PHARMACEUTICAL JURISPRUDENCE AND ETHICS (Pharmacy 180/181)

DEPARTMENT OF PHARMACY
COLLEGE OF PHARMACY
UNIVERSITY OF THE PHILIPPINES

Taft Avenue cor. Pedro Gil St.
Ermita, Manila

Compiled by

Margarita M. Gutierrez, RPh

Name _____
Section _____ Schedule _____
Instructors _____
_____

Table of Contents

VIII. RA 8423: Traditional and alternative medicines Act of 1997

Chapter 5: Control in the use of dangerous and counterfeit drugs

I. RA 9502: Universally accessible Cheapers Medicine Act
II. PD 881: Hazardous Substance Decree
III. RA 8203: Counterfeit law
IV. RA 9165: Comprehensive Dangerous Drugs Act of 2002

Chapter 6: Laws pertaining to Public Health

I. EO 51: Milk code
II. RA 8172: Asin Law
III. RA 8976: food fortification Law
IV. RA 9211: Tobacco Regulation Act of 2003

Chapter 2: Standards of Pharmaceutical Education and Practice

RA 9711: Food and Drug Administration (FDA) Act of 2009

Republic of the Philippines
Congress of the Philippines
Metro Manila

Fourteenth Congress
Second Regular Session

Begun and held in Metro Manila, on Monday, the twenty-eighth day of July, two thousand eight.

Republic Act No. 9711 August 18, 2009

AN ACT STRENGTHENING AND RATIONALIZING THE REGULATORY CAPACITY OF THE BUREAU OF FOOD AND DRUGS (BFAD) BY ESTABLISHING ADEQUATE TESTING LABORATORIES AND FIELD OFFICES, UPGRADING ITS EQUIPMENT, AUGMENTING ITS HUMAN RESOURCE COMPLEMENT, GIVING AUTHORITY TO RETAIN ITS INCOME, RENAMING IT THE FOOD AND DRUG ADMINISTRATION (FDA), AMENDING CERTAIN SECTIONS OF REPUBLIC ACT NO. 3720, AS AMENDED, AND APPROPRIATING FUNDS THEREOF

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

Section 1. The Bureau of Food and Drugs (BFAD) is hereby renamed the Food and Drug Administration (FDA).

Section 2. This Act shall be known as the **"*Food and Drug Administration (FDA) Act of 2009*"**.

Section 3. It is hereby declared a policy of the State to adopt, support, establish, institutionalize, improve and maintain structures, processes, mechanisms and initiatives that are aimed, directed and designed to: (a) protect and promote the right to health of the Filipino people; and (b) help establish and maintain an effective health products regulatory system and undertake appropriate health manpower development and research, responsive to the country's health needs and problems. Pursuant to this policy, the State must enhance its regulatory capacity and strengthen its capability with regard to the inspection, licensing and monitoring of establishments, and the registration and monitoring of health products.

Section 4. This Act has the following objectives:

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

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

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

Section 5. Section 4 of Republic Act No. 3720, as amended, is hereby further amended to read as follows:

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

"(a) To administer the effective implementation of this Act and of the rules and regulations issued pursuant to the same;

"(b) To assume primary jurisdiction in the collection of samples of health products;

"(c) To analyze and inspect health products in connection with the implementation of this Act;

"(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;

"x x x

"(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, traders, distributors, importers, exporters, wholesalers, retailers, consumers, and non-consumer users 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 propio* or upon verified complaint for health produts, whether or not registered with the FDA *Provided*, That for registered health products, the cease and desist order is valid for thirty (30) days and may be extended for sixty (60) days only after due process has been observed;

"(k) After due process, to order 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, and to require all concerned to implement the risk management plan which is a requirement for the issuance of the appropriate authorization;

"(l) To strengthen the post market surveillance system in monitoring health products as defined in this Act and incidents of adverse events involving such products;

"(m) To develop and issue standards and appropriate authorizations that would cover establishments, facilities and health products;

"(n) To conduct, supervise, monitor and audit research studies on health and safety issues of health products undertaken by entities duly approved by the FDA;

"(o) To prescribe standards, guidelines, and regulations with respect to information, advertisements and other marketing instruments and promotion, sponsorship, and other marketing activities about the health products as covered in this Act;

"(p) To maintain bonded warehouses and/or establish the same, whenever necessary or appropriate, as determined by the director-general for confiscated goods in strategic areas of the country especially at major ports of entry; and

"(q) To exercise such other powers and perform such other functions a8 may be necessary to carry out its duties and responsibilities under this Act."

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

"SEC. 5. The FDA shall have the following centers and offices:

"(a) The Centers shall be established per major product category that is regulated, namely:

"(1) Center for Drug Regulation and Research (to include veterinary medicine, vaccines and biologicals);

"(2) Center for Food Regulation and Research;

"(3) Center for Cosmetics Regulation and Research (to include household hazardous/urban substances); and

"(4) Center for Device Regulation, Radiation Health, and Research.

"These Centers shall regulate the manufacture, importation, exportation, distribution, sale, offer for sale, transfer, promotion, advertisement, sponsorship of, and/or, where appropriate, the use and testing of health products. The Centers shall likewise conduct research on the safety, efficacy, and quality of health products, and to institute standards for the same.

"(b) Each Center shall be headed by a director. The Centers shall be so organized such that each will have, at least, the following divisions:

"(1) Licensing and Registration Division, which shall be responsible for evaluating health products and establishments as covered by this Act for the purpose of issuance of authorizations and conditions to be observed;

"(2) Product Research and Standards Development Division, which shall be responsible for the conduct of research, development of standards and regulations, compliance monitoring, and the oversight and audit of related researches that would ensure safety, quality, purity and efficacy of health products, as covered in this Act; and

"(3) Laboratory Support Division, which shall be responsible for the conduct of research and appropriate testa and calibration, analyses and trials of products including, but not limited to, assays, and the conduct of oversight and/or audit of centers conducting bioavailability and bioequivalence tests and other tests as covered by this Act. It shall likewise provide direct line support to the centers which shall be separate and distinct per major product category that is regulated.

"(c) The Administration and Finance Office headed by the deputy director-general for administration and finance shall have, at least, the following divisions: the Human Resource Development Division; Property and Logistics Management Division; Human Resource Management Division; Assets and Financial Management Division; and the Information and Communication Technology Management Division.

"(d) The Policy and Planning Office which shall be under the Office of the Director-General shall have, at least, a training, advocacy and communications division and shall monitor the performance of the centers for product research and evaluation and standards development.

"(e) The Field Regulatory Operations Office headed by the deputy director-general for field regulatory operations shall include, among others, all the field offices, field or satellite laboratories and the regulatory enforcement units.

"(f) The Legal Services Support Center shall provide legal services to the entire FDA and shall be directly under the Office of the Director-General."

Section 7. Section 6 of Republic Act No. 3720, as amended, is hereby further amended, to read as follows:

"(a) The FDA shall be headed by a director-general, with the rank of undersecretary, who shall be tasked, among others, to determine the needed personnel and to appoint personnel, below the assistant director level in coordination with the Secretary of Health.

"(b) The director-general shall be assisted by two (2) deputy directors-general, one for administration and finance and another for field regulatory operations.

"(c) The director-general and deputy directors-general shall be appointed by the President of the Republic of the Philippines.

"(d) The director-general shall, referably, possess either a university degree in medicine or at least the relevant master's degree in pharmaceutical sciences or allied sciences, or equivalent executive course in any regulatory management. In addition, he/she shall have management experience in his/her field of discipline or profession and in any development, manufacturing, regulatory work or quality assurance of products as covered in this Act.

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

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

"(g) A 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. All persons who are candidates for appointment as director-general and deputy director-general must disclose all their incomes for the past three (3) years from all establishments regulated by this Act. The director-general and the two (2) deputy directors-gencral shall, upon assumption into office, declare any conflict of interest with any establishment covered by the FDA, including their foundiitions.

"(h) Each center and field office shall be headed by a director director who shall be assisted by an assistant director. These directors shall be appointed by the Secretary of Health.

"(i) The existing directors of the Bureau of Health Devices and Technology (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) yearn from their appointment, otherwise their appointment shall be revoked immediately."

Section 8. Section 7 of Republic Act No. 3720, as amended, is hereby further amended to read as follows:

"The FDA shall review its staffing pattern and position titles subject to the approval of the Secretary of Health."

Section 9. Section 10, subsections (a), (e), (f), (g), (h), (i), (q),(r), (v), and (w) of Republic Act No. 3720, as amended, are hereby further amended, and new subsections (x), (y), (z), (aa), (bb), (cc), (dd), (ee), (ff), (gg), (hh), (ii), (jj), (kk), (ll), and (mm) are hereby added to read as follows:

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

"(a) 'FDA' means the Food and Drug Administration.

"x x x

"(e) 'Food' means any processed substance which is intended for human consumption and includes drink for man, beverages, chewing gum and any substances which have been used as an ingredient in the manufacture, preparation or treatment of food.

"(f) 'Drug' means: (1) articles recognized in official pharmacopeias and formularies, including official homeopathic pharmacopeias, 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 humans 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.

"(g) '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 its intended function by such means.

"(2) 'Radiation device' means an electrical or electronic apparatus emitting any ionizing or non-ionizing electromagnetic or particulate radiation; or any sonic; infrasonic, or ultrasonic wave. It includes ionizing radiation emitting equipment which is not intentionally designed to produce radioactive materials.

"(3) 'Health-related device' means any device not used in health care but has been determined by the FDA to adversely affect the health of the people.

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

"x x x

"(q) 'Director-general' means the head of the FDA.

"(r) '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.

"x x x

"(v) '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, formnlating, filling, packing, repacking, 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.

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

"(x) 'Assay' is an analysis to determine the (1) presence of a substance and the amount of that substance, or (2) the pharmaceutical potency of a drug.

"(y) '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.

"(z) 'Bioavailability' means the rate and extent to which the active ingredient or therapeutic ingredient is absorbed from a drug and becomes available at the site of drug action.

"(aa) 'Bioequivalence' means the rate and extent of absorption to which the drugs do not show a significant difference from the rate and extent of the listed drug when administered at the same molar dose of the therapeutic ingredient under similar experimental conditions in either a single dose or multiple doses. Bioequivalence shall also refer to the absence of a signiticant difference on the rate and extent-to-which the active ingredient(s) of the sample and reference drug becomes available at the site of drug action when administered under the same molar dose and under similar conditions.

"(bb) 'Distributor/importer/exporter' means any establishment that imports or exports raw materials, active ingredients and/or finished products for its own use or for wholesale distribution to other establishments or outlets. If the distributor/importer/exporter sells to the

general public, it shall be considered a retailer.

"(cc) 'Distributor/wholesaler' means any establishment that procures raw materials, active ingredients and/or finished products from local establishments for local distribution on wholesale basis.

"(dd) 'Establishment' means a sole proprietorship, a partnership, a corporation, an institution, an association, or an organization engaged in the manufacture, importation, exportation, sale, offer for sale, distribution, donation, transfer, use, testing, promotion, advertising, or sponsorship of health products including the facilities and installations needed for its activities.

"(ee) '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, herb, or other botanical, amino acid, and dietary substance 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 usually is in the form of capsules, tablets, liquids, gels, powders or pills and not represented for use as a conventional food or as the sole item of a meal or diet or replacement of drugs and medicines.

"(ff) '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.

"(gg) 'Household/urban hazardous substance' is:

"(1) Any substance or mixture of substances intended for individual or limited purposes and which is toxic, corrosive, an irritant, a strong sensitizer, is flammable or combustible, or generates pressure through decomposition, heat or other means, if such substance or mixture of substances may cause substantial injury or substantial illness during or as a proximate result of any customary or reasonably foreseeable ingestion by children, but shall not include agricultural fertilizer, pesticide, and insecticide, and other economic poisons, radioactive substance, 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 clause (1) of this paragraph;

"(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; and

"(4) This term shall not apply to food, drugs, cosmetics, devices, or to substances intended for use as fuels when stored in containers and used in the heating, cooking or refrigeration system of a house, but such term shall apply to any article which is not in itself an agricultural pesticide but which is a hazardous substance, as construed in paragraph (1) of this section, by reason of bearing or containing such harmful substances described therein.

"(hh) 'In-vitro diagnostic reagents' are reagents and systems intended for use in the diagnosis of disease or other conditions, including a determination of the state of health, in order to cure, mitigate, treat or prevent disease or its sequelae.

"(ii) '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.

"(jj) 'Misbranding' means, in addition to definitions in existing laws, misinformation or misleading information on the label or other information materials authorized by the FDA. It shall not refer to copyright, trademark, or other intellectual property-like instruments.

"(kk) '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.

"(ll) '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 subcontract the manufacture of such product to a licensed manufacturer. In addition, a trader may also engage in the distribution and/or marketing of its products.

"(mm) 'Retailer' means any establishment which sells or offers to sell any health product directly to the general public."

Section 10. Section 11, subsections (a), (b), (d), (g), (j),(k) and (l) of Republic Act No. 3720, as amended, are hereby further amended to read as follows:

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

"(a) The manufacture, importation, exportation, sale, offering for sale, distribution, transfer, non-consumer use, promotion, advertising, or sponsorship of any health product that is adulterated, unregistered or misbranded.

"(b) The adulteration or misbranding of any health product.

"x x x

"(d) The giving of a guaranty or undertaking referred to in Section twelve (b) hereof which guaranty or undertaking is false, except by a person who relied upon a guaranty or undertaking to the same effect, signed by, and containing the name and address of the person or entity from whom he received in good faith the health products or the giving of a guaranty or undertaking referred to in Section twelve (b) which guaranty or undertaking is false.

"x x x

"(g) The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to health products if such act is done while such article is held for sale (whether or not the first sale) and results in such article being adulterated or misbranded *Provided*, That a retailer may sell in smaller quantities, subject to guidelines issued by the FDA.

"x x x

"(j) The manufacture, importation, exportation, sale, offering for sale, distribution, transfer, non-consumer use, promotion, advertisement, or sponsorship of any health product which, although requiring registration, is not registered. with the FDA pursuant to this Act.

"(k) The manufacture, importation, exportation, sale, offering for sale, distribution, transfer, or retail of any drug, device or in-vitro diagnostic reagent; the manufacture, importation, exportation, transfer or distribution of any food, cosmetic or household/urban hazardous substance; or the operation

of a radiation or pest control establishment by any natural or juridical person without the license to operate from the FDA required under this Act.

"(l) The sale, offering for sale, importation, exportation, distribution or transfer of any health product beyond its expiration or expiry date, if applicable.

"x x x

"The prohibited acts mentioned herein shall cover all applicable health products."

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

"SEC. 12. (a) Any person who violates any of the provisions of Section eleven hereof shall, upon conviction, suffer the penalty of imprisonment ranging from one (1) year but not more than ten (10) years or a fine of not less than Fifty thousand pesos (P50,000.00) but not more than Five hundred thousand pesos (P500,000.00), or both, at the discretion of the court: *Provided*, That if the offender is a manufacturer, importer or distributor of any health product, the penalty of at least five (5) years imprisonment but not more than ten (10) years and a fine of at least Five hundred thousand pesos (P500,000.00) but not more than Five million pesos (P5,000,000.00) shall be imposed *Provided*, *further*, That an additional fine of one percent (1%) of the economic value/cost of the violative product or violation, or One thousand pesos (P1,000.00), whichever is higher, shall be imposed for each day of continuing violation: *Provided*, *finally*, That health products found in violation of the provisions of this Act and other relevant laws, rules and regulations may be seized and held in custody pending proceedings, without hearing or court order, when the director-general has reasonable cause to believe from facts found by him/her or an authorized officer or employee of the FDA that such health products may cause injury or prejudice to the consuming public.

"x x x

"Should the offense be committed by a juridical person, the Chairman of the Board of Directors, the president, general manager, or the partners and/or the persons directly responsible therefore shall he penalized.

"Should the offense be committed by a foreign national, he/she shall, in addition to the penalties prescribed, be deported without further proceedings after service of sentence.

"x x x."

Section 12. Section 26, subsections (c) and (d) of Republic Act No. 3720, as amended, are hereby further amended and subsection (g) is hereby added thereto to read as follows:

"x x x

"(c) Hearings authorized or required by this Act shall be conducted by the FDA.

"(d) Upon preliminary findings of the conduct of prohibited act/s, the director-general shall issue the proper notices or orders to the person or persons concerned and such person or persons shall be given an opportunity to be heard before the FDA.

"x x x

"(g) Both criminal and administrative actions may be instituted separately and independent of one another."

Section 13. Section 29-A of Republic Act No. 3720, as amended, is hereby further amended, and new subsections are added to read as follows:

"SEC. 29-A. *Administrative Sanctions*. - Where there is finding of prohibited actions and determination of the persons liable thereto, after notice and hearing, the director-general is empowered to impose one or more of the following administrative penalties:

"(1) Cancellation of any authorization which may have been granted by the FDA, or suspension of the validity thereof for such period of time as the director-general may deem reasonable which shall not exceed one (1) year:

"(2) A fine of not less than Fifty thousand pesos (P50,000.00) but not more than Five hundred thousand pesos (P500,000.00). An additional fine of not more than One thousand pesos (P1,000.00) shall be imposed for each day of continuing violation; and

"(3) Destruction and/or appropriate disposition of the subject health product, and/or closure of the establishment for any violation of this Act, as determined by the director-general."

Section 14. A new Section 30 and a new headnote "Additional Powers and Functions of the Director-General" are hereby added to Republic Act No. 3720, which shall read as follows:

"SEC. 30. The Director-General shall also exercise the following powers:

"(1) To hold in direct or indirect contempt any person who disregards orders or writs he or she issues and impose the appropriate penalties following the same procedures and penalties provided in the Rules of Court;

"(2) 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 the investigation conducted by the FDA;

"(3) To obtain information from any officer or office of the national or local governments, government agencies and its instrumentalities;

"(4) To issue orders of seizure, to seize and hold in custody any article or articles of food, device, cosmetics, household hazardous substances and health products that is adulterated, counterfeited, misbranded or unregistered, or drug, in-vitro diagnostic reagent, biologicals, and vaccine that is adulterated or misbranded, when introduced into domestic commerce pending the authorized hearing under Republic Act No. 3720, as amended, Executive Order No. 175 (1987), and Republic Act No. 7394, otherwise known as the Consumers Act of the Philippines;

"(5) To call on the assistance of any department, office or agency and deputize members of the Philippine National Police or any law enforcement agency for the effective implementation of this Act; and

"(6) To exercise such powers and functions as may be necessary for the effective implementation of this Act."

Section 15. Two new sections shall be added, which shall be the new Sections 31 and 32 of Republic Act No. 3720, as amended, which shall read as follows:

"SEC. 31. 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 within that period, an administrative appeal has been perfected. One motion for reconsideration may be filled, which shall suspend the running of the said period."

"SEC. 32. The orders, rulings or decisions of the FDA shall be appealable to the Secretary of Health. An appeal shall be deemed perfected upon filing of the notice of appeal and posting of the corresponding appeal bond.

"An appeal shall not stay the decision appealed from unless an order from the Secretary of Health is issued to stay the execution thereof."

Section 16. Section 30 of Republic Act No. 3720, as amended, shall be renumbered as

Section 33, and the subsequent sections shall also be renumbered accordingly.

Section 17. Section 31, Chapter XIII of Republic Act No. 3720, as amended, is hereby further amended to read as follows:

"SEC. 34. *Fees and Other Income*. -

"(a) Upon the sole approval of the Secretary, the authorization and other fees shall annually be determined and reviewed by the FDA and any proposed increase shall be published in two (2) leading newspapers of general circulation.

"(b) There shall be determined and constituted additional fees such as sale of publications and services, assessment fees, fines, penalties, and other fees and charges outside the usual licensing and registration fees, to be known as 'other related regulatory fees'.

"(c) The Director-General of the FDA, upon approval of the Secretary, shall be authorized to promulgate rules and regulations governing the collection of the 'other related regulatory fees'. Upon approval of the Secretary, these fees shall likewise be reviewed periodically and any proposed increase shall be published in two (2) leading newspapers of general circulation."

Section 18. All income that the FDA is allowed to retain under Section 31 of the Universally Accessible Cheaper and Quality Medicines Act of 2008 shall, any provision of law to the contrary notwithstanding, be deposited in an authorized government depository bank as a special regulatory fund. 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 ofthe central office laboratory divisions and satellite laboratories in Davao, Cebu and other testing laboratories, in case the above laboratories will be increased, and other activities or services of the agency in the performance of its mandate.

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

The retention, use and application of this fund shall not be delayed, amended, altered or modified, or affected in any way by an order or directive from any executive office, but will be subject only to the general accounting rules and guidelines by the Commission on Audit (COA). The primary purpose of the fund as herein stated shall prevail over any other purpose that may be pursued by the FDA on its own initiative or through an order or directive by any higher office. The FDA shall submit to the Secretary of Health, the Secretary of Budget and Management and the Congressional Oversight Committee, created under Section 23 of this Act, a report on how the funds were utilized, including its accomplishments.

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.

Section 19. The FDA shall establish a Regulatory Enforcement Unit (REU) for a period not exceeding five (5) years from the effectivity of this Act. It shall be composed of at least five (5) qualified personnel in every region who shall be directly under the control and supervision of the Deputy Director-General for Field Regulatory Operations and shall be administratively supported by the field offices. They shall:

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

(b) Serve and execute rulings, orders, and decisions of the Director-General of the FDA; and

(c) Execute and serve search warrants and arrest warrants issued by the courts in connection with violations under this Act and related laws concerning the regulation of health products.

All law enforcement agents shall undergo the appropriate training to equip them with the necessary skills needed for this purpose. Their authority and functions shall be strictly limited to the implementation of the FDA's regulatory functions.

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

Section 20. A new chapter XIV and three new sections, Sections 35, 36, and 37 shall be introduced, which shall read as follows:

"CHAPTER XIV
"TESTING LABORATORIES AND FIELD OFFICES

"SEC. 35. The FDA is hereby mandated to improve, upgrade and increase the capability of the agency, to test, calibrate, assay and examine samples of health products. For the purpose of achieving the above mandate, there shall be established at least one (1) testing laboratory each in Luzon, Visayas and Mindanao, which shall have the necessary and appropriate state-of-the-art laboratory equipment and personnel complement. The main testing laboratories at the central office shall be maintained and shall serve as a support unit to the centers for product research and evaluation and standards development and shall serve as testing centers that would include assay and the conduct, supervision, oversight and/or audit of bioequivalence and bioavailability test/researches, among others. The existing laboratories in Cebu and Davao will be upgraded and transformed as quality assurance laboratories, while another one will be established in Subic, Zambales.

"The testing laboratories may be increased by the director-general, upon approval of the Secretary. Moreover, the director-general, upon approval of the Secretary, may call upon other government and private testing laboratories to conduct testing, calibration, assay and examination of samples of health products: *Provided*, That the private testing laboratories are accredited by the Philippine Accreditation Office (PAO) of the Department of Trade and industry (DTI) and the DOH."

"SEC. 36. The FDA shall establish field offices in all regions of the country to effectively implement its regulatory functions. The current regional food and drug regulatory officers and regional health physicists in every regional office of the DOH shall now be put under the FDA's sole control and supervision. The regional field office shall also assume primary jurisdiction in the collection of samples of food, drugs, devices and cosmetics being imported or offered for import at a port of entry other than Manila in his/her assigned region and where it appears that said items or products satisfy any of the conditions as provided for in Section 33(a) of Republic Act No. 3720, as amended, without prejudice to the exercise of the powers of the director-general provided under Sections 13 and 14 of this Act in the exercise of the agency's regulatory functions. The field offices shall be comprised of the following: (a) licensing, inspection and compliance division, which shall have charge of the inspection of food, drugs and cosmetic establishments engaged in their manufacture, importation, distribution, and sale; (b) satellite laboratory division; and (c) administrative division."

"SEC. 37. The FDA, with the approval of the Secretary, shall create organizational units which are deemed necessary to address emerging concerns and to be abreast with internationally acceptable standards. There shall be created additional plantilla positions to augment the human resource complement of the FDA, subject to existing rules and regulations."

Section 21. *Appropriations*. - The appropriations for the BFAD and the BHDT

included in the budget of the DOH under the current General Appropriations Act shall be used to carry out the implementation of this Act. The appropriation may be augmented by the income which the agency is authorized to use under this Act. Thereafter, such sums as may be necessary for its continued implementation shall be included in the annual General Appropriations Act.

Section 22. *Implementing Rules and Regulatiorts*. - The DOH shall promulgate, in consultation with the FDA, the implementing rules and regulations of this Act within one hundred twenty (120) days after the passage of this Act.

Section 23. *Congressional Oversight Committee*. - A Congressional Oversight Committee (COC) is hereby created composed of the Chairpersons of the Committees on Health and Appropriations of the House of Representatives and two (2) Members to be appointed by the Speaker, the Chairpersons of the Committees on Health and Finance of the Senate and two (2) Members to he appointed by the President of the Senate, to oversee the implementation of this Act for a period of five (5) years and to review the accomplishments and the utilization of income of the FDA. The secretariat of the COC shall be drawn from the existing personnel of the committees comprising the COC.

Section 24. *Transitory Provisions*. - The BFAD Director and Deputy Director shall serve as FDA Director-General and Deputy Director-General for Field Regulatory Operations, respectively. 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 Director-General. The current officials and employees of the BHDT shall be transferred to the Center for Device Regulation, Radiation Health, and Research. The current regional food and drug regulatory officers and regional health physicists under the Centers for Health Development of the DOH shall be transferred as far as practicable to the appropriate unit in the FDA as determined by the Director-General. There shall be no demotion in ranks and positions and no diminution in salaries. benefits, allowances and emoluments of all BFAD, BHDT and indicated Center for Health and Development (CHD) personnel transferred to the FDA. All positions, powers, functions and duties together with the facilities, equipment, supplies, records, files, appropriations, and funds for these bureaus and the indicated CHD personnel shall be transferred to the FDA.

Section 25. *Coverage*. - This Act shall govern all health products: *Provided*, That nothing in this Act shall be deemed to modify the sole and exclusive jurisdiction of other specialized agencies and special laws only insofar as the acts covered by these specialized agencies and 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.

Section 26. *Separability Clause*. - If any part, section or provision of this Act shall be declared invalid or unconstitutional, other provisions or parts thereof which are not affected thereby shall remain in full force and effect.

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

Section 28. *Effectivity Clause*. - This Act shall take effect fifteen (15) days after its publication in the Official Gazette or in two (2) newspapers of generhl circulation.

Approved,

(Sgd.) **PROSPERO C. NOGRALES**
Speaker of the House of Representatives

(Sgd.) **JUAN PONCE ENRILE**
President of the Senate

This Act which is a consolidation of Senate Bill No. 2645 and House Bill No. 3293 was finally passed by the Senate and the House of Representatives on June 3, 2009.

(Sgd.) **MARILYN B. BARUA-YAP**
Secretary General
House of Represenatives

(Sgd.) **EMMA LIRIO-REYES**
Secretary of Senate

Approved: **AUG 18 2009**

(Sgd.) **GLORIA MACAPAGAL-ARROYO**
President of the Philippines

RA 3720: Food, Drug, and Cosmetics Act

REPUBLIC ACT No. 3720

AN ACT TO ENSURE THE SAFETY AND PURITY OF FOODS, DRUGS, AND COSMETICS BEING MADE AVAILABLE TO THE PUBLIC BY CREATING THE FOOD AND DRUG ADMINISTRATION WHICH SHALL ADMINISTER AND ENFORCE THE LAWS PERTAINING THERETO.

CHAPTER I
Title

Section 1. This Act shall be known as the "Food, Drug, and Cosmetic Act."

CHAPTER II
Declaration of Policy

Section 2. It is hereby declared the policy of the State to insure safe and good quality supply of food, drug and cosmetic, and to regulate the production, sale, and traffic of the same to protect the health of the people.

Section 3. In the implementation of the foregoing policy, the Government shall in accordance with the provisions of this Act:

(a) Establish standards and quality measures for food, drug, and cosmetic.

(b) Adopt measures to insure pure and safe supply of food, drug, and cosmetic in the country.

CHAPTER III
Creation of the Food and Drug Administration

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

(a) To administer and supervise the implementation of this Act and of the rules and regulations issued pursuant to the same.

(b) To provide for the collection of samples of food, drug and cosmetic.

(c) To analyze and inspect food, drug and cosmetic in connection with the implementation of this Act.

(d) To establish analytical data to serve as basis for the preparation of food, drug and cosmetic standards, and to recommend standards of identity, purity, quality and fill of container.

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

(f) To levy, assess and collect fees for inspection, analysis and testing of products and materials submitted in compliance with the provisions of this Act.

(g) To certify batches of anti-biotic and anti-biotic preparations in compliance with the provisions of this Act.

Section 5. The Food and Drug Administration shall have the following Divisions:

(a) Inspection and Licensing Division, which shall have charge of the inspection of food, drug, and cosmetic

establishments engaged in their manufacture and sale.

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

Section 6. The Food and Drug Administration shall have a Food and Drug Administrator who shall be appointed by the Secretary of Health subject to the Civil Service rules and regulations. The compensation of said official shall be determined by the Secretary of Health.

Section 7. The Secretary of Health shall provide for the additional personnel needed to carry out the functions and duties of the Food and Drug Administration.

Section 8. The powers, functions and duties of the Division of Food and Drug Testing of the Bureau of Research and Laboratories and the Board of Food Inspection, all personnel in the Bureau of Health Services who are engaged in food and drug control work, together with all their equipment, supplies, records, files, personnel and balance of appropriations are transferred to the Food and Drug Administration.

CHAPTER IV
Board of Food and Drug Inspection

Section 9. The Board of Food Inspection is hereby converted into the Board of Food and Drug Inspection which shall consist of:

(a) A representative of the Department of Health to be designated by the Secretary of Health, as Chairman;

(b) A representative of the Department of Agriculture and Natural Resources;

(c) A representative of the Department of Commerce and Industry;

(d) An authorized designate of the Commissioner of Customs;

(e) An authorized representative of the Office of the Solicitor-General;

(f) A technical member to be designated by the Food and Drug Administrator with the approval of the Secretary of Health.

(g) The President of the Philippine Medical Association of his authorized representative;

(h) The President of the Philippine Dental Association or his authorized representative; and

(i) The President of the Philippine Pharmaceutical Association or his authorized representative.

Each member of the Board as well as the Board secretary shall receive a per diem of twenty pesos per meeting, hearing or investigation actually attended, but in no case shall the total per diem exceed two hundred pesos each per month.

It shall be the duty of the Board, conformably with the rules and regulations, to hold hearings and conduct investigations relative to matters touching the administration of this Act, to investigate processes of food, drug and cosmetic manufacture and to submit reports to the Food and Drug Administrator, recommending food and drug standards for adoption. Said Board shall also perform such additional functions, properly within the scope of the administration hereof, as may be assigned to it by the Food and Drug Administrator. The decisions of the Board shall be advisory to the Food and Drug Administrator.

CHAPTER V
Definitions

Section 10. For the purposes of this Act, the term:

(a) "Board" means the Board of Food and Drug Inspection.

(b) "Secretary" means the Secretary of Health.

(c) "Department" means the Department of Health.

(d) "Person" includes individual, partnership, corporation and association.

(e) "Food" means (1) articles used for food or drink for man, (2) chewing gum, and (3) articles used for components of any such article.

(f) "Drug" means (1) articles recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (2) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (3) articles (other than food) intended to affect the structure or any function of the body of man or animals; and (4) articles intended for use as a component of any articles specified in clauses (1), (2), or (3), but not include devices or their components, parts, or accessories.

(g) "Device" means instruments, apparatus, or contrivances, including their components, parts, and accessories, intended (1) for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or animals; or (2) to affect the structure or any function of the body of man or animals.

(h) "Cosmetic" means (1) articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and (2) articles intended for use as a component of any such articles.

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

(j) "Immediate container" does not include package liners.

(k) "Labeling" means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.

(l) "New drugs" mean:

(1) any drug the composition of which is such that said drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety of drugs, as safe for use under the conditions prescribed, recommended, or suggested in the labeling thereof.

(2) any drug the composition of which is such that said drug, as a result of investigations to determine its safety for use under such conditions, has become so recognized, but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions.

(m) If an article is alleged to be misbranded because the labeling is misleading, then in determining whether the labeling is misleading there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article to which the labeling relates under the conditions of use prescribed in the labeling thereof or under such conditions of use as are customary or usual.

(n) "Food additive" means any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise

affecting the characteristics of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food; and including any source of radiation intended for any such use), if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures to be safe under the conditions of its intended use.

CHAPTER VI
Prohibited Acts and Penalties

PROHIBITED ACTS

Section 11. The following acts and the causing thereof are hereby prohibited: (a) The manufacture, sale, offering for sale or transfer of any food, drug, device or cosmetic that is adulterated or misbranded.

(b) The adulteration or misbranding of any food, drug, device, or cosmetic.

(c) The refusal to permit entry or inspection as authorized by Section twenty-seven hereof or to allow samples to be collected.

(d) The giving of a guaranty or undertaking referred to in Section twelve (b) hereof which guaranty or undertaking is false, except by a person who relied upon a guaranty or undertaking to the same effect signed by, and containing the name and address of, the person residing in the Philippines from whom he received in good faith the food, drug, device, or cosmetic or the giving of a guaranty or undertaking referred to in Section twelve (b) which guaranty or undertaking is false.

(e) Forging, counterfeiting, simulating, or falsely representing or without proper authority using any mark, stamp, tag label, or other identification device authorized or required by regulations promulgated under the provisions of this Act.

(f) The using by any person to his own advantage, or revealing, other than to the Secretary or officers or employees of the Department or to the courts when relevant in any judicial proceeding under this Act, any information acquired under authority of Section nine, or concerning any method or process which as a trade secret is entitled to protection.

(g) The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to, a food, drug, device, or cosmetic, if such act is done while such article is held for sale (whether or not the first sale) and results in such article being adulterated or misbranded.

(h) The use, on the labeling of any drug or in any advertising relating to such drug, of any representation or suggestion that an application with respect to such drug is effective under Section twenty-one hereof, or that such drug complies with the provisions of such section.

(i) The use, in labeling, advertising or other sales promotion of any reference to any report or analysis furnished in compliance with Section twenty-six hereof.

PENALTIES

Section 12. (a) Any person who violates any of the provisions of Section eleven hereof shall, upon conviction, be subject to imprisonment of not less than six months and one day, but not more than five years, or a fine of not less than one thousand pesos, or both such imprisonment and fine, in the discretion of the Court.

(b) No person shall be subject to the penalties of subsection (a) of this section (1) for having sold, offered for sale or transferred any article and delivered it, if such delivery was made in good faith, unless he refuses to furnish on request of the Board of Food and Drug Inspection or an officer or employee duly designated by the Secretary, the name and address of the

person from whom he purchased or received such article and copies of all documents, if any there be, pertaining to the delivery of the article to him; (2) for having violated Section eleven (a) if he established a guaranty or undertaking signed by, and containing the name and address of, the person residing in the Philippines from whom he received in good faith the article, or (3) for having violated Section eleven (a), where the violation exists because the article is adulterated by reason of containing a coal-tar color not permissible under regulations promulgated by the Secretary under this Act, if such person establishes a guaranty or undertaking signed by, and containing the name and address, of the manufacturer of the coal-tar color, to the effect that such color is permissible, under applicable regulations promulgated by the Secretary under this Act.

(c) Any article of food, drug, device, or cosmetic that is adulterated or misbranded when introduced into the domestic commerce may be seized and held in custody pending proceedings pursuant to Section twenty-six (d) hereof, without a hearing or court order, when the Secretary has probable cause to believe from facts found by him or any officer or employee of the Food and Drug Administration that the misbranded article is dangerous to health, or that the labeling of the misbranded articles is fraudulent, or would be in a material respect misleading to the injury or damage of the purchaser or consumer.

CHAPTER VII
Definition and Standards for Food

Section 13. Whenever in the judgment of the Secretary such action will promote honesty and fair dealing in the interest of consumers, he shall, upon recommendation of the Food and Drug Administrator, promulgate regulations fixing and establishing for any food, under its common or usual name so far as practicable, a reasonable definition and standard of identity, a reasonable standard of quality, and/or reasonable standards of fill of container: *Provided*, That no definition and standard of identity and no standard of quality shall be established for fresh or dried fruits, fresh or dried vegetables.

ADULTERATED FOOD

Section 14. A food shall be deemed to be adulterated: (a) (1) If it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health;

(2) if it bears or contains any added poisonous or added deleterious substance other then one which is a pesticide chemical in or a raw agricultural commodity for which tolerances have been established and it conforms to such tolerances;

(3) if it consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food:

(4) if it has been prepared, packed, or held under unsanitary conditions whereby it may have become contaminated with filth, or whereby, it may have been rendered injurious to health;

(5) if it is, in whole or in part, the product of a diseased animal or of an animal which has died otherwise than by slaughter;

(6) if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health.

(b) (1) If any valuable constituent has been, in whole or in part, omitted or abstracted therefrom and same has not been substituted by any healthful equivalent of such constituent;

(2) if any substance injurious to health has been added or substituted;

(3) if damage or inferiority has been concealed in any manner; and

(4) if any substance has been added thereto or mixed or packed therewith so as to increase its bulk or weight, or reduce its quality or strength, or make it appear better or of greater value than it is.

(c) If it bears or contains a coal-tar color other than one which is permissible under existing regulations;

(d) If it is confectionery, and it bears or contains any alcohol or non-nutritive article or substance except harmless coloring, harmless flavoring, harmless resinous glass less coloring, harmless flavoring, harmless resinous glass not in excess of four-tenths of one per centum, natural gum and pectin: *Provided*, That this paragraph shall not apply to any confectionery by reason of its containing less than one-half of one per centum by volume of alcohol derived solely from the use of flavoring extracts, or to any chewing gum by reason of its containing harmless non-nutritive masticatory substances;

(e) If it is oleomargarine or margarine or butter and any of the raw material used therein consists in whole or in part of any filthy, putrid or decomposed substance, or such oleomargarine, margarine or butter is otherwise unfit for food.

MISBRANDED FOOD

Section 15. A food shall be deemed to be misbranded:

(a) If its labeling is false or misleading in any particular;

(b) If it is offered for sale under the name of another food;

(c) If it is an imitation of another food, unless its label bears in types of uniform size and prominence, the word "imitation" and, immediately thereafter, the name of the food imitated;

(d) If its container is so made, formed, or filled as to be misleading;

(e) If in package form unless it bears a label containing (1) the name and place of business of the manufacturer, packer, distributor; and (2) an accurate statement of the quantity of the contents in terms of weight, measure, numerial count: *Provided*, That under clause (2) of this paragraph reasonable variations shall be permitted, and exemptions as to small packages shall be established, by regulations prescribed by the Secretary.

(f) If any word, statement, or other information required by or under authority of this Act to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling), and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(g) If it purports to be or is represented as a food for which a definition and standard of identity has been prescribed unless (1) it conforms to such definition and standard, and (2) its label bears the name of the food specified in the definition and standard, and, insofar as may be required by such regulations, the common names of optional ingredients (other than spices, flavoring, and coloring) present in such food.

(h) If it purports to be or is represented as

(1) A food for which a standard of quality has been prescribed by regulations as provided by Section thirteen, and its quality falls below such standard, unless its label bears, in such manner and form as such regulations

specify, a statement that it falls below such standard; or

(2) a food for which a standard or standards of fill of container have been prescribed by regulations as provided by Section thirteen and it falls below the standard of fill of container applicable thereto, unless its label bears, in such manner and form as such regulations specify, statement that if falls below such standard.

(i) If it is not subject to the provisions of paragraph (g) of this section unless its label bears (1) the common or usual name of the food, if there be any, and (2) in case it is fabricated from two or more ingredients, the common or usual name of each such ingredient; except that spices, flavorings, and colorings, other than those sold as such, may be designated as spices, flavorings and colorings without naming each: *Provided*, That to the extent that compliance with the requirements of clause (2) of this paragraph is impracticable or results in deception or unfair competition, exemptions shall be established by regulations promulgated by the Secretary.

(j) If it purports to be or is represented for special dietary uses, unless its label bears such information concerning its vitamin, mineral and other dietary properties as the Secretary determined to be, and by regulations prescribes as necessary in order fully to inform purchasers as to its value for such uses.

(k) If it bears or contains any artificial flavoring, artificial coloring, or chemical preservative, unless it bears labeling stating that fact: *Provided*, That to the extent that compliance with the requirements of this paragraph is impracticable, exemptions shall be established by regulations promulgated by the Secretary. The provisions of this paragraph or paragraphs (g) and (i) with respect to artificial coloring shall not apply in the case of butter, cheese or ice cream.

Emergency Permit Control

Section 16. (a) Whenever the Secretary finds after investigation that the sale or distribution in domestic commerce of any class of food may be injurious to health, and that such injurious nature cannot be adequately determined after such articles have entered domestic commerce, he shall promulgate regulations also in accordance with the recommendations of the Food and Drug Administrator providing for the issuance, to manufacturers, processors, or packers of such class of food in such locality, of permits to which shall be attached such conditions governing the manufacture, processing, or packing of such class of food, for such temporary period of time, as may be necessary to protect the public health; and after the effective date of such regulations, and during such temporary period, no person shall manufacture, sell or offer for sale or transfer any such food manufactured, processed, or packed by any such manufacturer, processor, or packer unless such manufacturer, processor or packer holds a permit issued by the Secretary as provided by such regulations.

(b) The Secretary is authorized to suspend immediately upon notice any permit issued under authority of this section if it is found that any of the conditions of the permit have been violated.

(c) Any officer or employee duly designated by the Secretary shall have access to any factory or establishment, the operator of which holds a permit from the Secretary, for the purpose of ascertaining whether or not the conditions of the permit are being complied with, and denial of access for such inspection shall be ground for suspension of the permit until such access is freely given by the operator.

Tolerances for Poisonous Ingredients in Food

COAL-TAR COLOR FOR FOOD

Section 17. (a) Any poisonous or deleterious substance added to any food, shall be deemed to be unsafe except when such substance is required or cannot be avoided in its production or manufacture. In such case the Secretary

shall promulgate, upon recommendation of the Food and Drug Administrator, regulations limiting the quantity therein to such extent as he finds necessary for the protection of public health, and any quantity exceeding the limits so fixed shall also be deemed to be unsafe. In determining the quantity of such added substance to be tolerated in different articles of food the Secretary shall take into account the extent to which the use of such article is required or cannot be avoided in the production or manufacture of such article and the other ways in which the consumer may be affected by the same or other poisonous or deleterious substances.

(b) The Secretary shall, upon recommendation of the Food and Drug Administrator, promulgate regulations providing for the listing of coal-tar colors which are harmless and suitable for use in food.

CHAPTER VIII
Drug and Devices

ADULTERATED DRUGS AND DEVICES

Section 18. A drug or device shall be deemed to be adulterated: (a) (1) If it consists in whole or in part of any filthy, putrid, decomposed substance; or (2) if it has been prepared, packed, or held under insanitary conditions contaminated with filth or whereby it may have been rendered injurious to health; or (3) if it is a drug and its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or (4) if it is a drug and it bears or contains, for purposes of coloring only, a coal-tar color other than a permissible one.

(b) If it purports to be or is represented as a drug the name of which is recognized in an official compendium, and its strength differs from, or its quality or purity falls below, the standard set forth in such compendium, except that whenever tests or methods of assay as are prescribed are, in the judgment of the Secretary, insufficient for the making of such determination the Secretary, shall promulgate, upon recommendation of the Food and Drug Administrator, regulations prescribing appropriate tests or methods of assay in accordance with which such determination as to strength, quality or purity shall be made. No drug defined in an official compendium shall be deemed to be adulterated under this paragraph because it differs from the standard of strength, quality or purity in strength, quality, or purity from such standards is plainly stated on its label.

(c) If it is not subject to the provisions of paragraph (b) of this section and its strength differs from, or its purity of quality falls below, that which it purports or its represented to possess.

(d) If it is a drug and any substance has been (1) mixed or packed therewith so as to reduce its quality or strength or (2) substituted wholly or in part therefor.

MISBRANDED DRUGS AND DEVICES

Section 19. A drug or device shall be deemed to be misbranded: (a) If its labeling is false or misleading in any particular.

(b) If in a package form unless it bears a label containing (1) the name and place of business of the manufacturer, packer, or distributor; (2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count: *Provided*, That reasonable variations shall be permitted and exemptions as to small packages shall be established by regulations prescribed by the Secretary.

(c) If any word, statement, or other information required by or under authority of this Act to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(d) If it is for use by man and contains any quantity of the narcotic or hypnotic substance alpha-eucaine, barbituric acid, beta-eucaine, bromal, cannabis, cabromal, chloral, coca, cocaine,

codeine, heroin, marihuana, morphine, opium, paraldehyde, peyote, or sulfonmethane; or any chemical derivative of such substance, which derivative has been recommended by the Secretary, after investigation, and by regulations, designated as, habit forming; unless its label bears the name, and quantity or proportion of such substance or derivative and in juxtaposition therewith the statement "Warning May be habit forming."

(e) If it is a drug and is not designated solely by a name recognized in an official compendium unless its label bears (1) the common or usual name of the drug, if such there be; and (2) in case it is fabricated from two or more ingredients, the common or usual name of each active ingredient, including the quantity, kind, and proportion of any alcohol, and also including whether active or not, the name and quantity of proportion of any bromides, ether, chloroform, acetanilid, acetophenetidin, amidopyrine, antipyrine, atropine, hyoscine, hyoscyamine, arsenic, digitalis, digitalis glucosides mercury, ouabain, strophantin, strychnine, thyroid, or any derivative or preparation of any such substances, contained therein: *Provided*, That where compliance with this paragraph in impracticable, exemptions shall, upon recommendation of the Food and Drug Administrator, be established by regulations promulgated by the Secretary.

(f) Unless its labeling bears (1) adequate directions for use; and (2) such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as necessary for the protection of users: *Provided*, That where any requirement of clause (1) of this paragraph, as applied to any drug or device, is not necessary for the protection of the public health, the Secretary shall, upon recommendation of the Food and Drug Administrator, promulgate regulations exempting such drug or device from such requirement.

(g) If it purports to be a drug the name of which is recognized in an official compendium, unless it is packaged and labeled as prescribed therein: *Provided*, That the method of packing may be modified with the consent of the Secretary.

(h) If it has been found by the Secretary to be a drug liable to determination, unless it is packaged in such form and manner, and its label bears a statement of such precautions, as the Secretary shall by regulations require as necessary for the protection of the public health.

(i) (1) If it is a drug and its container is so made, formed, or filled as to be misleading; or

(2) if it is an imitation of another drug; or

(3) if it is offered for sale under the name of another drug.

(j) If it is dangerous to health when used in the dosage, or with the frequency of duration prescribed, recommended or suggested in the labeling thereof.

(k) If it is, or purports to be, or is represented as a drug composed wholly or partly of any kind of penicillin, streptomycin, chlortetracycline, chloramphenicol, bacitracin, or any other anti-biotic drug, or any derivative thereof, unless (1) it is from a batch with respect to which a certificate of release has been issued pursuant to Section twenty-two (a), and (2) such certificate of release is in effect with respect to such drug: *Provided*, That this paragraph shall not apply to any drug or class of drugs exempted by regulations promulgated under Section twenty-one (a), (b) and (c).

EXEMPTION IN CASE OF DRUGS AND DEVICES

Section 20. (a) The Secretary is hereby directed to promulgate regulations exempting from any labeling or packaging requirement of this Act drugs and devices which are, in accordance with the practice of the trade, to be processed, labeled, or repacked in substantial quantities at establishments other than those where originally processed or packed, on condition that such drugs and devices are not adulterated or misbranded, under the provisions of this Act upon removal from such processing, labeling, or repacking establishment.

(b) (1) Drugs intended for use by man which:

(A) are habit-forming

(B) because of its toxicity or other potentiality for harmful effect, or the method of its use is not safe for use except under the supervision of a practitioner licensed by law to administer such drug;

(C) are new drugs whose application are limited to investigational use shall be dispensed only (1) upon a written prescription of a practitioner licensed by law to administer such drug, or (2) upon an oral prescription of such practitioner which is reduced promptly to writing and filed by the pharmacist, or (3) by refilling any such written or oral prescription if such refilling is authorized by the prescriber either in the original prescription or by oral order which is reduced promptly to writing and filed by the pharmacist. The act of dispensing a drug contrary to the provisions of this paragraph shall be deemed to be an act which results in the drug being misbranded while held for sale.

(2) Any drug dispensed by filling or refilling a written prescription of a practitioner licensed by law to administer such drug shall be exempt from the requirements of Section nineteen, except paragraphs (a), (1), (2) and (3), and the packaging requirements of paragraphs (g) and (h), if the drug bears a label containing the name and address of the dispenser, the serial number and date of the prescription or of its filling, the name of prescriber, and, if stated in the prescription the name of the patient, and the directions of use and cautionary statements, if any, contained in such prescription.

(3) The Secretary may by regulation remove drugs subject to Section nineteen (d) and Section twenty-one from the requirements of Subsection (b) (1) of this Section, when such requirements are not necessary for the protection of the public health.

(4) A drug which is subject to subsection (b) (1) of this section shall be deemed to be misbranded if at any time prior to dispensing, its label fails to bear the statement "Caution: Food, Drug and Cosmetics Law prohibits dispensing without prescription." A drug to which subsection (b) (1) of this Section does not apply shall be deemed to be misbranded if at any time prior to dispensing, its label bears the caution statement quoted in the preceding sentence.

NEW DRUGS

Section 21. (a) No person shall manufacture, sell, offer for the sale or transfer any new drug, unless an application filed pursuant to

subsection (b) is effective with respect to such drug.

(b) Any person may file with the Secretary, thru the Food and Drug Administration, an application with respect to any drug subject to the provisions of subsection (a). Such persons shall permit to the Secretary thru the Food and Drug Administration as a part of the application (1) full reports of investigations which have been made to show whether or not such drug is safe for use; (2) a full list of the articles used as components of such drug; (3) a full statement of the composition of such drug; (4) a full description of the methods used in and the facilities and controls used for the manufacture, processing, and packing of such drug; (5) such samples of such drug and of the articles used as components hereof as the Secretary may require; and (6) specimens of the labeling proposed to be used for such drug.

(c) Within one hundred and eighty days after the filing of an application under this subsection, or such additional period as may be agreed upon by the Secretary and the applicant, the Secretary shall either (1) approve the application if he then finds that none of the grounds for denying approval specified in subsection (d) applies, or (2) give the applicant notice of an opportunity for a hearing before the Secretary under subsection (d) on the question whether such application is approvable.

(d) If the Secretary finds, after due notice to the applicant and giving him an opportunity for a hearing, that (1) the investigation, reports of which are required to be submitted to the Secretary pursuant to subsection (b), do not include adequate tests by all methods reasonably applicable to show whether or not such drug is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof; (2) the results of such tests show that such drug is unsafe for use under such conditions or do not show that such drug is safe for use under such conditions; (3) the methods used in, and the facilities and controls used for the manufacture, processing, and packing of such drug are inadequate to preserve its identity, strength, quality, and purity; or (4) upon the basis of the information submitted to him as part of the application, or upon the basis of any other information before him with respect to such drug, he has insufficient information to determine whether such drug is safe for use under such conditions; or (5) evaluated on the basis of the information submitted to him as part of the application, and any other information before him with respect to such drug, there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof; or (6) based on a fair evaluation of all material facts, such labeling is false or misleading in any particular; he shall issue an order refusing to approve the application.

(e) The effectiveness of an application with respect to any drug shall, after due notice and opportunity for hearing to the applicant, by order of the Secretary be suspended if the Secretary finds (1) that clinical experience, tests by new methods, or tests by methods not deemed reasonably applicable when such application became effective show that such drug is unsafe for use under the conditions of use upon the basis of which the application became effective, or (2) that the application contains any untrue statement of a material fact. The order shall state the findings upon which it is based.

(f) An order refusing to permit an application with respect to any drug to become effective shall be revoked whenever the Secretary finds that the facts so require.

(g) The Secretary shall promulgate regulations for exempting from the operation of this section drugs intended solely for investigational use by experts

qualified by scientific training and experience to investigate the safety and effectiveness of drugs.

CHAPTER IX
Certification of Drugs containing Penicillin, Streptomycin, Chlortetracycline, Chloramphenicol or Bacitracin.

Section 22. (a) The Secretary, pursuant to regulations promulgated by him shall provide for the certification of batches of drugs composed wholly or partly of any kind of penicillin, streptomycin, chlortetracycline, chloramphenicol, bacitracin, or any anti-biotic drug, or any derivative thereof. A batch of such drug shall be certified if such drug has such characteristics of identity, strength, quality and purity, as the Secretary prescribes in such regulations as necessary to adequately insure safety and efficacy of use, but shall not otherwise be certified. Prior to the effective date of such regulations the Secretary, in lieu of certification, shall issue a release for any batch which, in his judgment, may be released without risk as to the safety and efficacy of its use. Such release shall prescribe the date of its expiration and other conditions under which it shall cease to be effective as to such batch and as to portions thereof. For purposes of this section and of Section nineteen (k), the term "anti-biotic drug" means any drug intended for use by man containing any quantity of any chemical substance which is produced by micro-organism and which has the capacity to inhibit or destroy micro-organism in dilute solution (including the chemically synthesized equivalent of any such substance).

(b) Whenever in the judgment of the Secretary, the requirements of this section and of Section nineteen (k) with respect to any drug or class of drugs are not necessary to insure safety and efficacy of use, the Secretary shall promulgate regulations exempting such drug or class of drugs from such requirements.

(c) The Secretary shall promulgate regulations exempting from the requirement of this section and of Section nineteen (k), (1) drugs which are to be stored, processed labeled, or repacked at establishments other than those where manufactured, on condition that such drugs comply with all such requirements upon removal from such establishments; (2) drugs which conform to applicable standards of identity, strength, quality, and purity prescribed by these regulations and are intended for use in manufacturing other drugs; and (3) drugs which are intended for investigational use by experts qualified by scientific training and experience to investigate the safety and efficacy of drugs.

CHAPTER X
Cosmetics

ADULTERATED COSMETICS

Section 23. A cosmetic shall be deemed to be adulterated: (a) If it bears or contains any poisonous or deleterious substances which may render it injurious to users under the conditions of use prescribed in the labeling thereof, or under the conditions of use as are customary or usual: *Provided*, That this provision shall not apply to coal-tar hair dye, the label of which bears the following legend conspicuous displayed thereon: "Caution: This product contains ingredients which may cause skin irritation on certain individuals and a preliminary test according to accompanying directions should first be made. This product must not be used for dyeing the eyelashes or eyebrows; to do so may cause blindness", and the labeling of which bears adequate directions for such preliminary testing. For the purposes of this paragraph and paragraph (e) the term "hair dye" shall not include eyelash dyes or eyebrow dyes.

(b) If it consists in whole or in part of any filthy, putrid, or decomposed substance.

(c) If it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health.

(d) If its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health.

(e) If it is not a hair dye and it bears or contains a coal-tar color other than one which is permissible.

MISBRANDED COSMETIC

Section 24. A cosmetic shall be deemed to be misbranded:

(a) If its labeling is false or misleading in any particular.

(b) If in package form unless it bears a label containing (1) the name and place of business of the manufacturer, packer, or distributor; and (2) an accurate statement of the quantity of the contents in terms of weight, measure, of numerical count: *Provided*, That under reasonable variations shall be permitted and exemptions as to small packages shall be established by regulations prescribed by the Secretary.

(c) If any word, statement, or other information required by or under authority of this Act, to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(d) If its container is so made, formed, or filled as to be misleading.

REGULATIONS MAKING EXEMPTIONS

Section 25. The Secretary shall promulgate regulations exempting from any labeling requirements of this Act cosmetic which are, in accordance with the practice of the trade, to be processed, labeled, or repacked in substantial quantities at establishments other than those where originally processed or packed, on condition that such cosmetics are not adulterated or misbranded under the provisions of this Act upon removal from such processing, labeling, repacking establishment.

CHAPTER XI
General Administration Provisions, Regulations, Hearings and Institution of Criminal Action

Section 26. (a) Except as otherwise provided in this section, the Secretary of Health shall, upon recommendation of the Food and Drug Administrator, issue rules and regulations as may be necessary to enforce effectively the provisions of this Act.

(b) The Commissioner of Customs, the Commissioner of Internal Revenue and the Secretary of Health shall jointly prescribe regulations for the efficient enforcement of the provisions of Section thirty, except as otherwise provided therein. Such regulations shall be promulgated upon the recommendation of the Food and Drug Administrator and shall take effect at such time, after due notice, as the Secretary of Health shall determine.

(c) Hearings authorized or required by this Act shall be conducted by the Board of Food and Drug Inspection which shall submit its recommendation to the Food and Drug Administrator.

(d) When it appears to the Food and Drug Administrator from the report of the Food and Drug Laboratory that any article of food or any drug, or cosmetic secured pursuant to Section twenty-eight of this Act is adulterated or misbranded, he shall cause notice thereof to be given to the person or persons concerned and such person or persons shall be given an opportunity to be heard before the Board of Food and Drug Inspection and to submit evidence impeaching the correctness of the finding or charge in question.

(e) When a violation of any provisions of this Act comes to the knowledge of the Food and Drug Administrator of such character that a criminal prosecution ought to be instituted against the offender, he shall certify the facts to the Secretary of Justice through the Secretary of Health, together with the chemist's report, the findings of the Board of Food and Drug Inspection, or

other documentary evidence on which the charge is based.

(f) Nothing in this Act shall be construed as requiring the Food and Drug Administrator to certify for prosecution pursuant to sub-paragraph (e) hereof, minor violations of this Act whenever he believes that public interest will be adequately served by a suitable written notice or warning.

FACTORY INSPECTION

Section 27. (a) For purposes of enforcement of this Act, officers or employees duly designated by the Secretary, upon presenting appropriate credentials to the owner, operator, or agent in charge, are authorized (1) to enter, at reasonable hours, any factory, warehouse, or establishment in which food, drugs, devices or cosmetics are manufactured, processed, packed or held, for introduction into domestic commerce or are held after such introduction, or to enter any vehicle being used to transport or hold such food, drugs, devices, or cosmetics, in domestic commerce; and (2) to inspect, in a reasonable manner, such factory, warehouse, establishment, or vehicle and all pertinent equipment, finished and unfinished materials, containers, and labeling therein.

Section 28. (a) If the officer or employee making any such inspection of a factory, warehouse or other establishment has obtained any sample in the course of the inspection, upon completion of the inspection and prior to leaving the premises he shall give to the owner, operator, or agent in charge a receipt describing the samples obtained.

(b) Whenever in the course of any such inspection of a factory or other establishment where food is manufactured, processed, or packed, the officer or employee making the inspection obtains a sample of any such food, and an analysis is made of such sample for the purpose of ascertaining whether such food consists in whole or in part of any filthy, putrid or decomposed substance, or is otherwise unfit for food, a copy of the results of such analysis shall be furnished promptly to the owner, operator, or agent in charge.

PUBLICITY

Section 29. (a) The Secretary may cause to be disseminated information regarding food, drugs, devices, or cosmetics in situations involving, in the opinion of the Secretary, imminent danger to health, or gross deception of the consumer. Nothing in this Section shall be construed to prohibit the Secretary from collecting, reporting, and illustrating the results of the investigations of the Department.

CHAPTER XII
Imports and Exports

Section 30. (a) The Commissioner of Customs shall cause to be delivered to the Food and Drug Administration samples taken at random from every incoming shipment of food, drugs, devices, and cosmetics which are being imported or offered for import into the Philippines giving notice thereof to the owner or consignee. The quantity of such samples shall be fixed by regulation issued by the Secretary. If it appears from the examination of such samples or otherwise that (1) such article has been manufactured, processed, or packed under insanitary conditions, or (2) such article is forbidden or restricted from sale in the country in which it was produced or from which it was produced or from which it was exported, or (3) such article is adulterated, misbranded, or in violation of Section twenty-one, then the Food and Drug Administrator shall so inform the Commissioner of Customs and such article shall be refused admission, except as provided in subsection (b) of this section. The Commissioner of Customs shall then cause the destruction of any such article refused admission unless such article is exported, under regulations prescribed by the Commissioner of Customs, within ninety days of the date of notice of such refusal or within such additional time as may be permitted pursuant to such regulations. If the food, drugs, devices, and cosmetics being imported or offered for import into the Philippines arrives at a port of entry other than Manila, the collection of such samples shall be the responsibility of the Regional Health Director having jurisdiction over the port of entry and such samples shall be forwarded to the Food and Drug Administration.

(b) Pending decision as to the admission of an article being imported or offered for import, the Commissioner of Customs may authorize delivery of

such article to the owner or consignee upon execution by him of a good and sufficient bond providing for the payment of such liquidated damages in the event of default as may be required pursuant to regulations of the Commissioner of Customs. If it appears to the Secretary that an article included within the provisions of clause (3) of subsection (a) of this section can, by relabeling or other action, be brought into compliance with the Act or rendered other than a food, drug, device, or cosmetic, final determination as to admission of such article may be deferred, and upon filing to timely written application by the owner or consignee, and the execution by him of a bond as provided in the preceding provisions of this subsection, the Secretary may, in accordance with regulations, authorize the applicant to perform such relabeling or other actions specified in such authorization with regulations (including destruction or export of rejected articles or portions thereof, as may be specified in the Secretary's authorization). All such relabeling or other action pursuant to such authorization shall be in accordance with regulations and be under the supervision of an office or employee of the Bureau of Customs designated by the Commissioner of Customs and a duly authorized representative of the Food and Drug Administrator.

(c) All expenses (including travel, per diem or subsistence, and salaries) of officers or employees of the Philippines in connection with the destruction provided for in subsection (a) of this section and the supervision of the relabeling or other action authorized under the provisions of subsection (b) of this section, the amount of such expenses to be determined in accordance with regulations, and all expenses in connection with the storage, cargo, or labor with respect to any article refused admission under subsection (a) of this section, shall be paid by the owner or consignee, and in default of such payment, shall constitute a lien against any future importations made by such owner or consignee.

(d) A food, drug, device, or cosmetic intended for export shall not be deemed to be adulterated or misbranded under this Act if it (1) conforms with the specifications of the foreign purchaser, (2) is not conflict with laws of the country to which it is intended for export, and (3) is labelled on the outside of the shipping package to show that it is intended for export. But if such article is sold or offered for sale in domestic commerce, this subsection shall not exempt it from any of the provisions of this Act.

CHAPTER XIII
Financing

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

CHAPTER XIV
Repealing Clause and Effectivity

Section 32. If any provision of this Act or the application of such provision to any person or circumstance is held invalid, the remainder of this Act or the application of such provision to other persons of circumstances should not be affected thereby.

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

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

Approved: June 22, 1963.

DEPARTMENT OF HEALTH ADMINISTRATIVE ORDERS

A. Administrative order No. 220 s 1974
B. Administrative order No. 420 s 1982
C. Administrative order No. 55 1989
D. Administrative order No. 56 1988
E. Administrative order No. 64 1989
F. Administrative order No. 66 1989
G. Administrative order No. 67 1989
H. Administrative order No. 79 1989
I. Administrative order No. 85 1990
J. Administrative order No. 99 1990

AO 220s 1974

Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

Manila
June 13, 1974

ADMINISTRATIVE ORDER
No. 220 s. 1974

SUBJECT: DRUGS: CURRENT GOOD MANUFACTURING PRACTICE IN MANUFACTURE, PROCESSING, PACKING OR HOLDING

Summary: This order prescribes the conditions and requirements for good manufacturing practice applied to premises, equipment, personnel, product and warehousing.

1. Definitions- the definitions and interpretations contained in section 10 of the Food, Drug and Cosmetics Act RA 3720 are applicable to such terms when used in this regulation. The following definitions shall also apply:

a) "***Component***" (raw material) means any ingredient intended for use in the manufacturing of drugs, including those that may not appear in the finished product.

b) "***Batch***" means a specific homogenous quantity of a drug or in case of drug produced according to single manufacturing order during the same cycle of manufacture.

c) "***Lot***" means a batch or any portion of batch of a drug produced by a continuous process,an amount of drug produced in a unit of time or quantity in a matter that assures its uniformity and in either case which is identified by a distinctive lot number and has uniform character and quality within specified limits.

d) "***Lot number***" or "***control number***" means any distinctive combination of letters or numbers, both, by which the complete history of the manufacture, control, packaging and distribution of a batch or lot of a drug is determined.

e) "***Active ingredient***" means any substance of a which is intended to furnish pharmacological activity or other effect in the diagnosis, cure, mitigation, treatment, or prevention of disease or to affect the structure or any function of the body of man or other animals.

f) "***Inactive ingredient***" means any substance other than "active ingredient" present in a drug.

g) "***Materials approval unit***" means an organizational element having the authority and responsibility to approve or reject raw materials, in-process materials, packaging components, and final products.

h) "***Strength***" means (i) the concentration of known active drug substance in formulation (for example, w/w, w/v, or unit dose /volume basis) and/or (ii) potency, that is, the specific ability or capacity of the product as indicated by appropriate laboratory tests or by adequately controlled clinical data obtained through the administration of the product in the manner intended to effect a given result (s) expressed, for example, in terms of units by reference to a standard).

2. Current Good Manufacturing Practice
The criteria in paragraphs 3 to 14 inclusive, shall apply in determining whether the methods used in, or the facilities or controls used for, the manufacture, processing, packing or holding of a drug conform to or are operated or administered in conformity with current good manufacturing practice to assure that a drug meets the requirements of the act as to safety, and has the identify and strength and meets the quality and purity characteristics which it purports or is represented to possess, as required by section 18 (a) of the Food, Drug and Cosmetic Act (Republic Act 3720) . The regulations permit the use of precision automatic, mechanical, or electronic equipment in the production and control of drugs when adequate inspection and checking procedures are used to assure proper performance.

3. **Buildings**
Buildings shall be maintained in a clean and orderly manner and shall be of suitable size, construction and location in relation to surroundings to facilitate adequate cleaning, maintenance, and proper operations for their intended purpose - - - the manufacturing, processing, packing, labeling or holding of a drug. The buildings shall:

a) Provide adequate space for:

1. Orderly placement of equipment and materials to minimize any risks of mix-ups between different drugs, drug components, in-process materials, packaging, or labeling, and to minimize the possibility of cross – contamination of one drug by another drug (s);

2. The receipt, storage and withholding from use of components pending sampling, Identification and testing prior to release by the materials approval unit for manufacturing or packaging.

3. The holding of rejected components prior to disposition in such a way as to preclude the possibility of their use in any manufacturing or packaging procedure;

4. The storage of components approved for use;

5. Any manufacturing and processing operation performed on the drug;

6. Any packaging and labeling operations;

7. Storage of components approved for use;

8. Control and production-laboratory operations.

b) Provide adequate lighting, ventilation, and when necessary for the intended production or control purposes, facilities for adequate air-pressure, microbiological, dust, screening, filtering, humidity, and temperature control to –

1) Minimize contamination of products by extraneous adulterants (including cross – contamination of one product by dust or particles of ingredients arising from th manufacture, storage, or handling of another drug).

2) Minimize dissemination of microorganism from one area to another.

c) Provide for adequate locker facilities and hot and cold water washing facilities including soap or detergent, air drier or single service towels, and clean toilet facilities near working areas.

d) Provide an adequate supply of potable water (PHS standards) under continuous positive pressure in plumbing system free of defects which could cause or contribute to contamination of the product. Drains shall be adequate in size and where connected directly to a sewer, shall be equipped with traps to prevent back siphonage.

e) Provide suitable housing and space for the care of all laboratory animals.

f) Provide for safe and sanitary disposal of sewage, trash and other refuse.

4. **Equipment**
Equipment used for the manufacture, processing, packing, labeling, holding, testing or control of drugs shall be maintained in a clean and orderly manner and shall be of suitable design, size, construction and location in relation to surroundings to facilitate cleaning, maintenance and operation for its intended purpose.

The equipment shall:
a) Be so constructed that all surfaces that come into contract with a drug shall not be reactive, additive or absorptive so as to alter the safety, identity, strength, quality or purity of the drug or its components, beyond the official or other established requirements.

b) Be constructed that any substance required for operation of the equipment, such as lubricants or coolants, do not come in contact with drug products.

c) Be constructed and installed to facilitate adjustment, disassembly, cleaning and maintenance as necessary to assure the reliability of control procedures, uniformity of production and exclusion from drugs or contaminants (for example, pesticides, lubricants), including contaminants from previous and current operations (for example, crosscontamination with penicillin or any other drug).

d) Be of suitable type, size and accuracy for any intended testing, measuring, mixing, weighing, or other processing or storage operations.

5. **Personnel**
a) The personnel responsible for directing the manufacture and control of the drug shall be adequate in number and background of education and experience to assure that the drug has the safety, identity, strength, quality and purity that it purports to possess. All personnel shall have the capabilities commensurate with their assigned functions, thorough understanding of the manufacturing or control operations which they perform, the necessary training and experience relating to individual products, and adequate information concerning the reasons for and the application of the pertinent provisions of this part to their respective functions.

b) Personnel having direct contact with drugs shall have periodic health checks, and shall be free from communicable disease and open lesions on he exposed surface of the body.

6. Components (Raw Materials)
Components used in the manufacture and processing of drugs (including those components that undergo chemical change or are eliminated in the process) shall be withheld from such use until they have been identified, sampled and tested for conformance with established specifications that are appropriate and adequate, and are released by the materials approval unit. Control of components shall include the following:

a) Each container of components shall be examined visually for damage or contamination in transit, including examination for breakage of seals when indicated;

b) An adequate number of samples shall be taken from a representative number of component containers and shall be subjected to one or more identity tests, including at least one laboratory test for identity.

c) Representative samples of all components shall be appropriately examined, including when indicated microscopic examination, for evidence of filth, insect infestation or other extraneous contamination.

d) Representative samples of components particularly liable to contamination with highly toxic substances (for example, heavy metals), as indicated by tests for such substances in monographs of the official compendia, shall be tested to assure that official compendia or other appropriate limits for such impurities are not exceeded.

e) Representative samples of all components intended to be used as active ingredients shallbe tested to determine their strength per unit of weight or measure

to assure compliance with adequate specification for such strength.

f) Representative samples of components subject to microbiological contamination (such as those of animal and botanical origin) shall be subjected to microbiological tests. Such samples shall contain no micro-organisms which are objectionable in view of the intended use of the components.

g. Approved components shall be appropriately marked and retested as necessary to assure that they conform to appropriate specifications of identity, strength, quality and purity at the time of use. This requires the following

1. Approve components are so handled and stored as to guard against their contaminating other drugs by dust or other particles resulting from such handling and storing. Similarly, approved components are so handled and stored as to guard against their being contaminated by other preparations, substances, dust or other particles resulting from such handling storing.

2. Approved components shall be rotated in such a manner that the oldest stock is used first.

3. Rejected components shall be so marked and held as to preclude the possibility of their use in any manufacturing or processing procedures.

4. Appropriate records shall be maintained of the name of supplier, lot number of each component, date and amount received, and examinations and tests performed. Said records shall also show any components rejected and their disposition. An individual inventory record shall be maintained for each components lot showing the amount of component used in each batch of drug manufactured or processed.

h) A reserve sample of all active ingredients consisting of at least twice the quantity necessary for all required tests of identity, quality, purity and strength shall be retained for at least 2 years after distribution of the last drug lot incorporating the active ingredient, whichever is shortest.

7 Master –Formula and Batch Production Records

a) To assure drug batch uniformity, a master –formula record for each drug product and each batch size of such drug product shall be prepared, endorsed, and dated by a competent and responsible individual and shall be independently checked, reconciled, endorsed and dated by a second competent and responsible individual. Master-formula record, or 1 year after the expiration date of this last drug batch, whichever is shortest. The master-formula record shall include:

1. The name of the product, a description of its dosage form, and a specimen or copy of each label and all other labeling contained in a retail package of the drug. (In private formula production, upon receipt of a written order for a portion of the drug stored in bulk form, a specimen or copy of the label to be used in filling that order shall be attached to the master- formula record prior to production of the batch records). Also included shall be copies of the final draft of each label and all other labeling contained in a retail package of the drug and their printing authorization, dated and endorsed by the responsible person or persons approving the draft.

2. The name and weight or measure of each ingredient per dosage unit or per unit of weight or measure of the finished drug, and a statement of total weight or measure of any dosage unit.

3. A complete list of ingredients designated by names or codes sufficiently specific to indicate any special quality characteristics: an accurate statement of the weight or measure of each ingredient regardless of whether it appears in the finished product, except that reasonable variations may be permitted in the amount of components necessary in the preparation in dosage form provided that the variations are stated in master-formula; an appropriate statement concerning any calculated excess of an ingredient; and appropriate statement of theoretical weight or measure at various stages of processing and a statement of the theoretical yield.

4. A description of the containers, closures, and packaging, and finishing materials.

5. Manufacturing and control instructions, procedures, specifications, special notations, and precautions to be followed.

b) Readily accessible records shall be prepared for each batch of drug produced and shall include complete information relating to the production and control of each such batch.

Said records shall be retained for at least 2 years, after batch distribution is complete, or 1 year after the batch expiration date, whichever is shortest. The records relating to production, including packaging, labeling, and control of each batch, plus copies of the labeling bearing the lot number or control numbers used on the batch, shall be readily available during such retention period. The batch records shall include:

1) An accurate reproduction of the appropriate master-formula record checked and endorsed by a competent, responsible individual.

2) Records of each step in the manufacturing, processing, packaging, labeling, testing, and controlling of the batch, including dates, individual major equipment and lines employed, specific identification of each batch of components used in course of processing, in-process and laboratory-control results, and the endorsements of the individual actively performing and the individual actively supervising or checking each step in the operation.

3) A batch number that permits determination of all laboratory-control procedures and results on the batch, and all lot or control numbers

appearing on the labeling of drugs from that batch, including copies of the labeling bearing the lot or control numbers used on the final containers of the batch.

4) A record with complete investigative history of any mix-ups, errors, and unsatisfactory drug products found during and after drug manufacturing, processing, packaging, labeling, testing, controlling and distributing of the batch. This investigative history shall be evaluated, appropriate action shall be taken. Said record shall indicate the evaluation and action.

8. Production and Control Procedures

Production and control procedures shall include all reasonable precautions, including the following, to assure that the drugs produced have the safety, identity, strength, quality and purity they purport to possess:

a) Each critical step in the process such as the selection, weighing, and measuring during various stages of the processing, and the determination of the finished yield, shall be performed by a competent, responsible individual, and checked by a second competent responsible individual; or if such steps in the processing are controlled by precision automatic, mechanical or electronic equipment, their proper performance is adequately checked by one or more competent individuals. The written record of the critical steps in the process shall be initiated by the individual performing the critical step and also initiated by the individual charged with checking each critical step.

b) All containers, lines and equipment used in producing a batch of drugs shall be distinctly labeled at all times to identify accurately and completely their contents, the stage of processing, and the batch. For equipment and lines, placement of this identification distribution until released by the materials approval unit on the basis of satisfactory control tests.

1) Returned goods shall be identified and held. If the condition of the container, carton, or labeling is such as to cast doubt on the identity, strength, quality or purity of the drug, the returned goods shall be destroyed or subjected to the complete protocol of testing (to assure that the material will meet all appropriate standards and specifications) before being returned to stock for warehouse, distribution or repacking. No returned goods shall be re-processed unless they have been found by appropriate tests not to have undergone any significant physical, chemical or microbiological degradation and not to have become contaminated with extraneous substances or filth. Records of returned goods shall be maintained and shall indicate the amount returned, ate and actual disposition of the product, such as reprocessed, destroyed or returned to stock.

9. Product Containers

Suitable specifications, test methods, cleaning procedures, and when indicated, sterilization procedures shall be used to assure that containers, closures, and other component parts of drug packages are suitable for their intended use. The container shall comply with applicable compendial requirements when used for an official product. Containers, closures and other component parts of drug packages shall not be reactive, additive, or absorptive so as to alter safety, identity, strength, quality or purity of the drug or its components beyond the official or other established requirements, and shall provide adequate protection against deterioration or contamination of the drug. Containers closures and other component parts of the drug packages shall be handled and stored in a manner to protect them from contamination and deterioration and to avoid mix-ups.

10 Packaging and Labeling

Packaging and labeling operations shall be adequately controlled: to assure that only those drug products that have met the standards and specifications established in the master-formula records shall be distributed, to prevent mix-ups between drugs during filling, packaging and labelling operations; to assure that correct labels and labeling are employed for the drugs; and to identify the finished product with a lot or control number that permits determination of the history of the manufacture and control of the batch. The lot or control number shall be identified as such on the label. An hour, day, or shift code is appropriate as a lot or control number for the drug products manufactured or processed in continuous production equipment.

Packaging and labeling operations shall:
a) Be separated (physically or spatially) from operations on any other drugs in a manner adequate to avoid mix-ups. Two or more packaging/labeling operations having drugs, containers, or labeling similar in appearances shall not be processed simultaneously on adjacent or nearby lines unless these operations are separated by a physical barrier;

b) Provide for an inspection of the facilities prior to use to assure that all other drugs and previously done labeling have been removed;

c) Include the following labeling controls:

1) The holding of labels and package labeling upon receipt plus review and proofing against an approved final copy by a competent, responsible individual to assure that they are accurate in respect to identify, content, and conformity with the approved copy before release to inventory.

2) The maintenance and storage of each type label and package labeling representing different products, strengths or dosage forms

in separate compartments, drawers, or containers suitably identified. Said compartments, drawers or containers shall have prominently affixed to them a specimen of the label or labeling they contain or some other adequate means of identification to avoid mix-ups;

3) A perpetual check of current labels and package labeling. Stocks of outdated and obsolete labels and other package labeling shall be destroyed.

4) Restrict access to labels and package labeling storage areas to persons responsible for them.

d) Provide strict control of the package labeling issued for use with the drug. Such issue shall be carefully checked by a competent, responsible person for identity and conformity to the labeling specified in the batch production records. Said records shall identify the labelling and the quantities issued and used and shall reasonably reconcile any discrepancy between the quantity of the drugs finished and quantities of the labeling issued. All excess package labeling bearing lot or control numbers shall be destroyed. In the event of any significant, unexplained discrepancy, distribution of batch record of the batch in question and other associated batches of the drugs that may have been involved in such discrepancy shall be prevented. A statement regarding the discrepancy, the facts underlying the discrepancy, an explanation determined by an appropriate investigation, and resultant action shall also be entered on the batch record of the batch or batches in question and shall also be signed by a competent, responsible individual.

e) Provide for adequate examination and laboratory testing of any adequate number of representative samples of finished products after packaging and labeling to safeguard against any error in the finishing operations and to prevent distribution of any batch until all specified tests have been met. Manufacturers, however, may perform adequate examination of an adequate number of representative samples of their finished drug products after packaging and labeling in lieu of laboratory testing in the case of, and only in the case of, those tablet or capsule dosage forms of drugs which, in addition to having had all necessary laboratory tests on the bulk (but unpacked drug), are not similar in physical appearance to any other final dosage form product found within that manufacturing establishment. Repackers who, in accordance with the practice of the trade, repack tablet or capsule dosage forms of drugs in substantial quantities in establishment other than those where originally processed or packed may meet these requirements of adequate examination and laboratory testing by complying with all of the following conditions:

1) The drug received by the repacker in bulk containers is readily distinguishable visually from all other drugs in his possession and in the possession of the supplier of the drug;

2) The repacker has in his possession, and in good faith relies on a valid guarantee or undertaking (referred to in section 12(b) (2) of the Food, Drug and Cosmetic Act (RA 3720) from the manufacturer of the bulk drug setting forth that the time of delivery to the repacker said drug complied with the Act.

3) A labeled sample package of the drug, for which the manufacturer furnishes protocol (s) of laboratory tests showing that the drug meets appropriate standards of identity, strength, quality and purity, and which sample package bears a label identical (except for the quantity of content statement) to the label on the bulk package of the capsules or tablets, is shipped by the manufacturer to the repacker for comparison with the appearance and labeling of the article in the bulk container. Such sample package contains at least twice the quantity of drug required to conduct all the tests performed on the batch of the drug. The sample package and a sufficient number of finished labeled containers of the repacked drug to contain at least 2 years after distribution has been completed, or 1 year after the drug's expiration date, whichever is shortest.

4) Prior to repacking, a visual comparison is conducted by a competent, responsible person to assure that the drug to be repacked from bulk is identical in appearance to that in the sample package and the labeling of the bulk package and the sample package show the same drug identity and composition

.

5) The repacker labels the drug with a suitable expiration date in accordance with the stability requirements of No. 13) to assure that the drug meets appropriate standard of identity, strength, quality and purity at the time of use.

6) The label of the repacked drug bears a lot or control number and the repacker maintains records for at least 2 years after drug distribution has been completed, or 1 year after the drug's expiration date whichever is the shortest, from which the lot or control number of the bulk drug used in the repacking can be ascertained.

f) Gang printing of cut labels or cartons should be avoided especially when labels or the cartons for different products or different strengths of the product are of same size and have identical or similar format/color schemes.

11 Laboratory Controls

Laboratory control shall include the establishment of scientifically sound and appropriate specifications, standards, and test procedures (for example identity, weight variation, disintegration, homogeneity) to assure that components, drug preparations in the course of processing, and finished products conform to appropriate standards of identity, strength,quality and purity. Laboratory controls shall include:

a) The establishment of master records containing appropriate specifications for the acceptance of each lot of components, containers, and closures used in drug production and packaging and a description of the sampling and testing procedures used for them. Said samples shall be representative and adequately identified. Such records shall also provide for appropriate resetting of components, containers and closures subject to deterioration.

b) A reserve sample of all active ingredients and all components which appear in significant quantities in the finished drug product. These reserve samples shall consist of at least twice the quantities necessary to perform all required tests. Said samples shall be retained for at least 2 years after distribution of the last drug lot incorporating such active ingredient or component, whichever is shortest
.

c) The establishment of master records, when needed containing specifications and a description of sampling and testing procedures for in-process drug preparations. Such samples shall be adequately representative and properly marked.

d) The establishment of master records containing a description of sampling procedures, testing procedures, and appropriate specifications for finished drug products. Such samples shall be representative and properly marked.

e) Adequate provision for checking the identity and strength for all active ingredients of drug products and for assuring:

1) Compliance with satisfactory criteria for assuring sterility of drugs purporting to be sterile.

2) Compliance with satisfactory criteria of non pyrogenicity as required by an official compendium or as indicated by the manner in which the drug is to be used;

3) Freedom of ophthalmic ointments from foreign particles, such as metal, plastic, or other harsh and abrasive substances, to the extent possible under current good manufacturing practice.

4) That the drug release pattern of sustained release products is tested by laboratory methods used in establishing appropriate specifications related to clinical safety and effectiveness to assure conformance to such specifications.

5) That all components are adequately tested to conform to such specifications for example particle size, as are necessary to assure reasonable uniform rates of absorption, biological availability, and the stability of the drug products.

f) Adequate provisions for auditing the reliability, accuracy, precision and performance of laboratory test procedures and laboratory instruments used.

g) A property identified reserve sample (including at least two labeled containers of the final dosage form) of at least twice the quantity of the finished drug lot required to conduct all appropriate tests performed shall be retained for at least 2 years after drug distribution has been completed, or 1 year after the drug's expiration date, whichever is shortest. The reserve sample need not contain units for sterility testing and pyrogens. Identification of this sample shall include the labeling used on the finished product.

h) Provisions for retaining complete records of all date, including analytical raw data, concerning laboratory tests performed, including the dates and endorsements of individuals obtaining the samples, making the tests, releasing lots (component and finished material) from storage, and provision for specifically relating the tests to each batch or lot of drug, component, and animals to which they apply. Such records shall be retained for at least 2 years after the drug distribution has been completed, or 1 year after the drug's expiration date, whichever is shortest, except for stability data as provided for by paragraph 13 f. shall include, where applicable., Input lines, output lines and operator control. All containers, lines and equipment used in producing a batch of drugs shall be stored and handled in a manner adequate to prevent mix-ups or contamination with other drugs.

c) Equipment, utensils and containers shall be thoroughly cleaned and properly stored and have previous batch identification removed between batches, or at suitable intervals in continuous production operations to minimize the hazard of contamination with microorganisms and to prevent other contamination and mix-ups. Equipment being employed for consecutive identical product batches shall be thoroughly cleaned at suitable intervals. All equipment used in the handling of sterile products shall be appropriately cleaned and, when necessary, sterilized prior to use.

c) Appropriate procedures, such as the following, shall be taken to minimize the hazard of contamination with microorganisms in the production of parenteral drugs, ophthalmic solutions and other drugs purporting to be sterile.

d)

1) Filling operations shall be performed with adequate physical segregation from similar operations on any other drugs to avoid cross-examination.

2) Proper control of air movement and air filtration prior to entry and discharge shall be provided in all sterile areas to minimize microbiological contamination, particulate matter, and cross –contamination of one drug with another.

e) Appropriate to procedures shall be taken to minimize the hazard of cross contamination of non-penicillin products by penicillin in those establishments that manufacture, store, or handle penicillin as well as non-penicillin products.

f) To assure the uniformity and integrity of products, there shall be adequate in-process control, such as checking the weights and disintegration time of tablets, and fill of liquids, the adequacy of mixing, the homogeneity of suspensions, and the clarity of solutions. Such in-process testing shall be done at appropriate intervals during each individual operations, when practicable, using readily accessible, adequate and suitable equipment. A written record of all such tests shall be maintained, including the date and time of each test, the product name and batch number, and the quantitytested, the results and the initials of the person performing the test.

g) Competent and responsible personnel shall check actual against theoretically yields of each batch of drug, or at appropriate intervals in continuous production operations, and in the event of any significant unexplained discrepancies shall prevent distribution of the batch in question and other associated batches of drugs that may have been involved. A satisfactory explanation for any significant discrepancy between theoretical and actual yields shall be entered on the batch record and signed by the person who investigated the discrepancy. This record shall also contain a statement on criteria used in accepting or rejecting such a batch.

h) In-process batches of drugs found unacceptable to the firm shall be held until a determination as to their disposition has been made. Appropriate records shall be maintained which reflects the reason(s) for unacceptability and the ultimate disposition of this material.

i) Certifiable antibiotics and insulin are to be withheld from distribution until the certification certificate is actually received.

i) Provision that firms which manufacture non-penicillin products, including certifiable antibiotic products, on the same premises or use the same equipment as that used for manufacturing penicillin products or that operate under any circumstances that may reasonably be regarded as conducive to contamination of other drugs by penicillin, shall test such non-penicillin products to determine whether any have become crosscontaminated by penicillin.

Such products shall not be marketed if intended for use by man and the product is contaminated with an amount of penicillin equivalent to 0,05 unit or more of penicillin G per maximum single dose recommended in the labeling of a drug intended for parenteral administration, or an amount of penicillin equivalent to 0.5 unit or more of penicillin G per maximum single dose recommended in the labeling of a drug intended for oral use.

j) Provision that animals used in laboratory tests and procedures shall be adequately housed, fed and maintained under suitable conditions of temperature and humidity. They shall be identified and records maintained as to use and date and time of use.

k) Adequate regular retesting and recording of results on products and components subject to deterioration.

12. Finished-Goods Warehouse Control Distribution Records

Finished-good warehouse control and distribution records shall include an adequate perpetual inventory control system or other suitable system for warehoused finished goods so that he distribution of each lot drug, identified by lot or control number, can be readily determined to facilitate its recall, if necessary, from all consignee of the manufacturer or repacker. Records within the system shall contain the name and the address of the consignee, date and quantity shipped, and lot or control number of drug. Records shall be retained for at least 2 years after drug distribution has been completed or 1 year after the drug's expiration date, whichever is shortest. Finished-goods warehouse control shall also include a system whereby the oldest approved stock is distributed first, whenever possible, to assure the quality of the product.

13 Stability

There shall be assurance of the stability of components, drug preparations in the course of processing and finished drugs. The stability shall be:

a) Determined by reliable, meaningful and specific test methods.

b) Determined on products in the container in which they are marketed to assure, among other things, that the container is not reactive, additive, or absorptive so as to alter the safety, identity, strength, quality or purity of the drug or its components beyond the official or other established requirements.

c) Determined on any solution of a drug product which is to be prepared, as directed in its labeling, at the time of dispensing.

d) Determined in relation to specifications necessary to assure reasonable uniform rates of absorption and the biological availability of the drug product as well as in relation to the specifications for composition and physical characteristics of the drug product.

e) Expressed as an expiration date with related conditions of storage on the drug label. When the drug

is marketed in the dry state for use in preparing a solution or suspension, the labeling shall bear an expiration period for such solution or suspension as well as an expiration date for the dry product.
Expiration dates and periods shall be justified by (1) readily available date from stability studies or (2) readily available date showing that samples from each marketed batch of the drug are laboratory tested at appropriate intervals so that any batch of drug that falls below any of its professed standards of safety, identity, strength, quality or purity prior to the expiration date is recalled from channels of distribution. Expiration dates, including the redating of drug products, shall be calculated from time of inception of the latest set of pertinent laboratory tests. An expiration date shall assure that the drug maintains its safety, identity, strength, quality or purity until that date if related conditions of storage are met.

f) Records shall be maintained of the expiration dates and periods used in the labeling of each batch or lot of drug and said records shall be maintained for at least 2 years after drug distribution has been completed or I year after the drug's expiration date, whichever is shortest.

14 Complaint Files

Records shall be maintained of all written or verbal complaints regarding each product.
Complaints shall be evaluated by competent and responsible personnel and where indicated, appropriate action shall be taken. The record shall indicate the evaluation and action. Said complaint files shall be maintained for at least 2 years after drug distribution has been completed, or 1 year after the drug's expiration date, whichever is shortest.

This regulation shall take effect thirty (30) days after publication in the Official Gazette.

(**Sgd) CLEMENTE S. GATMAITAN, M.D. M.P.H**.
Secretary
Recommended by:

(**Sgd) L.M. PESIGAN**
Food and Drug Administrator

Annotation: This is part of the requirement for licensing of drug manufacturer
Provided for under Administrative Order No. 56 s. 1989