from its original expiry the CPR shall be considered valid and existing until a decision or resolution by the FDA is rendered on the application for renewal.

- (3) *Assignment and Transfer of Pending Applications, Existing Product Registration.* Assignment or transfer of a valid and unexpired CPR or of a pending application for renewal thereof shall be considered an amendment to the CPR so long as the assignee or transferee is also a valid LTO holder and shall submit a sworn statement of acceptance including the responsibility/liability for the product assigned or transferred.

**Sec. 4. Grounds for Disapproval of Application and Suspension or Cancellation of License, Registration, or Authorization.** Any of the following or similar instances shall be a ground for the disapproval of an application, suspension, revocation or cancellation, of an existing LTO, CPR, or any authorization:



#### **A. License to Operate**

- (1) The application requirements submitted show that the establishment does not meet the required technical requirements or appropriate standards;
- (2) The applicant made misrepresentations, false entries, or withheld any relevant data contrary to the provisions of the law, these Rules and Regulations or appropriate standards;
- (3) The owner has violated any of the terms and conditions of its license;
- (4) Such other analogous grounds or causes as determined by the FDA.

#### **B. Authorization/Certificate of Product Registration.**

- (1) The application requirements submitted show that the establishment does not meet the required technical requirements or appropriate standards;
- (2) The applicant made misrepresentations, false entries, or withheld any relevant data contrary to the provisions of the law or these Rules and Regulations or appropriate standards;
- (3) The holder or owner has violated any of the terms and conditions of its authorization or registration;
- (4) The label of the health product is false and misleading or does not conform with current labeling requirements;
- (5) The holder or owner of the CPR/authorization, without legitimate reason, fails to sell the health product or fails to cause it to be marketed during an uninterrupted period of at least three (3) years from date of issuance or renewal of the registration, or the last date of operation or marketing;
- (6) Such other analogous grounds or causes as determined by the FDA.

Nothing in this section shall restrict the FDA or the DOH in imposing the penalty of suspension, revocation, or cancellation of license, registration, or authorization for administrative violations of any other relevant laws or their implementing rules and regulations.

Any notice of disapproval of applications for license, registration, or authorization or suspension, revocation, or cancellation of an existing license, registration, or authorization must clearly state the ground/s on which the disapproval, suspension, revocation, or cancellation is based.

**Sec. 5. Other Rules.** The Director General shall promulgate such other rules and regulations, subject to the approval of the Secretary of Health, to govern licensing and registration.

**Sec. 6. Requirements for Every Incoming Shipment of Health Products.** The FDA in coordination with the Bureau of Customs, Bureau of Quarantine and other concerned agencies is mandated to undertake and adopt measures relating to importation of health products such as, but not limited to, sampling and examination, in accordance with relevant existing laws and regulations, of every incoming shipment of health products.

## **ARTICLE II**

### **LABELING OF HEALTH PRODUCTS**

**Sec. 1. General Provision.** Consistent with the state policy of protecting the consumer against hazards to health and safety and providing information and education to facilitate sound choice in the proper exercise of their rights, all health products must be labeled and conform to the requirements on labeling set by the FDA.

**Sec. 2. Rules and Regulations on Labeling.** Unless subsequently amended or superseded, the existing rules on labeling shall remain in effect. The Director General shall promulgate such other rules and regulations, subject to the approval of the Secretary of Health.

**Sec. 3. Exception to the Requirements of Labeling.** Subject to rules and regulations to be promulgated by the Secretary of Health upon recommendation of the Director General, health products may be exempted from the requirement of labeling which are, in accordance with the practice of trade, to be processed, labeled, or repacked in substantial quantities at establishments other than those where originally processed or packed. The exemption from the requirement of labeling is subject to the condition that such health products are not adulterated or misbranded upon removal from such processing, labeling, or repacking establishment.



**ARTICLE III**  
**TOBACCO AND OTHER PRODUCTS**

**Sec. 1. Rationale.** The FDA has full jurisdiction over the regulation of all health products.

**Sec. 2. Tobacco.** The DOH, tasked with protecting the public's health against the injurious effects arising from the use of tobacco and tobacco products, has the responsibility of regulating tobacco and tobacco products through the FDA.

- a. Rules and Other Issuances to Implement this Section. Within a reasonable period from the date of effectivity of these Rules and Regulations, the FDA shall prepare and recommend for the approval to the Secretary of Health, the appropriate rules and regulations and other issuances to implement this Section.
- b. Protection against Tobacco Industry Interference. The FDA shall act to protect the formulation and implementation of rules and regulations under this Section from commercial and other vested interests of the tobacco industry, including organizations, entities, associations, individuals, and others that work to further the interests of the tobacco industry.

The FDA shall not deal with the tobacco industry or individuals or entities that work to further the interests of the tobacco industry, except to the extent strictly necessary to effectively regulate, supervise, or control the tobacco industry in relation to tobacco and tobacco products.

**Sec. 3. Other Products.** Nothing in the FDA Act of 2009 shall be deemed to modify the jurisdiction of other specialized agencies and special laws only insofar as the acts covered by these specialized agencies and laws except the health aspects of such products.

**Sec. 4. Identification of Policy Areas.** The FDA shall promulgate the appropriate rules and regulations and other issuances to identify and define the policy areas that are not covered by specialized agencies and special laws, including, but not limited to, those covered by Republic Act No. 9211, Executive Order No. 245, Executive Order No. 18, and Presidential Decree No. 1468.

**ARTICLE IV**  
**LABORATORY ACCREDITATION**

**Sec. 1. Accreditation of Private Testing Laboratories.** Testing, calibration, assay, examination, measurement and analytical service results/reports of health products from private testing laboratories shall only be recognized by the FDA if these testing laboratories have prior and valid accreditation from the Philippine Accreditation Office (PAO) of the Department of Trade and Industry (DTI) and the Department of Health through the Food and Drug Administration.

**Sec. 2. Application Requirements and Procedure for Accreditation.** The Director General shall promulgate the rules and regulations on the procedure for accreditation of private testing laboratories, subject to the approval by the Secretary of Health.

**Sec. 3. Grant of Accreditation.** The Certificates of Accreditation granted to private testing laboratories by the FDA shall be *prima facie* evidence of the validity of the accreditation with respect to the defined scope of activity indicated in the certificate.

An accreditation shall be specific to a defined scope of activity of the accredited laboratory relating to any conduct of test, calibration, assay, examination, measurement and analytical service with respect to health products. Any variation in the defined and approved scope shall require an application for a new accreditation.

The grant of accreditation shall carry the following responsibilities, among others:

- a. An accredited laboratory shall keep and maintain all records of every testing conducted in a manner, and for a period, provided under FDA regulations and make them readily available at any time for purposes of inspection, verification, and/or audit by the officers authorized by the FDA.
- b. The accredited laboratory shall allow the FDA full access to other records, such as, but not limited to, raw data, contracts and receipts, any laboratory equipment and facilities and shall provide the FDA, when it so requests, test reports, raw data, methods of analysis and other pertinent documents.
- c. An accredited laboratory shall inform and notify the FDA in writing of any findings of non-conformance in the test results/analysis





conducted of a marketed health product, within forty-eight (48) hours after the result of analysis has been prepared, attaching to the said notice the request for analysis including relevant information provided by the laboratory's clients to aid the conduct of investigation. Such information provided by the accredited laboratory shall be accorded utmost confidentiality until the commencement of administrative action against the company producing or distributing the health product in question.

- d. An accredited laboratory shall inform the FDA in writing of any change in its DTI - PAO accreditation.

**Sec. 4. Grounds for Disapproval of Application, Cancellation or Suspension of Accreditation.** Any or all of the following instances, in so far as applicable, shall be a ground for the disapproval of an application for accreditation, or cancellation or suspension of an existing accreditation, *motu proprio* or upon petition, to wit:

- a. The requirements submitted or based on audit/inspection show that the laboratory does not meet the prescribed standards followed by the PAO or FDA;
- b. The accreditation from the DTI-PAO has expired or has been cancelled, suspended or otherwise withdrawn;
- c. The applicant fraudulently filed or misrepresented, falsified or withheld any relevant data or information regarding the laboratory, its equipment or the methods used in, or the facilities and controls used for, the conduct of test, calibration, assay, examination, measurement, or analytical service with respect to samples of health products or its accreditation was obtained fraudulently or contrary to the provisions of this Article;
- d. The applicant conducts testing which is not within the scope of activity in the Certificate of Accreditation;
- e. Such other grounds as may be provided by relevant laws, rules and regulations.

**Sec. 5. Accreditation Fees.** Private testing laboratories which seek accreditation under these rules shall be assessed and shall pay the applicable laboratory accreditation fees in accordance with existing schedule of fees prescribed by the FDA. Fees paid are not refundable or non-transferable.



**ARTICLE V**  
**Advertisements, Promotions, Sponsorship,  
and Other Marketing Activities**

**Sec. 1. General Provision.** Consistent with the state policy of protecting the consumer against misleading, deceptive, false, erroneous impression regarding any health product's character, value, quantity, composition, merit, or safety, efficacy or quality, and in order to provide information and education to facilitate sound choice in the proper exercise of their rights, all advertisements, promotions, sponsorship, and other marketing activities about the health product must adhere to the standards, guidelines, and regulations of the FDA. For this purpose, advertisements, promotions, sponsorship, and other marketing activities on health products shall refer to those addressed to the general public in any form of media.

**Sec. 2. General Rules on Advertisements, Promotions, Sponsorship, and Other Marketing Activities of any Health Product.**

- a. No health product that has not been registered or authorized shall be advertised, promoted or subjected to any marketing activities;
- b. No claim in the advertisement, promotion and sponsorship, and other marketing activities shall be made other than those contained in the approved label or packaging of the health product, or as duly approved by the FDA;
- c. No claims, therapeutic or scientific otherwise, shall be made that has not been duly approved by the FDA;
- d. All health products that are permitted to be promoted must specifically state the authority or reference number that approved the same promotional, sponsorship, or marketing activities.

**Sec. 3. Responsibilities of Manufacturer, Owner, Distributor, Advertiser and/or Their Agents.** A manufacturer, owner, distributor, advertiser, and/or its agents are mandated to strictly observe the above prohibitions and strictly adhere to the standards, guidelines, and rules and regulations prescribed by the FDA.

Any violation, thereon, shall subject the product to seizure, confiscation, and/or suspension or revocation of the authorization; the establishment to

suspension or revocation of the authorization; and/or the erring entity, person or persons acting for and on its behalf to other punitive sanctions as authorized by law.

**Sec. 4. Rationalization of Marketing Practice.** Subject to existing laws on consumer protection, the Director General shall promulgate policies and directives that would rationalize promotional and marketing practices, such as but not limited to, scientific and product information dissemination and advocacy activities when appropriate.



## BOOK III

### UNIFORM RULES OF PROCEDURES

#### ARTICLE I GENERAL PROVISIONS

**Sec. 1. Title.** These Rules shall be known as the “Uniform Rules of Procedures of the Food and Drug Administration (FDA)”.

**Sec. 2. Applicability.** These Rules shall apply to all cases concerning violations of R.A. No. 3720 as further amended by R.A. No. 9711, and other relevant laws being administered or implemented by the FDA and not pertaining to the sole and exclusive jurisdiction of other specialized agencies, tribunals, bodies or committees, including violations of the Rules and Regulations, Administrative Circulars and Orders issued pursuant to the said laws. Excepted also in these Rules are cases pertaining to actions for recalls, banning or withdrawal of health products, which shall be covered by separate rules of procedures.

**Sec. 3. Interpretation.** In case of doubt, these Rules shall be liberally construed to carry out the objectives of promoting the just, speedy and inexpensive resolution of cases.

**Sec. 4. Rules of Evidence.** The technical rules of evidence prevailing in the courts of law shall not be strictly applied hereto.

**Sec. 5. Suppletory Application of the Rules of Court and of the Administrative Code.** In the absence of any applicable provision in these Rules, the pertinent provisions of the Administrative Code, Executive Order No. 26, series of 1992, and the Rules of Court, shall suppletorily apply.

#### ARTICLE II VENUE OF ACTIONS

**Sec. 1. Venue of Actions.** Actions shall be filed, at the option of the complainant or petitioner, with the FDA Central Office or at the FDA Regional Office: (a) Where the establishment complained of is located; (b) Where the product was purchased; (c) Where the product was manufactured; or (d) Where the complainant or petitioner resides.



### **ARTICLE III**

#### **PARTIES**

**Sec. 1. Who may be parties.** Natural or juridical persons may be parties. The party initiating the action shall be called "Complainant/Petitioner" and the opposing party, the "Respondent".

**Sec. 2. Actions against entity without juridical personality.** When two or more persons associated in any business, transact such business under a common name, whether it comprises names of such persons or not, the association may be sued under such common name.

### **ARTICLE IV**

#### **COMMENCEMENT OF ACTIONS**

**Sec. 1. Action; How Commenced.** An action is commenced: (a) upon the filing of a complaint or petition by a party; or (b) Upon the initiative of the FDA pursuant to its own administrative investigation.

Referral by the Consumer Arbitration Officer or other government office or officers shall, upon appropriate verification/investigation, be treated as FDA-initiated action.

**Sec. 2. Fees and Other Charges.** Appropriate fees and other charges may be imposed pursuant to the schedule of fees promulgated by the FDA.

**Sec. 3. Complaint or Petition by a Party.** The Complaint or Petition shall indicate the full name and addresses of the parties and shall set forth in concise manner, the claims, the relief prayed for, and the date of the pleading. The Complaint or Petition must be signed by the party or counsel representing him/her, stating in either case his/her address which should not be a post office box.

The Complaint or Petition must likewise be supported by an affidavit that the affiant has read the pleading and that the allegation therein are true and correct of his/her personal knowledge or based on authentic documents.

The Complaint or Petition shall contain a sworn certification: (a) that he/she has not theretofore commenced any action or filed any claim involving the same issues in any court, tribunal or quasi-judicial agency and to the best of his/her knowledge, no such similar action or claim is pending therein; (b) if there is such other pending action or claim, a complete statement of the

present status thereof; and (c) if he/she should hereafter learn that the same or similar action or claim has been filed or is pending, he/she shall report that fact within five (5) days therefrom.

**Sec. 4. Actions initiated by FDA.** For actions initiated by the FDA, the Food and Drug Regulation Officer (FDRO) or any official or personnel of the FDA investigating the case, the Report of Violation shall constitute as the Complaint.

The Report of Violation shall clearly state the acts or omissions in violation of the law, rules and regulation, the party or person who committed the violation, shall be accompanied by the record of inspection and if applicable, the report of analysis with respect to the products.

The record of inspection shall indicate:

- a. The time and date of inspection;
- b. The FDA license number of the establishment inspected, if any, and the validity of such License to Operate;
- c. The name and place or exact address of the establishment and the person who committed the violation;
- d. The manner of the collection of samples, if any;
- e. The inventory of the product from where the sample is taken; and
- f. The findings of inspection and other relevant facts.

**Sec. 5. Cases Referred by the Consumer Arbitration Officer or Government Office or Officer.** Cases referred by the Consumer Arbitration Officer or government office or officer shall undergo the FDA verification/investigation and shall proceed in accordance with Section 4 of this Article.

**Sec. 6. Anonymous Complaints/Petitions; Requests for Confidentiality.** Anonymous complaints and complaints/petitions by parties requesting confidentiality of their identities shall undergo the FDA verification/investigation and shall likewise proceed in accordance with Section 4 of this Article.

## **ARTICLE V**

### **SERVICE OF PLEADINGS AND OTHER PAPERS**

**Sec. 1. Filing and Service of Pleadings.** All pleadings and other papers in connection with the case shall be filed with the docketing unit in the FDA Central Office or appropriate FDA Regional Office.



**Sec. 2. Service of Summons, Notices, Decisions and Orders.** (a) Summons, notices, and copies of decisions and orders shall be served on the parties to the case personally by the duly authorized process server or other authorized officer of the FDA, or by registered mail, and such other acceptable modes of service. (b) The serving officer shall submit his return within three (3) days from date of service thereof, stating legibly in his return, his name, the name of person served, and the date of receipt, which return shall be immediately attached to and shall form part of the records of the case. If no service was effected, the serving officer shall state the reason therefore in his return.

## **ARTICLE VI**

### **PLEADINGS OR MOTIONS**

**Sec. 1. Prohibited Pleadings or Motions.** The following pleadings and motions shall be prohibited:

- a. Motion to dismiss, except a motion to dismiss based on lack of jurisdiction, which must be raised at the earliest opportunity;
- b. Motion for extension of time to file answer, affidavit, position paper and other pleadings;
- c. Counterclaim or Cross-Claim;
- d. Third Party Complaint;
- e. Motion to Intervene;
- f. Dilatory Motion for Postponement;
- g. Motion for Bill of Particulars;
- h. Reply;
- i. Motion for Reconsideration of interlocutory orders or interim relief orders;
- j. Second Motion for Reconsideration.

## **ARTICLE VII**

### **PROCEEDINGS BEFORE THE FDA**

**Sec. 1. Docketing of Cases.** All complaints, petitions, formal charges and referrals shall be properly received and docketed at the FDA Central Office or at the FDA Regional Office.

**Sec. 2. Summons.** Within five (5) days from the commencement of action, summons shall be served on the respondent/s, attaching thereto the Complaint/Petition and the supporting documents, and requiring him/her to file his/her Answer within a non-extendible period of ten (10) days from receipt of the summons.



**Sec. 3. Temporary and/or Preventive Measure Order.** At any time after the commencement of the administrative action and before judgment, a temporary and/or preventive measure order may be issued by the FDA.

- a. The Regional Field Director may issue cease and desist orders *motu proprio* or upon verified complaint for health products, whether or not registered with the FDA. However, for registered health products, the cease and desist order is only valid for thirty (30) days but it may be extended for another sixty (60) days if deemed appropriate, in a summary hearing, by the Regional Field Director.
- b. With prior approval of the Director-General, the Regional Field Director, for the purpose of preventing the disposition or tampering of evidence, the continuance of acts being complained of, and the flight of the respondent, as the case may be, may order:
  - (1) The seizure of the health products subject of the complaint or action;
  - (2) The padlocking of the warehouse, building, factory, store, shop, or any other structure where the said health products are contained or stored;
  - (3) The withholding of such health products from being transported or transferred;
  - (4) The seizure of paraphernalia, machines, vehicles and the like believed to have been used in the commission of the offense.

## **ARTICLE VIII**

### **PRELIMINARY CONFERENCE**

**Sec. 1. Preliminary Conference/Clarificatory Hearing.** Except on *motu proprio* cases, the Regional Field Director, may upon motion of any party schedule the Preliminary Conference, which shall not be later than fifteen (15) days from the receipt of the Answer, to consider the following issues:

- (1) The simplification of the issues;
- (2) The necessity or desirability of amendments to the pleadings;
- (3) The possibility of obtaining stipulations or admissions of facts and of documents;
- (4) Such other matters as may aid in the prompt disposition of the case.





When deemed appropriate by the Regional Field Director or upon motion by either party, clarificatory hearing may be held during the Preliminary Conference.

## **ARTICLE IX** **SUBPOENA**

**Sec. 1. *Subpoena duces tecum and ad testificandum.*** The Regional Field Director may issue *subpoena duces tecum* and *subpoena ad testificandum*, requiring the production of such books, contracts, correspondence, records, statement of accounts and other documents and/or the attendance or testimony of parties and witnesses as may be material to the investigation of the case.

## **ARTICLE X** **POSITION PAPER**

### **Sec. 1. Submission of Position Paper and Supporting Evidence.**

(a) In cases where a Preliminary Conference/Clarificatory hearing is conducted, within fifteen (15) days from the termination thereof, the parties shall simultaneously submit their respective position paper with supporting affidavits and other documentary evidence.

(b) In *motu proprio* cases, the respondent shall submit his/her position paper with supporting affidavits and other documentary evidence within fifteen (15) days from receipt of the Summons.

(c) The supporting affidavits shall take the place of direct testimony. Affidavits and supporting documentary evidence which were annexed to the complaint or formal charge, and the answer, as the case may be, and forming part of the records of the case, are deemed automatically reproduced for purposes of presentation of evidence and need not be annexed to the position papers. They shall, however, be distinctly identified for reference in the position paper.

## **ARTICLE XI** **DECISION AND ADMINISTRATIVE PENALTIES/SANCTIONS**

**Sec. 1. When a case is submitted for decision.** The case shall be deemed submitted for decision from the time of receipt of the filed last pleading, brief



or memorandum as may be required by these Rules or the expiration of the period for its filing.

**Sec. 2. Findings and Recommendation of the Regional Field Director.**

Within fifteen (15) days from the time the case is submitted for decision, the Regional Field Director shall make his/her findings and recommendations in writing. The recommendation shall be clear and concise, and shall contain statements on: (a) the relevant facts of the case; (b) the issue/s involved; (c) applicable law and/or jurisprudence; (d) conclusions and reasons therefor; and (c) the relief/s granted, if any, and the suggested administrative penalty/ies imposed, if any. He/she shall forthwith elevate all records to the Office of the Deputy Director-General for Field Operations for review.

**Sec. 3. Review and Recommendations of the Deputy Director General for Field Operations.**

Within fifteen (15) days from receipt of the findings and recommendations of the Regional Field Director, the Deputy Director General for Field Operations shall forthwith transmit to the Director General his/her own findings, reviews, and recommendations.

**Sec. 4. Decision of the Director-General.** The Director General shall issue a decision in writing, within fifteen days (15) days from the receipt of the records and the recommendation of the Deputy Director General for Field Operations. The decision shall contain the following: (a) the relevant facts of the case; (b) the issue/s involved; (c) applicable law and/or jurisprudence; (d) conclusions and reasons therefor; and (c) the relief/s granted, if any, and the administrative penalty/ies imposed, if any.

**Sec. 5. Imposition of Administrative Penalties.** The Director-General shall have the power to impose administrative penalties upon the respondent, if warranted, and even if these have not been prayed for by the complainant but required by the nature of the violation, to wit:

- (1) The seizure and condemnation, destruction and/or appropriate disposition of the subject health product;
- (2) The imposition of an administrative fine in such amount as deemed reasonable, which shall in no case be less than Fifty Thousand Pesos (Php50,000.00) nor more than Five Hundred Thousand Pesos (Php500,000.00) depending on the gravity of the offense, and the additional administrative fine of not more than One Thousand Pesos (Php1,000.00) for each day of continuing violation;



- (3) Suspension of the validity of the License To Operate (LTO), Certificate of Product Registration (CPR), or other appropriate authorizations for a period which shall not exceed one (1) year;
- (4) Revocation of LTO, CPR or appropriate authorization;
- (5) Closure of the establishment
- (6) Other penalties provided by relevant laws being administered or implemented by the FDA.

## **ARTICLE XII**

### **FINALITY OF DECISIONS/APPEAL**

**Sec. 1. Finality of Decision.** The orders, rulings or decisions of the FDA shall become final and executory fifteen (15) days after the receipt of a copy thereof by the party adversely affected, unless the Director General finds that public health requires the immediate execution thereof.

**Sec. 2. Motion for Reconsideration or Appeal.** Within fifteen (15) days from receipt of the Decision, the adverse party may file a Motion for Reconsideration with the Director General or a Notice of Appeal with the Secretary of Health.

**Sec. 3. Motion for Reconsideration.** The Motion for Reconsideration shall be in writing and shall point specifically the findings or conclusions of Decision which are not supported by the evidence or which are contrary to law. Only one (1) motion for reconsideration shall be filed, which shall suspend the running of the period for filing the appeal. However, a Pro-Forma Motion for Reconsideration shall not suspend the period for filing an appeal.

**Sec. 4. Appeal.** The appeal shall be taken by filing Notice of Appeal with the FDA and the posting of the corresponding appeal bond

**Sec. 5. Appeal does not stay execution.** An appeal does not stay the decision appealed from unless an order from the Secretary of Health is issued to stay the execution thereof.



### ARTICLE XIII EXECUTION OF DECISIONS

**Sec. 1. Execution.** (a) As soon as a decision becomes final and executory, either upon motion of the interested party or *motu proprio*, the Director General shall, or in instances of appealed cases, the Secretary shall direct the Director General to, issue an Order of Execution with the corresponding Writ of Execution, requesting the Regional Enforcement Unit of the FDA to execute said decision. No deputation is necessary.

(b) Any department, office or agency and deputized members of the Philippine National Police (PNP), the National Bureau of Investigation (NBI), or any law enforcement agency (other than the Regulatory Enforcement Unit) may be enlisted for the effective execution of the orders, rulings or decisions of the FDA.

### ARTICLE XIV OTHER PROVISIONS

**Sec. 1. Treatment of Pending Cases.** All cases for violations of relevant laws being administered or implemented by the FDA, their corresponding implementing rules and regulations, or FDA-promulgated issuances, which are still pending with the various FDA offices on the date of effectivity of these Rules and Regulations, shall continuously be adjudicated in accordance with the rules of procedures and designations existing immediately prior to the effectivity of these Rules and Regulations.



## BOOK IV

### ARTICLE I TRANSITORY PROVISIONS

**Sec. 1. Continuation of Appointments.** The Bureau of Food and Drugs (BFAD) Director and BFAD Deputy Director shall perform the powers, functions and responsibilities of the respective position of FDA Director-General and Deputy Director-General for Field Regulatory Operations, until the positions shall have been approved and new appointments are made and issued by the President of the Republic of the Philippines. The current officials and employees of the BFAD shall be transferred, as far as practicable, to the appropriate unit in the FDA as determined by the FDA Director-General.

The current officials and employees of the Bureau of Health Devices and Technology (BHDT) shall be transferred to the Center for Device Regulation, Radiation Health, and Research.

The current regional food and drug regulation officers and regional health physicists under the Centers for Health Development (CHD) of the DOH shall be transferred, as far as practicable, to the appropriate unit in the FDA as determined by the FDA Director-General.

The existing directors of the BHDT and division chiefs of the BFAD shall be given preference for appointment as directors and assistant directors of their respective Centers; Provided that, if the current officers of the BFAD and the BHDT applying for the above positions lack the required third level civil service eligibility, they will have to comply with the said requirement within three (3) years from their appointment, otherwise their appointment shall be revoked immediately.

**Sec. 2. No Demotion in Ranks and Positions and No Diminution in Salaries, Benefits, Allowances and Emoluments.** There shall be no demotion in rank and position and no diminution in salaries, benefits, allowances and emoluments of all BFAD, BHDT and indicated CHD personnel transferred to the FDA.

**Sec. 3. Transfer of Positions and Functions; Transfer of Facilities, Equipment, etc.** All positions, powers, functions and duties, together with the facilities, equipment, supplies, records, files, appropriations, and funds of the present existing bureaus and the indicated CHD personnel shall be transferred to the FDA.



The following Organizations within the FDA are hereby established:

1. Center for Drug Regulation and Research. The appropriate personnel, and their equipment, supplies, materials, records and facilities, from the Product Services Division, Regulation Division I and II (BFAD) who are tasked with regulating drugs are hereby placed as part of the Licensing and Registration Division, and the Product Research and Standards Development Division. The appropriate personnel and equipment assigned to regulate drug products under the Laboratory Services Division (BFAD) are hereby placed as part of its Laboratory Support Division. An Officer-in-Charge shall be designated by the Secretary of Health within thirty (30) days from the promulgation of these Rules and Regulations. Thereafter, the designated Officer-in-Charge shall submit within one hundred eighty (180) days from such designation, subject to the concurrence of the FDA Director General, the list of personnel, equipment and other accountable resources to the Secretary of Health.
2. Center for Food Regulation and Research. The appropriate personnel, and their equipment, supplies, materials, records, and facilities from the Product Services Division, Regulation Division I and II (BFAD) who are tasked with regulating food products are hereby placed as part of the Licensing and Registration Division, and the Product Research and Standards Development Division. The appropriate personnel and equipment assigned to regulate food products under the Laboratory Services Division (BFAD) are hereby placed as part of its Laboratory Support Division. An Officer-in-Charge shall be designated by the Secretary of Health within thirty (30) days from the promulgation of these Rules and Regulations. Thereafter, the designated Officer-in-Charge shall submit within one hundred eighty (180) days from such designation, subject to the concurrence of the FDA Director General, the list of personnel, equipment and other accountable resources to the Secretary of Health.
3. Center for Cosmetics Regulation and Research. The appropriate personnel, and their equipment, supplies, materials, records, and facilities, from the Product Services Division, Regulation Division I and II (BFAD) who are tasked with regulating cosmetic products are hereby placed as part of the Licensing and Registration Division, and the Product Research and Standards Development Division. The appropriate personnel and equipment assigned to regulate cosmetic products under the Laboratory Services Division (BFAD) are hereby placed as part of its Laboratory Support Division. An Officer-in-Charge



shall be designated by the Secretary of Health within thirty (30) days from the promulgation of these Rules and Regulations. Thereafter, the designated Officer-in-Charge shall submit within one hundred eighty (180) days from such designation, subject to the concurrence of the FDA Director General, the list of personnel, equipment and other accountable resources to the Secretary of Health.

4. Center for Device Regulation, Radiation Health, and Research. The personnel from the Bureau of Health Devices and Technology, along with their equipment, supplies, materials, records and facilities are hereby placed under the Center for Device Regulation, Radiation Health, and Research. The Director IV and Director III of BHDT are hereby designated as the Center Director and Center Assistant Director, respectively. In the meantime, the Director IV shall submit within one hundred eighty (180) days, subject to the concurrence of the FDA Director General, the specific task assignment of the Center's personnel that would constitute its Licensing and Registration Division, Product Research and Standards Development Division, Laboratory Support Division and Radiation Regulation Division. Any personnel, equipment, records, supplies and materials from BFAD assigned to do device regulation shall be also placed under this Center.
5. In the case of the Radiation Regulation Division in the preceding paragraph, it shall have the function of issuing certificates of compliance with technical requirements as basis for the issuance of appropriate authorizations regarding the use of radiation devices and operation of radiation facilities until such time that the appropriate division of the Regional Field Offices shall have been provided with appropriately equipped personnel to perform such function.
6. 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. Accordingly, the respective Center Directors through the chiefs of the laboratory support divisions shall coordinate and cooperate with each other as regards the utilization of the current BFAD central laboratory facilities until such time when they shall have been adequately upgraded, equipped, and staffed to administer, manage, and operate their own testing laboratories for their respective Centers.



7. The current satellite laboratories in Cebu and Davao shall exercise the powers and functions of the satellite laboratory division.
8. Administration and Finance Office. The personnel, along with their equipment, supplies, materials, records and facilities from BFAD and BHDT who are tasked to perform Human Resource Management, Human Resource Development, Property and Logistics Management (including Transport), Procurement, Assets and Financial Management, and Information and Communication Technology Management shall be placed under the subject Office. The Secretary of Health shall designate an Officer-in-Charge for the subject Office within thirty (30) days from the promulgation of these Rules and Regulations. Thereafter, the Officer-in-Charge shall submit within one hundred eighty (180) days from such designation, subject to the concurrence of the FDA Director General, the list of personnel, equipment and accountable resources to the Secretary of Health.
9. Policy and Planning Office. The personnel of Policy Planning and Advocacy Division, along with their equipment, supplies, materials, records and facilities, of BFAD and BHDT, who are tasked to perform policy development, planning, training, advocacy, communications, inter-office relations, media relations, shall be placed under the subject Office. The Secretary of Health shall designate an Officer-in-Charge for the subject Office within thirty (30) days from the promulgation of these Rules and Regulations. Thereafter, the Officer-in-Charge shall submit within one hundred eighty (180) days from such designation, subject to the concurrence of the FDA Director General, the list of personnel, equipment and accountable resources to the Secretary of Health.
10. Field Regulatory Operations Office. The personnel of the DOH Centers for Health Development (CHD), along with their equipment, supplies, materials, and records who are tasked to perform drug, food, cosmetics, devices and radiation health regulation shall constitute the initial human resource complement of the FDA Regional Offices and be placed under the supervision of the Field Regulatory Operations Office. As far as practicable, the regional offices shall be temporarily transferred to the Regional Offices of the Bureau of Quarantine. For this purpose, the transfer shall be done in accordance with a schedule to be established by the FDA. The FDA Laboratories in Subic, Cebu, and Davao, shall serve as the testing laboratories for the Luzon, Visayas and Mindanao regions, respectively. The Secretary of Health shall designate an Officer-in-Charge for the subject Field Regulatory and Operations Office and the Officer-in-Charge for each of the FDA





Regional Offices within thirty (30) days from the promulgation of these Rules and Regulations. Thereafter, the Officers-in-Charge of the said Offices shall submit within one hundred eighty (180) days from such designation, subject to the concurrence of the FDA Director General, the list of personnel, equipment and other assets to the Secretary of Health. The Officer-in-Charge of each of the Regional Field Offices shall in particular submit within one hundred eighty (180) days the specific task assignment of the Regional Field Offices personnel that would constitute its Licensing, Inspection and Compliance Division, Satellite Laboratory Division, as appropriate, and its Administrative Division.

11. Legal Services Support Center. The personnel, along with their equipment, supplies, materials, records, and facilities from BFAD and BHDT who are tasked to provide legal services shall be placed under the subject Office. The Secretary of Health shall designate an Officer-in-Charge for the subject Office within thirty (30) days from the promulgation of these Rules and Regulations. Thereafter, the Officer-in-Charge shall submit within one hundred eighty (180) days from such designation, subject to the concurrence of the FDA Director General, the list of personnel, equipment and other assets to the Secretary of Health.
12. The Office of the Director General and the Offices of the Deputy Director General (2). The FDA Director and Deputy Directors shall submit the list of personnel, equipment and other assets of their respective offices to the Secretary of Health within one hundred eighty (180) days from such appointment.

**Sec. 4. Establishment of the Regulatory Enforcement Units.** In the meantime that the Regulatory Enforcement Unit in each of the regions has not yet been established, the FDA may seek the assistance of other government law enforcement agencies in the implementation of its regulatory functions.

**Sec. 5. Existing Procedures, Rules and Regulations on the BFAD and BHDT.** Unless amended, superseded or repealed in these Rules and Regulations or issuances subsequently promulgated by the FDA, the existing rules and regulations issued by the BFAD & BHDT shall remain valid and in effect. Unless new procedures are established, the current procedures being enforced for the implementation of the FDA Act of 2009, other laws and their respective rules and regulations implemented by FDA shall remain in effect.

**Sec. 6. Human Resource Development and Expansion.** The head of the FDA or its Officer-in-Charge shall within sixty (60) days from appointment



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**Sec. 6. Human Resource Development and Expansion.** The head of the FDA or its Officer-in-Charge shall within sixty (60) days from appointment



submit to the Secretary of Health the list of vacant positions to be filled-up under the new FDA structure and the proposed positions to be created for the optimum fill-up of the FDA, including the budgetary requirement and source of funding, in accordance with Section 18 of RA 9711. Thereafter, the FDA shall publish the vacant positions to be filled-up to select and appoint qualified personnel in accordance with the appropriate civil service laws, rules and regulations.

**Sec. 7. Other Concerns.** Any other concerns not specifically covered by the above Articles shall be addressed by the issuance of subsequent policies and guidelines.


## **ARTICLE II**

### **SEPARABILITY, REPEALING, AND EFFECTIVITY CLAUSES**

**Sec. 1. Separability Clause.** If any of the provisions of these Rules and Regulations is found by a court of competent jurisdiction to be void or unenforceable, in whole or in part, such provision shall be deemed deleted from these Rules and Regulations but the remaining provisions thereof shall remain in full force and effect.


**Sec. 2. Repealing Clause.** All provisions of existing administrative orders, circulars, regulations and other issuances inconsistent with these Rules and Regulations are hereby repealed or amended accordingly, provided that nothing in these rules shall be deemed to modify the existing regulations issued pursuant to special laws implemented by the FDA, such as but not limited to the following: Executive Order No. 51 (Milk Code), Republic Act No. 8203 (Special Law on Counterfeit Drugs), Republic Act No. 8976 (Food Fortification Law), Republic Act No. 8172 (ASIN Law), and Republic Act No. 9502 (Cheaper Medicines Act).


**Sec. 3. Effectivity Clause.** These Rules and Regulations shall take effect after fifteen (15) days following its publication in a newspaper of national circulation and upon submission to the University of the Philippines Law Center.

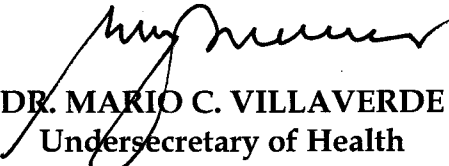
  
**ENRIQUE T. ONA, MD, FPCS, FACS**  
**Secretary of Health**

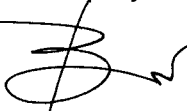


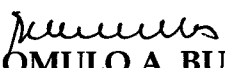
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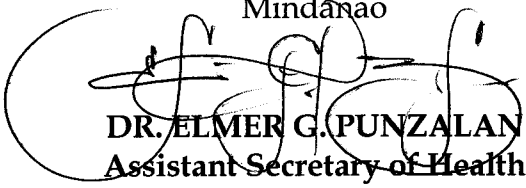
  
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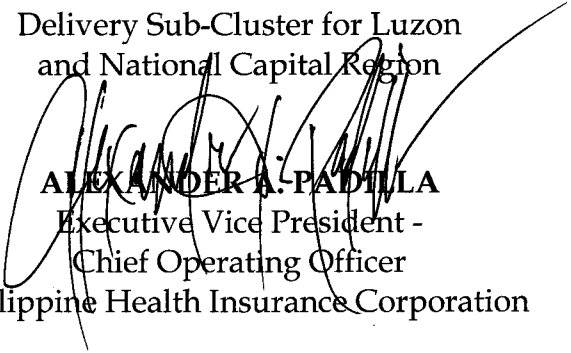
  
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