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.

REPUBLIC ACT No. 5921

AN ACT REGULATING THE PRACTICE OF PHARMACY AND SETTING STANDARDS OF PHARMACEUTICAL EDUCATION IN THE PHILIPPINES AND FOR OTHER PURPOSES.

ARTICLE 1
Objectives and Implementation

Section 1. *Objectives.* This Act provides for and shall govern (a) the standardization and regulation of pharmaceutical education; (b) the examination for registration of graduates of schools of pharmacy and (c) the supervision, control and regulation of the practice of pharmacy in the Philippines.

Section 2. *Enforcement.* For the purposes of implementing the provisions of this Act, the Council of Pharmaceutical Education and the Board of Pharmacy are hereby created.

ARTICLE II
The Council of Pharmaceutical Education

Section 3. *The Council of Pharmaceutical Education and its composition.* The Council of Pharmaceutical Education shall be composed of the Secretary of Education, Chairman, the Undersecretary of Health Services, the Food and Drug Administrator, the Chairman of the Board of Pharmacy, the dean of the College of Pharmacy, University of the Philippines, the dean of a college of pharmacy, representing duly accredited private schools of pharmacy, and a representative of the bona fide national pharmaceutical organizations in the Philippines.

It shall be incumbent upon all deans of duly accredited colleges of pharmacy of private colleges and universities by agreement among themselves to promulgate rules and regulations regarding the selection of one from among their group to represent them in the said Council and it shall be incumbent upon all presidents of bona fide national pharmaceutical organizations in the Philippines by agreement to promulgate rules and regulations regarding the selection of one from among them to represent them in the said Council.

The members of the Council shall hold office until their successors have been appointed, elected or designated and duly qualified.

Section 4. *Functions.* The functions of the Council of Pharmaceutical Education shall be:

(a) To promulgate rules and regulations relative to Pharmaceutical Education in the Philippines;

(b) To submit such rules and regulations, which shall have a binding effect, for implementation to the proper agencies such as Department of Education, the Board of Pharmacy, the bona fide national pharmaceutical organizations in the Philippines and others;

(c) To recognize and accredit colleges of pharmacy in the different private colleges and universities; and

(d) To approve the accreditation of community or prescription pharmacies, pharmaceutical manufacturing laboratories and hospital pharmacies for purposes of pharmacy internship.

Section 5. *Meetings and traveling expenses.* The Council of Pharmaceutical Education shall meet at least once a month for regular business and as often as the Council may decide. The Chairman and members of the Council of Pharmaceutical Education shall not be entitled to any compensation except for traveling expenses in connection with their official duties as herein provided.

ARTICLE III
The Board of Pharmacy and Examination and Registration of Pharmacists

Section 6. *The Board of Pharmacy and its Composition.* The Board of Pharmacy shall be composed of a Chairman and two members who shall be appointed by the President of the Philippines with the consent of the Commission of Appointments, from a list of nominees recommended by the Commissioner of Civil Service who shall secure such lists from bona fide professional national organizations of pharmacists which should be certified in accordance with Republic Act Numbered Five hundred forty-six.

Section 7. *Qualification of Board members.* To be appointed a member of the Board of Pharmacy, a person shall be:

(a) A natural born citizen of the Philippines;

(b) A duly registered pharmacist and has been in the practice of pharmacy for at least ten years;

(c) Of good moral character and of recognized standing in the pharmaceutical profession;

(d) At the time of appointment, not a member of the faculty of any school, college or university offering courses in pharmacy; nor have any direct or indirect pecuniary interests in such school or college of pharmacy; and

(e) A member of good standing of any bona fide national pharmaceutical association of the Philippines.

Section 8. *Tenure of office and fees of board members.* The Chairman and members of the Board of Pharmacy shall hold office for three years after appointment or until their successors shall have been appointed and duly qualified: *Provided*, That members of the first Board to be appointed after the approval of this Act shall hold office for the following terms: Chairman for three years, one member for two years and one member for one year:*Provided*, further, That any chairman or member may be reappointed for another term of three years but in no case shall be serve continuously for more than six years. The most senior member of the Board shall automatically be the Chairman.

The Chairman and members of the Board shall each receive the sum of ten pesos for each applicant examined regardless of whether or not he is already in the government service when appointed.

Section 9. *Removal of the Board members.* The chairman or member of the Board may be removed by the President of the Philippines if found guilty of neglect of duty, incompetence, malpractice, or unprofessional, unethical, immoral, or dishonorable conduct, after having been given the opportunity to defend himself in a proper administrative investigation. The President may in his discretion suspend such member under investigation:*Provided, however*, That the period of suspension shall not exceed sixty days after which the latter shall be automatically reinstated pending the outcome of the investigation.

Section 10. *Executive Officer of the Board.* The Commissioner of Civil Service shall be the Executive Officer of the Board and shall conduct the examination given by it according to the rules and regulations promulgated by him and approved by the President of the Philippines. The Secretary of the Board of Examiners in accordance with Republic Act Numbered Five hundred and forty six shall also be the Secretary of the Board. To assist both officials, there shall be appointed from the ranking employees of the Board of Examiners, an Assistant Secretary, a Legal Officer and a Records Officer with compensation of eight thousand eight hundred thirty-two pesos, seven thousand two hundred thirty-six pesos and five thousand nine hundred twenty-eight pesos, respectively who may also perform identical functions for the other existing examination boards. All the records of the Board including examination papers, minutes of deliberation and records of administrative proceedings shall be kept by the Secretary of the Board.

Section 11. *Powers and duties of the Board.* The Board of Pharmacy, conformably with the provisions of this Act is vested with authority:

(a) To examine applicants for the practice of pharmacy;

(b) To issue certificates of registration or pharmacists.

(c) To reprimand any pharmacist or to suspend or revoke his certificate of registration on the grounds as provided for in Section thirteen hereof, after a formal administrative investigation has been conducted by it.

(d) To promulgate from time to time the necessary rules and regulations for the effective enforcement of this Act, subject to the approval of the President upon advice of the Commissioner of Civil Service;

(e) To study the conditions affecting the practice of pharmacy in the Philippines;

(f) To check the employment of qualified personnel in drug stores, hospital pharmacies, drug or pharmaceutical laboratories, cosmetic laboratories and similar establishments for which the Board may designate inspectors from the Board of Pharmacy; and

(g) To encourage the development of botanical gardens and their inspection particularly the propagation of Philippine medicinal plants with the cooperation of the Department of Agriculture and Natural Resources.

Section 12. *Detailmen, requirements, qualifications and fees.* Any person who shall be employed as detailman by any pharmaceutical or drug laboratory or other manufacturers of medical, dental pharmaceutical, biological and veterinary products and by distributors, dealers or wholesalers of said products, doing business directly or indirectly in the Philippines, shall be

required, at the beginning of each year, to register with the Board of Pharmacy that he is employed as such.

(a) An applicant for registration shall be, preferably, a graduate of a college of pharmacy.

There shall be an initial fee of twenty pesos upon registration and thereafter fifteen pesos shall be charged annually for renewal. Upon payment of said fees, the proper credential shall be issued to the applicant.

(b) It shall be incumbent upon the drug establishments referred to in this section to require that detailmen employed or to be employed by them possess the necessary credentials issued by the Board of Pharmacy as provided for herein.

For purposes of this section, a detailman is one who represents any duly authorized manufacturer, dealer, distributor, representative or wholesaler of drugs, pharmaceuticals, biologic products and devices, whose primary duty is to introduce or reacquaint a product or products prepared, distributed or made by said manufacturers, dealer, distributor, representative or wholesaler to the physician, dentist, pharmacist, veterinarian or any other qualified person and which forms part of their program for promotion by describing its use, composition, action, dosage, administration, contra-indication, advantages and other salient information relative to said drug, pharmaceutical, biological product or device.

Section 13. *Grounds for reprimand, suspension or revocation of registrant certificate.* Any of the following shall be sufficient ground for reprimanding a pharmacist, or for suspending or revoking his certificate of registration:

(a) Conviction by a court of competent jurisdiction of any violation as penalized in sections forty and forty-one hereof;

(b) Immoral or dishonorable conduct which includes conviction by a competent court of any criminal offense involving moral turpitude;

(c) Fraud or deceit in the acquisition of the certificate of registration;

(d) Gross negligence, ignorance or incompetence in the practice of his profession resulting in the injury damage or death of another;

(e) Malpractice, including aiding or abetting the commission of criminal abortion or sex crimes through illegal compounding, dispensing or sale of abortive or sex drugs as the case may be;

(f) Acting as a dummy of an alien or of a person who is not qualified to establish and operate a retail drugstore;

(g) Addiction to alcoholic beverage or to any habit-forming drug rendering him incompetent to practice his profession;

(h) Insanity;

(i) False or extravagant or unethical advertisements wherein other things than his name, profession, limitation of practice, office and home address and the like are mentioned; and

(j) Violations of any provision of the Code of Ethics which may be adopted as part of the Rules and Regulations of the Board.

Section 14. *Administrative Investigation.* Administrative investigations shall be conducted by all the members of the Board sitting en banc. The existing rules of evidence shall be observed as far as practicable during administrative investigations.

If the Board, by majority vote of the members, shall find that the charges are sustained by evidence adduced, it may at its discretion reprimand the respondent or revoke or suspend his certificate of registration. In case of suspension, it shall be for a period of not more than six months. Where the certificate of registration has been revoked as herein provided, the Board may, after the expiration of six months and upon application, issue a new certificate of registration in place of a revoked certificate without the necessity of undergoing any examination if the respondent in the meanwhile has conducted himself in an exemplary manner.

Section 15. *Procedure and rules.* The Board of Pharmacy upon receipt of a formal complaint under oath against any pharmacist, shall furnish the latter a copy of the complaint which he shall answer within ten days from receipt hereof. If the Board of Pharmacy, after careful study of the records, finds that there is a valid grounds to the charge it shall conduct a formal investigation setting the dates of hearing thereof. For this purpose, a subpoena or subpoena duces tecum may be issued by the Chairman of the Board. The proceedings shall at all times be recorded. The investigation shall be terminated and resolved within ninety days from the time of the first date of hearing has been set and heard.

Section 16. *Right of respondent.* The respondent pharmacist shall be entitled to be heard by himself or be represented by counsel; to have a speedy and public hearing to confront and to cross-examine witnesses against him; to summon and present witnesses in his behalf; and to any other process for the protection of his individual or civil rights.

Section 17. *Appeal from judgment.* The decision of the Board of Pharmacy shall automatically become final thirty days from notice to respondent, unless the latter after receipt of the decision and within the same period has appealed to the President of the Philippines.

Section 18. *Candidate for board examination.* A candidate for the board examination in Pharmacy shall have the following qualifications:

(a) He shall be a natural-born citizen of the Philippines;

(b) He shall be of good moral character;

(c) He shall have completed an Internship Program which shall consist of at least nine hundred sixty hours, one-half of which shall be spent equally distributed in a prescription pharmacy, a pharmaceutical manufacturing laboratory and a hospital pharmacy duly accredited by the Council of Pharmacy and the rest of the hours of internship shall be spent in any or all of the said establishments at the choice of the candidate.

For this purpose, the above-mentioned prescription pharmacy, pharmaceutical manufacturing laboratory and hospital pharmacy shall keep a separate record of Pharmacy students who have undergone said internship program directly under their control and as a result thereof shall issue the proper certificate of said hours of internship. It shall also be the duty of said establishments to submit annually a complete report of the names of those who have undergone training under their supervision and the corresponding number of hours of internship credit of each of the pharmacy students to their respective colleges or school and to the Board of Pharmacy for proper accreditation; and

(d) He shall have graduated with a degree of Bachelor of Science in Pharmacy or with an equivalent degree from a school, college or university duly accredited by the Council of Pharmaceutical Education after satisfactorily completing a standard pharmacy course of not less than five academic years.

Section 19. *Scope of Examination.* The pharmacist examination shall consist of both theoretical and practical examinations. The theoretical examination shall include subjects in Chemistry, Biological Sciences and Pharmacy.

The Chemistry subjects shall include (1) General, Inorganic, Pharmaceutical and Physical Chemistry, (2) Organic and Medicinal or Pharmaceutical Chemistry, (3) Qualitative, Quantitative and Drug Assaying. The Biological Science subjects shall include (4) Physiology and Biochemistry, (5) Microbiology and Public Health, (6) Pharmacology and Toxicology. The Pharmacy subjects shall include (7) Botany and Pharmacognosy, (8) General Pharmacy, (9) Compounding and Dispensing, (10) Physical and Manufacturing Pharmacy, (11) Pharmacy Administration, and (12) Pharmaceutical Jurisprudence and Ethics. The subjects shall be weighted as follows: Chemistry, thirty per cent; Biological Science, twenty per cent; Pharmacy, fifty per cent.

The practical examination shall consist of (1) Identification and Analysis of Drugs, (2) Preparation of Official Pharmaceuticals, (3) Compounding and Dispensing of Prescriptions and Fixing of Prices of Prescriptions, and (4) Manufacturing Pharmacy and Quality Control. The practical examination shall be weighted as follows: Identification and Analysis of Drugs, thirty per cent; Compounding of Official Pharmaceutical Preparations, Dispensing and Fixing of Price of Prescription and Manufacturing Pharmacy and Quality Control, seventy per cent.

It shall be the duty of the Board of Pharmacy to prepare the schedules of the theoretical and practical examinations and the syllabus of each subject to be given two months before the dates of the examination wherein they are to be used.

Section 20. *Ratings required.* In order to pass the examination, a candidate must obtain on the basis of one hundred per cent a general average of seventy-five per cent or over in both the theoretical and practical examinations, with no ratings below fifty per cent in more than two subjects in the theoretical examinations:*Provided*, That any candidate who passed in the theoretical examination but failed in the practical examination, may, upon taking a re-examination, repeat only the practical examination and vice-versa: *Provided, further*, That any candidate who fails to pass the theoretical or practical examination in three successive attempts shall not be admitted in the fourth examination unless be could present to the Board a certification that he had enrolled and undergone within the year preceding, a pre-board review course from a duly accredited college of Pharmacy.

Section 21. *Holding of examination.* Examination for registration to practice pharmacy in the Philippines shall be given twice a year in the City of Manila and environment as the Board of Pharmacy may fix.

Section 22. *Fees for examination and registration.* The Board of Pharmacy shall charge for each applicant for examination the sum of fifty pesos, and after passing the Board examinations, for each certificate of registration twenty pesos; and for each duplicate registration certificate, ten pesos. All fees shall be paid to the cashier of the Board of Examiners and all expenses, including the fees of the Board members shall be disbursed by him from such funds.

ARTICLE IV
Practice of Pharmacy

Section 23. *Definition of practice of pharmacy.* A person shall be deemed to be practicing pharmacy within the meaning of this Article, who shall, for fee, salary, percentage or other reward paid or given directly to himself or indirectly through another, prepare or manufacture, analyze, assay, preserve, store, distribute or sell any medicine, drug, chemicals, cosmetics, pharmaceuticals, devices or contrivances used in pursuance thereof; or render pharmaceutical service in any office or drug and cosmetic establishment where scientific, technological or professional knowledge of Pharmacy is applied; or engage in teaching scientific, technological or professional pharmacy subject in a college of pharmacy; or conduct or undertake scientific pharmaceutical research for biological and bacteriological testings and examinations.

However, persons performing executive managerial or administrative functions and their subordinate personnel employed in the pharmaceutical laboratories referred to in the second paragraph of Section twenty-seven hereof shall not be considered for purposes of this definition, considered persons in the practice of pharmacy.

Section 24. *Prerequisite for the practice of pharmacy.* No person shall engage in the practice of pharmacy in the Philippines unless he is at least twenty-one years of age, has satisfactorily passed the corresponding examination given by the Board of Pharmacy, and is a holder of a valid certificate of registration duly issued to him by said Board.

Section 25. *Sale of medicine, pharmaceuticals, drugs and devices.* No medicine, pharmaceutical, or drug of whatever nature and kind or device shall be compounded, dispensed, sold or resold, or otherwise be made available to the consuming public except through a prescription drugstore or hospital pharmacy, duly established in accordance with the provisions of this Act.

Pharmaceutical, drug or biological manufacturing establishments, importers and wholesalers of drugs, medicines, or biologic products are authorized to sell their products only at wholesale to duly established retail drugstore or hospital pharmacies.

Section 26. *Markings and inhibition to the sale of drug samples.* No sample of any drug, biological product, device or proprietary medicine, given or intended to be given for free to the physician and other qualified person by any manufacturer or distributor of its representative or detailman as part of its program or promotion, may be sold.

The statement "Sample, not for sale" shall appear conspicuously on the container, package or carton of the drug or device to be given.

Section 27. *Pharmacist required and compensation.* Every pharmacy, drugstore or hospital pharmacy whether owned by the government or a private person or firm shall at all times when open for business be under the personal and immediate supervision of a registered pharmacist: *Provided*, That no pharmacist shall have personal supervision of more than one such establishment. In cases where a drug establishment operates in more than one shift, each shift must be under the supervision and control of a registered pharmacists.

Drug or pharmaceutical laboratories or similar establishments engaged in the repackaging, manufacture or sale of drugs, biologic products and pharmaceutical products in quantities greatly in excess of the therapeutic doses of each substance; such processes involving the preparation, quality control or repackaging of said products shall for each respective operation be under the direct and immediate supervision of a registered pharmacist, or, in the sale of pharmaceuticals, medicines and drugs at wholesale, such business shall be conducted under the immediate supervision of a registered pharmacist practicing only in such establishment.

Every pharmacist employed as such in any of the establishments mentioned in this section whose capitalization is not less than ten thousand pesos shall receive, notwithstanding any provisions of law to the contrary, a minimum compensation similar to that of government pharmacists.

Section 28. *Display of certificate required.* It shall be the duty of every pharmacist engaged in the practice of pharmacy either on his own account or under the employ of another, to display his certificate of registration in a prominent and conspicuous place in pharmacy, drugstore, hospital pharmacy or drug establishment which he operates or in which he is employed. No pharmacist shall with his knowledge allow his certificate of registration to be displayed in such establishments when he is not actually employed or operating therein in his professional capacity.

Section 29. *Responsibility for quality of drugs.* In cases of drugs, pharmaceuticals or poisons sold in their original packings, the seal of which has not been broken or tampered with, the liability that may arise because of their quality and purity , rests upon the manufacturer or in his absence, upon the importer, the distributor, representative or dealer who was responsible for their distribution or sale.

It shall be unlawful for any reason, whoever, to manufacture, prepare, sell or administer any prescription, drug, pharmaceutical or poison under any fraudulent name, direction or pretense or to adulterate any drug, pharmaceutical, medicine or poison so used, sold or offered for sale. Any drug, pharmaceutical, medicine or poison shall be held to be adulterated or deteriorated within the meaning of this section if it differs from the standard of quality or purity given in the United States Pharmacopoeia or National Formulary, both in their latest edition or, in lieu thereof, in any standard reference for drugs and medicines given official recognition; and those which fall within the meaning as provided for in the Food, Drug and Cosmetic Act, (Republic Act Numbered Thirty-seven hundred twenty).

Section 30. *Filling and refilling of prescription.* No prescription shall be filled or compounded except by a registered pharmacist in the employ of the drugstore or pharmacy. It shall be incumbent upon the pharmacist so compounding or filling the prescription to see to it that every

component of the prescription called for metes the standard or purity and quality given in the standard references. Students undergoing pharmaceutical internship may assist said pharmacist in the compounding and dispensing of the prescription called for.

No prescription shall be refilled except upon express order of the person so prescribing.

Section 31. *Label of dispensed medicine.* Upon every box, bottle, or other package containing medicine sold or dispensed by a pharmacist based on prescription, there shall be pasted, affixed or imprinted a seal of label bearing, among others, the name and address of pharmacy; the names and quantities of the ingredients; required doses thereof, its expiration date if any; the name of the prescriber, date and the number of prescription; and the direction for its use.

Every prescription, which in its preparation, contains any quantity of a drug which is habit-forming, or a derivative of such drug, shall have in the label attached to the container the added statement "Warning may be habit forming.

Every prescription for external use filled in the drugstore shall bear a red label showing in black ink the components of such prescription and the words "For external use only" at the bottom of the label.

Section 32. *Record books for prescription.* All prescriptions dispersed in the drugstore shall be recorded in the book kept for the purpose indicating therein, among others, the name of the manufacturer, the original stock, lot and control numbers of the main ingredients of the prescriptions, which book shall be open to inspection by the proper authorities at any time of the day when the pharmacy is open to the public and must be preserved for a period of not less than two years the last entry in it has been made. All prescription shall be attached to said book for prescriptions and numbered consecutively and shall be preserved for the same length of time as the prescription book.

Section 33. *Inhibition against use of cipher or unusual terms in prescriptions and prescription switching.* No pharmacist shall compound or dispense prescriptions, recipes or formulas which are written in ciphers, codes or secret keys or in which they are employed unusual names of drugs which differ from the names ordinarily used for such drugs in standard pharmacopoeias or formularies.

No pharmacist dispensing or compounding prescriptions shall substitute the drug or drugs called for in the prescription with any other drug or substance or ingredient without prior consultation with, and a written consent of, the person prescribing.

Section 34. *Provisions relative to dispensing of violent poisons.* Every pharmacist who dispenses, sells or otherwise delivers any of the violent poisons intended for medicinal use, to wit: arsenical preparations, phosphorus; corrosive sublimate; atropine, strychnine, or any of their salts, hycocyanic acid or any of its salts; oil of bitter almonds containing hydrocyanic acid or prassic acid; oil of mirbane (Nitro-benzene); and such other poisonous substances which may from time to time be classified under this category by the Food and Drug Administration; shall do so only upon prescription of a duly licensed physician, dentist or veterinarian. He shall make or cause to be made in a separate book, kept for the purpose, an entry stating the date of each sale and the name and address of the purchaser, the name and quantity of the poison sold and the purpose for which it was claimed to be purchased, before delivering it to the purchaser.

No prescription, the prescribed dose of which contains a dangerous quantity of poison, shall be filled without first consulting the prescribing authority and verifying the prescription. The pharmacist before delivery of such poison to the purchaser shall acquaint the latter of its poisonous character.

The pharmacist shall also affix to every box, bottle or other package containing any dangerous or poisonous drug, another label of red paper upon which shall be printed in large letters the word "Poison" and a vignette representing a skull and bones before delivering it to the purchaser.

No poison specified in this section shall be sold or otherwise delivered to any person less than eighteen years of age or who is mentally deranged or under the influence of liquor or one who is apparently addicted to opiate and other habit-forming drugs.

The books kept for the purpose of recording the sale of violent poisons shall be open at all times to the inspection of the proper authorities, and every such book shall be preserved for at least five years after the last entry in it has been made.

Should any of the poisons above-stated be intended for purposes other than medicinal, the same may be sold without a prescription by the pharmacist but the other requirements of this section must be complied with.

Section 35. *Provisions relative to dispensing of less violent poisons.* Every pharmacist who dispenses, sells or delivers any poison which is less violent in category as classified by the Food and Drug Administration may do so even without the prescription of a physician and its sale may be recorded in the poison book. The other requirements as provided for in Section thirty-four hereof, however, shall be complied with.

Section 36. *Receptacle for poisonous drugs.* The poisonous drugs specified in Section thirty-four and thirty-five hereof shall be kept in a cabinet to be provided in every pharmacy carrying such drugs in stock and the same shall be kept securely-locked when not in use.

Section 37. *Provisions relative to dispensing of abolifecients or anti-conceptional substances and devices.* No drug or chemical product or device capable of provoking abortion or preventing conception as classified by the Food and Drug Administration shall be delivered or sold to any person without a proper prescription by a duly licensed physician.

The pharmacist in charge of a drug store or pharmacy after filling a prescription containing abortive or anti-conceptional substance or devices shall record in a separate register book for abortives and anti-conceptionals, the following data;

(a) Number and date of the prescription;

(b) Name and address of the physician;

(c) Name, quantity and manufacturer of the drug;

(d) Name and address of the purchaser;

(e) Date of filling the prescription; and

(f) Signature of the pharmacist filling the prescription.

Section 38. *Provisions relative to dispensing of potent drugs.* Every pharmacist who dispenses, sells or delivers any drug, which falls under the classification of the Food and Drug Administration as potent drugs shall do so only upon prescription of a duly licensed physician, dentist or veterinarian.

Section 39. *Requirements for the opening and operation of drugstores and pharmacies.* The minimum requirements necessary for the opening and operation of drugstores and pharmacies shall be in accordance with the rules and regulations to be prescribed by the Food and Drug Administration in accordance with the provisions of this Act. Only natural-born Filipino citizens who are registered pharmacists can apply for the opening of a retail drugstore.

Section 40. *Penal provisions.* Any person who shall violate any of the provisions of Sections twelve, twenty-four, twenty-five, twenty-six, twenty-seven and twenty-nine of this Act or any person who shall make false representation to procure a registration certificate as pharmacist for himself or for another; or any person who shall allow anyone in his employ who is not a registered pharmacist to engage in the practice of pharmacy; or any person who shall falsely display within the establishment the certificate of registration of a pharmacist who is not actually and regularly employed therein as such or to act as a dummy for any alien or an unqualified person for the purpose of opening and operating a retail drugstore; shall, upon conviction thereof, be sentenced to a fine of not less than one thousand pesos but not exceeding four thousand pesos or to an imprisonment of not less than six months and one day but not more than four years, in the discretion of the court.

Section 41. *Other penalties.* Any pharmacist who shall violate any of the provisions of Sections twenty-eight, thirty, thirty-one, thirty-two, thirty-three, thirty-four, thirty-five, thirty-seven and thirty-eight of this Act or any pharmacist after his certificate of registration has been lawfully suspended or revoked, who continues to engage in the practice of pharmacy, shall, upon conviction thereof, be sentenced to a fine of not less than one hundred pesos but shall not exceed five hundred pesos or to an imprisonment of not less than thirty days but not more than four months, in the discretion of the court.

Any person other than citizens of the Philippines having been found guilty of any violation as provided for in this and the preceding section shall, after having paid the fine or having served his sentence or both when so required be also subject to deportation.

Section 42. *Definition of terms.* For purposes of this Act, the term (a) "Pharmacy" or "Drug Store" means a place or establishment where drugs, chemical products, active principles of drugs, pharmaceuticals, proprietary medicines or pharmaceutical specialties, devices, and poisons are sold at retail and where medical, dental and veterinary prescriptions are compounded and dispensed.

(b) "Drug or Pharmaceutical Laboratory" or Pharmaceutical Manufacturing Laboratory" means an establishment where pharmaceuticals, proprietary medicines or pharmaceutical specialties are prepared, compounded, standardized and distributed or sold.

(c) "Wholesaler" means and includes every person who acts as a jobber, merchant, broker or agent, who sells or distributes for resale pharmaceuticals, proprietary medicines or pharmaceutical specialties.

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

(e) "Drug" means (1) articles recognized in the official United States Pharmacopoeia, official Hemeopathic Pharmacopoeia of the United States or official National Formulary, or any of their supplements; (2) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or animals; (3) articles (other than food) intended to effect 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.

(f) "Pharmaceuticals", "Proprietary Medicines" or "Pharmaceutical Specialties" means any drug, preparation or mixture of drugs marked under a trade name and intended for the cure, mitigation or prevention of disease in man or animals.

(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 effect the structure or any function of the body of man or animals.

(h) "Biologic Products" are viruses, sera, toxins and analogous products used for the prevention or cure of human diseases.

(i) "Poison" is any drug, active principle, or preparation of the same, capable of destroying life or seriously endangering health when applied externally to the body or introduced internally in moderate doses.

(j) "Cipher" means a method of secret writing that substitutes other letters or characters for the letter intended or transposes the letter after arranging them in blocks or squares.

(k) "Code" means a system of words or other symbols arbitrarily used to represent words.

(l) "Secret Keys" means a characteristics style or symbols kept from the knowledge of others or disclosed confidentially to but one of few.

Section 43. *Final Provisions.* To carry out the provisions of this Act, there is hereby authorized to be appropriated, out of any funds in the National Treasury not otherwise appropriated, the sum of thirty thousand pesos within the fiscal year of the approval hereof. Thereafter, such funds as are necessary for the maintenance and operation of the Board of Pharmacy and of the Council of Pharmaceutical Education shall be included in the annual General Appropriations Act.

Section 44. *Repealing clause.* The following are hereby repealed: Sections seven hundred seventeen to seven hundred fifty-seven inclusive, Sections two thousand six hundred seventy-

five to two thousand six hundred seventy-seven inclusive of the Revised Administrative Code, as amended; and such other laws or part of laws, executive orders, administrative orders; circulars, regulations and memoranda inconsistent or incompatible with this Act.

Section 45. *Separability of provisions.* If any part, section or provision of this Act shall be held invalid or unconstitutional, no other part, section or provision thereof shall be affected thereby.

Section 46. *Effectivity.* This Act shall take effect upon its approval.

Approved: June 21, 1969

Republic of the Philippines
Congress of the Philippines
Metro Manila

Eighth Congress
Second Regular Session

Begun and held in Metro Manila, on Monday, the twenty-fifth day of July, nineteen hundred and eighty-eight.

Republic Act No. 6675 September 13, 1988

AN ACT TO PROMOTE, REQUIRE AND ENSURE THE PRODUCTION OF AN ADEQUATE SUPPLY, DISTRIBUTION, USE AND ACCEPTANCE OF DRUGS AND MEDICINES IDENTIFIED BY THEIR GENERIC NAMES

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

Section 1. ***Title*** – This Act shall be known as the **"*Generics Act of 1988*."**

Section 2. ***Statement of Policy*** – It is hereby declared the policy of the State:

To promote, encourage and require the use of generic terminology in the importation, manufacture, distribution, marketing, advertising and promotion, prescription and dispensing of drugs;

To ensure the adequate supply of drugs with generic names at the lowest possible cost and endeavor to make them available for free to indigent patients;

To encourage the extensive use of drugs with generic names through a rational system of procurement and distribution;

To emphasize the scientific basis for the use of drugs, in order that health professionals may become more aware and cognizant of their therapeutic effectiveness; and

To promote drug safety by minimizing duplication in medications and/or use of drugs with potentially adverse drug interactions.

Section 3. ***Definition of Terms*** – The following terms are herein defined for purposes of this Act:

(1) "*Generic Name or Generic Terminology*" is the identification of drugs and medicines by their scientifically and internationally recognize active ingredients or by their official generic name as determined by the Bureau of Food and Drugs of the Department of Health.

(2) "*Active Ingredient*" is the chemical component responsible for the claimed therapeutic effect of the pharmaceutical product.

(3) "*Chemical Name*" is the description of the chemical structure of the drug or medicine and serves as the complete identification of a compound.

(4) "*Drug Product*" is the finished product form that contains the active ingredients, generally but not necessarily in association with inactive ingredients.

(5) "*Drug Establishment*" is any organization or company involved in the manufacture, importation, repacking and/or distribution of drugs or medicines.

(6) "*Drug Outlets*" means drugstores, pharmacies, and any other business establishments which sell drugs or medicines.

(7) "*Essential Drugs List*" or "National Drug Formulary" is a list of drugs prepared and periodically updated by the Department of Health on the basis of health conditions obtaining in the Philippines as well as on internationally accepted criteria. It shall consist of a core list and a complementary list.

(8) "*Core List*" is a list of drugs that meets the health care needs of the majority of the population.

(9) "*Complementary List*" is a list of alternative drugs used when there is no response to the core essential drug or when there is hypersensitivity reaction to the core essential drug or when for one reason or another, the core essential drug cannot be given.

(10) "*Brand Name*" is the proprietary name given by the manufacturer to distinguish its product from those of competitors.

(11) "*Generic Drugs*" are drugs not covered by patent protection and which are labeled solely by their international non-proprietary or generic name.

Section 4. ***The Use of Generic Terminology for Essential Drugs and Promotional Incentives*****.** – (a) In the promotion of the generic names for pharmaceutical products, special consideration shall be given to drugs and medicines which are included in the Essential Drugs List to be prepared within one hundred eighty (180) days from approval of this Act and updated quarterly by the Department of Health on the basis of health conditions obtaining in the Philippines as well as on internationally accepted criteria.

(b) The exclusive use of generic terminology in the manufacture, marketing and sales of drugs and medicines, particularly those in the Essential Drugs List, shall be promoted through such a system of incentives as the Board of Investments jointly with the Department of Health and other government agencies as may be authorized by law, shall promulgate in accordance with existing laws, within one hundred eighty (180) days after approval of this Act.

Section 5. ***Posting and Publication*** – The Department of Health shall publish annually in at least two (2) newspapers of general circulation in the Philippines the generic names, and the corresponding brand names under which they are marketed, of all drugs and medicines available in the Philippines.

Section 6. ***Who Shall Use Generic Terminology*** - (a) All government health agencies and their personnel as well as other government agencies shall use generic terminology or generic names in all transactions related to purchasing, prescribing, dispensing and administering of drugs and medicines.

(b) All medical, dental and veterinary practitioners, including private practitioners, shall write prescriptions using the generic name. The brand name may be included if so desired.

(c) Any organization or company involved in the manufacture, importation, repacking, marketing and/or distribution of drugs and medicines shall indicate prominently the generic name of the product. In the case of brand name products, the generic name shall appear prominently and immediately above the brand name in all product labels as well as in advertising and other promotional materials.

(d) Drug outlets, including drugstores, hospital and non-hospital pharmacies and non-traditional outlets such as supermarkets and stores, shall inform any buyer about any and all other drug products having the same generic name, together with their corresponding prices so that the buyer may adequately exercise, his option.

Within one (1) year after approval of this Act, the drug outlets referred to herein, shall post in conspicuous places in their establishments, a list of drug products with the same generic name and their corresponding prices.

Section 7. ***Provision on Quality, Manufacturer's Identity and Responsibility*** – In order to assure responsibility for drug quality in all instances, the label of all drugs and medicines shall have the following: name and country of manufacture, dates of manufacture and expiration. The quality of such generically labeled drugs and medicines shall be duly certified by the Department of Health.

Section 8. ***Required Production*** – Subject to the rules and regulations promulgated by the Secretary of Health, every drug manufacturing company operating in the Philippines shall be required to produce, distribute and make available to the general public the medicine it produces, in the form of generic drugs.

Section 9. ***Rules and Regulations*** – The implementation of the provisions of this Act shall be in accordance with the rules and regulations to be promulgated by the Department of Health. Rules and regulations with penal sanctions shall be promulgated within one hundred eighty (180) days after approval of this Act and shall take effect fifteen (15) days after publication in the Official Gazette or in two (2) newspapers of general circulation.

Section 10. ***Authority to Import*** – Within three (3) years from the effectivity of this Act, extendible by the President for another two (2) years and during periods of critical shortage and absolute necessity, the Department of Health is hereby authorized to import raw materials of which there is a shortage for the use of Filipino-owned or controlled drug establishments to be marketed and sold exclusively under generic nomenclature. The President may authorize the importation of raw materials tax and duty-free. The Secretary of Health shall ensure that the imported raw materials are allocated fairly and efficiently among Filipino-owned or controlled drug establishments. He shall submit to the Office of the President and to Congress a quarterly report on the quantity, kind and value of the raw materials imported.

Section 11. ***Education Drive*** – The Department of Health jointly with the Department of Education, Culture and Sports, Philippine Information Agency and the Department of Local Government shall conduct a continuous information campaign for the public and a continuing education and training for the medical and allied medical professions on drugs with generic names as an alternative of equal efficacy to the more expensive brand name drugs. Such educational campaign shall include information on the illnesses or symptoms which each generically named drug is supposed to cure or alleviate, as well as its contraindications. The Department of Health with the assistance of the Department of Local Government and the

Philippine Information Agency shall monitor the progress of the education drive, and shall submit regular reports to Congress.

Section 12. ***Penalty*** – A) Any person who shall violate Section 6(a) or 6(b) of this Act shall suffer the penalty graduated hereunder, viz:

(a) for the first conviction, he shall suffer the penalty of reprimand which shall be officially recorded in the appropriate books of the Professional Regulation Commission.

(b) for the second conviction, the penalty of fine in the amount of not less than two thousand pesos (P2,000.00) but not exceeding five thousand pesos (5,000.00) at the discretion of the court.

(c) for the third conviction, the penalty of fine in the amount of not less than five thousand pesos (P5,000.00) but not exceeding then thousand pesos (P10,000.00) and suspension of his license to practice his profession for thirty (30) days at the discretion of the court.

(d) for the fourth and subsequent convictions, the penalty of fine of not less than ten thousand pesos (P10,000.00) and suspension of his license to practice his profession for one year or longer at the discretion of the court.

B) Any juridical person who violates Section 6(c), 6(d), 7 or 8 shall suffer the penalty of a fine of not less than five thousand pesos (P5,000.00) nor more than ten thousand pesos (P10,000.00) and suspension or revocation of license to operate such drug establishment or drug outlet at the discretion of the Court: Provided,That its officers directly responsible for the violation shall suffer the penalty of fine and suspension or revocation of license to practice profession, if applicable, and by imprisonment of not less than six (6) months nor more than one (1) year or both fine and imprisonment at the discretion of the Court: and Provided, further, That if the guilty party is an alien, he shall be ipso facto deported after service of sentence without need of further proceedings. C) The Secretary of Health shall have the authority to impose administrative sanctions such as suspension or cancellation of license to operate or recommend suspension of license to practice profession to the Professional Regulation Commission as the case may be for the violation of this Act. Section 13. Separability Clause – If any provision of this Act is declared invalid, the remainder or any provision hereof not affected thereby shall remain in force and effect.

Section 14. ***Repealing Clause*** – The provisions of any law, executive order, presidential decree or other issuances inconsistent with this Act are hereby repealed or modified accordingly.

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

Approved,

(Sgd.) **RAMON V. MITRA**
Speaker of the House of Representatives

(Sgd.) **JOVITO R. SALONGA**
President of the Senate

This Act which is a consolidation of Senate Bill NO. 453 and House Bill No. 10900 was finally passed by the Senate and the House of Representatives on August 25, 1988 and August 31, 1988, respectively.

(Sgd.) **QUIRINO D. ABAD SANTOS, JR.**
Secretary General
House of Represenatives

(Sgd.) **EDWIN P. ACOBA**
Secretary of Senate

Approved: **September 13, 1988**

(Sgd.) **CORAZON C. AQUINO**
President of the Philippines

REPUBLIC OF THE PHILIPPINES CONGRESS OF THE PHILIPPINES METRO MANILA

SECOND REGULAR SESSION

Begun and held in Metro Manila, on Monday, the twenty-second day of July, nineteen hundred and ninety-six

[REPUBLIC ACT NO. 8203]

AN ACT OF PROHIBITING COUNTERFEIT DRUGS, PROVIDING PENALTIES FOR VIOLATIONS AND APPROPRIATING FUNDS THEREFOR

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

SECTION 1. ***Title*** – This Act shall be known as the "Special Law on Counterfeit Drugs."

SECTION 2. ***Declaration of Policy*** -It is hereby the policy of the State to protect and promote the right to health of the people and instill health consciousness among them as provided in Section 15 Article 11 of the Constitution.

It is also further declared the policy of the State that in order to safeguard the health of the people, the State shall provide for their protection against counterfeit drugs.

SECTION 3. ***Definition of Terms*** – For purposes of this Act, the terms:

(a) Drugs shall refer to any chemical compound or biological substance, other than food, intended for use in the treatment, prevention or diagnosis of disease in man or animals, including but not limited to:

(1) any article recognized in the official United States Pharmacopoeia – National Formulary (USP-NF), official Homeopathic Pharmacopoeia of the United States, Philippines National Drug Formulary, British Pharmacopoeia, any National Compendium or any supplement to any of them;
(2) any article intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or animals;
(3) any article other than food intended to affect the structure or any function of the body of man or animals;
(4) any article intended for use as a component of any articles specified in clauses (1), (2), (3) not including devices or their components, parts, or accessories; and
(5) herbal and/or traditional drugs which are articles of plant or animal origin used in folk medicine which are:
(a) recognized in the Philippine National Drug Formulary; (b) intended for use in the treatment or cure or mitigation of disease symptoms, injury or body defect in man; (c) other than food, intended to affect the structure or any function of the body of man; (d) in finished or ready-to-use dosage form; and (e) intended for use as a component of any of the articles specified in clauses (a), (b), (c) and (d).
(b) Counterfeit drug/medicine refers to medicinal products with the correct ingredients but not in the amounts as provided hereunder, wrong ingredients, without active ingredients, with sufficient quantity of active ingredient, which results in the reduction of the drug's safety, efficacy, quality, strength or purity. It is a drug which is deliberately and fraudulently mislabeled with respect to identity and/or source or with fake packaging, and can apply to both branded and generic products. It shall also refer to:

1) the drug itself or the container or labeling thereof or any part of such drug, container or labeling bearing without authorization the trademark, trade name or other identification mark or imprint or any likeness to that which is owned or registered in the Bureau of Patent, Trademark and Technology Transfer (BPTTT) in the name of another natural or juridical person;

2) a drug product refilled in containers by unauthorized persons if the legitimate labels or marks are used;

3) an unregistered imported drug product, except drugs brought in the country for personal use as confirmed and justified by accompanying medical records;

4) a drug which contains no amount of or a different active ingredient or less than eighty percent (80%) of the active ingredient it purports to possess as distinguished from an adulterated drug including reduction or loss or efficacy due to expiration.

(c) Brokering shall refer to any act of facilitating the disposal or sale or counterfeit drugs, including acts of agency.
(d) Bureau shall refer to the Bureau of Food and Drugs (BFAD) of the Department of Health (DOH).
(e) Department shall refer to the Department of Health
(f) Business establishment shall refer to any entity, whether a single proprietorship, partnership, or corporation engaged in or doing business in the Philippines.
(g) Owner shall refer to a person or group of persons who is the registered owner of a license to operate a business or business undertaking in the Philippines or the branch manager or operator, licensee, franchisee, or any person acting on behalf of he corporate entity.
(h) Residence shall refer to a private dwelling or abode where a person lives, either as owner or lessee, or usurfructuary including, for purposes of this Act, its yard, garage, storage rooms or premises.

SECTION 4 ***Prohibited Acts.*** – The following acts are declared unlawful and therefore prohibited;

a) The manufacture, sale, or offering for sale, donation, distribution, trafficking, brokering, exportation, or importation or possession of counterfeit drugs as defined in Section 3 hereof not otherwise covered by Republic Act No. 3720, as amended. The presence or availability of such counterfeit drugs within the premises of any entity engaged in the sale, manufacture or distribution of drugs and/or pharmaceutical products or in a private residence, or in public or private vehicle, or in the premises not covered by a valid license to operate from the Bureau, shall constitute a prima facie evidence of violation of this Act: Provided, however, That this presumption shall not apply to the legitimate owners of trademarks, trade names or other identifying marks, or the legitimate or authorized representatives or agents of such owners who have in their possession counterfeit drugs which bear the trademarks, trade names or marks if they can show the sales invoices or official receipts evidencing their purchase from a drugstore, manufacturer or distributor suspected by them of dealing in counterfeit drugs involving the trademarks, trade names and other similar identifying marks registered in their names: Provided, further, That such counterfeit products shall be reported and immediately turned over to the Bureau: Provided, finally, That compliance with the

preceding provision shall be made within a reasonable period from the date of purchase of such counterfeit drugs as indicated in the sales invoice, official receipt, or other similar documents abovementioned to the time the counterfeit drugs are reported and turned over to the Bureau;

b) Possession of any such counterfeit drugs. However, any person found in possession of counterfeit drugs, in violation of this subsection, shall be exempted from liability under the provisions of this Act after:

1) presentation of sales invoices, official receipts or other legally acceptable documents evidencing his purchase thereof from a drugstore, distributor, manufacturer, hospital pharmacy or dispensary; or any other person or place duly licensed to sell and/or dispense drugs or medicines and indicating therein the batch and lot numbers, as well as the expiry dates of such drugs; or

2) presentation of certificates and other documents evidencing the importation or exportation of the counterfeit drugs found in his possession as required by existing laws, including those documents required in the preceding paragraph covering the commercial transactions involving counterfeit drugs.

In both cases, the subject counterfeit drugs must not on their face appear to be as such, or do not bear any marking or any patently unusual characteristic sufficient to arouse the suspicion of a reasonable and prudent person that such drugs are counterfeit. Furthermore, the amount or volume of counterfeit drugs held is such that it does not negate or is inconsistent with the averment that the same are for personal use, notwithstanding the presentation by the possessor of medical records and other similar documents accompanying and justifying the use of such drugs;

c) Forging, counterfeiting, simulating or falsely representing, or without proper authority, using any mark, stamp, tag, label or other identification mark or device authorized or required by Republic Act No. 3720, as amended, and/or the regulations promulgated under this Act;

d) Photocopying, duplicating, altering, printing, transferring, obliterating or removing the approved label or any part thereof, lawfully belonging to another person, for the purpose of using such label or a part thereof on any counterfeit drug: Provided, That if the person who committed any of the acts enumerated in this paragraph and the person who used the labels produced thereby are not one and the same person and the former had knowledge of the purpose for which the labels are intended, the former shall also be liable under this Act notwithstanding the failure of the latter to achieve the intended purposes; and

e) Making, selling, or concealing any punch, dye, plate or any other equipment or instrument designed to print, imprint or reproduce the trademark, trade name or other identifying mark of another registered producer or any likeness thereof, upon any drug product or device or its container or label without authority from the legitimate owners of the trademark or trade name.

SECTION 5*. Parties Liable* -The following persons shall be liable for violation(s) of this Act:

a) the manufacturer, exporter or importer of the counterfeit drugs and their agents: Provided, That the agents shall be liable only upon proof of actual or constructive knowledge that the drugs are counterfeit;

b) the seller, distributor, trafficker, broker or donor and their agents, upon proof of actual or constructive knowledge that the drugs sold, distributed, offered or donated are counterfeit drugs;

c) the possessor of counterfeit drugs as provided in Section 4 (b) hereof;

d) the manager, operator or lessee of the laboratory or laboratory facilities used in the manufacture of counterfeit drugs;

e) the owner, proprietor, administrator or manager of the drugstore, hospital pharmacy or dispensary, laboratory or other outlets or premises where the counterfeit drug is found who induces, causes or allows the commission of any act herein prohibited;

f) the registered pharmacist of the outlet where the counterfeit drug is sold or found, who sells or dispenses such drug to a third party and who has actual or constructive knowledge that said drug is counterfeit; and

g) should the offense be committed by a juridical person the president, general manager, the managing partner, chief operating officer or the person who directly induces, causes or knowingly allows the commission of the offense shall be penalized.

SECTION 6. ***Administrative Proceedings*****.-**The Bureau is hereby further authorized to undertake the following administrative actions:

a) upon verified information on the existence of suspected counterfeit drugs in the possession of any manufacturer, seller or distributor, the duly authorized officers of the bureau or any officer deputized by the Bureau for the purpose shall segregate, seal and after having obtained a valid search warrant from a competent court, seize such counterfeit drugs and take them into custody: Provided, That in case the suspected counterfeit drugs are found in a private residence, as defined in Section 3 of this Act or in other premises not covered by a valid license to operate issued by the Bureau, the duly authorized officer of the Bureau or deputized officer thereof shall secure a search warrant for the purpose of seizing and taking into custody such suspected counterfeit drugs;

b) if, after the appropriate examination of the samples by the Bureau, the seized drugs are determined or found to be counterfeit, the Bureau shall, within (15) days from their seizure, issue an order directing the preventive closure of the business establishment for a period not exceeding thirty (30) days. Thereafter, administrative proceedings shall be initiated by the Bureau against the parties concerned where they shall have the opportunity to be heard and present evidence on their behalf; and

c) to ensure the effective enforcement of the foregoing, the Bureau may enlist the assistance of the national or local law enforcement agencies.

SECTION 7. ***Administrative Sanctions*** – Upon finding that the drugs examined are counterfeit and the determination of the parties liable thereof, the Bureau shall impose any or all of the following sanctions:

a) permanent closure of the establishment concerned and the revocation of its license to business;

b) a fine of not less than One hundred thousand pesos (P100,000) but not more than Five

hundred thousand pesos (P500,000);

c) upon order of the Court, forfeiture, confiscation, and destruction of products found to be counterfeited and the equipment, instruments, and other articles used in violation of this Act;

d) filing of an appropriate proceedings against the registered pharmacist with the Professional Regulations Commission for cancellation of professional license;

e) filing of criminal charges against the violator (s), which can be instituted independently from the administrative case: Provided, That the dismissal of the criminal case shall not lift the closure order, except when it is a dismissal on the merits or for lack of basis: Provided, further, That the withdrawal of the private criminal complaint shall not be a ground for the dismissal of the administrative proceedings; and

f) permanent disqualification of the person concerned, whether natural or juridical, from owning or operating an establishment engaged in any business activity under the supervision of the Bureau.

SECTION 8. ***Penalties***. – The commission of any of the acts prohibited under Sections 4 and 6 of this Act shall be punished by:

a) imprisonment of not less than six (6) months and one (1) day; but not more than six (6) years for more possession of counterfeit drugs as provided for in Section 4(b) hereof; or

b) imprisonment of six (6) years and one (1) day, but not more than ten (10) years or a fine of not less than One hundred thousand pesos (P100,000) but not more than Five hundred thousand pesos (P500,000) or both such imprisonment and fine at the discretion of the court in any other case mentioned in Section 4 hereof; or

c) imprisonment of not less than six (6) months and one (1) day, but not more than two (2) years and four (4) months if the counterfeit drug is intended for animals; or

d) imprisonment of not less than six (6) years and one (1) day but not more than ten (10) years for any manufacturer, seller or distributor who shall conceal, substitute, dispose or destroy any drug as may have been segregated and sealed by the Bureau or who shall break, alter or tamper any mark or seal used by the Bureau to identify those segregated drugs as provided for under Section 6(a) of this Act. Any other person who breaks, alters or tampers any mark or seal used by the Bureau to identify the segregated drugs shall suffer the penalty of not less than six (6) months and one (1) day, but not more than six (6) years imprisonment; or

e) if, as a result of the use of the drug found to be counterfeit, the illness sought to be cured is aggravated or physical injury or suffering results therefrom, a punishment of imprisonment from twelve (12 years to fifteen (15) years and a fine ranging from One hundred thousand pesos (P100,000) to Five hundred thousand pesos (P500,000) shall be meted out; or

f) should a counterfeit drug be the proximate cause of death of a victim, who unknowingly purchased and took a counterfeit drug, the penalty of life imprisonment and a fine of Five hundred thousand pesos (P500,000) to Five million pesos (P5,000,000) shall be imposed.

In case any act prohibited in Section 4 hereof is also punishable under other laws, the offender shall, if warranted by the evidence, be prosecuted under the law prescribing the highest penalty.

SECTION 9. ***Appropriations*** – The amount necessary to carry out the provisions of this Act shall be included in the General Appropriations Act for the year following its enactment and every year thereafter.

SECTION 10. ***Implementation*** – The Bureau of Food and Drugs of the Department of Health is hereby authorized to administer and supervise the implementation of this Act.

SECTION 11. ***Implementing Rules and Regulations.*** – Within ninety (90) days from the approval of this Act, the Bureau of Food and Drugs, in consultation with the Department of Health, shall promulgate the rules and regulations implementing the provisions of this Act. The implementing rules and regulations issued pursuant to this section shall take effect thirty (30) days after its publication in two (2) national newspapers of general circulation.

SECTION 12. ***Separability Clause*** – If, for any reason, any portion or provision of this Act is subsequently declared unconstitutional or invalid, such declaration shall not nullify the other portions or provisions hereof.

SECTION 13. ***Repealing Clause***. – all laws, decrees, executive or administrative orders, rules or regulations inconsistent with the provisions of this Act are hereby or modified accordingly.

SECTION 14. ***Effectivity***. – This Act shall take effect fifteen (15) days after its publication in at least two (2) national newspapers of general circulation.

Approved,

(Sgd) JOSE DE VENECIA, JR.
Speaker of the House of Representatives

(Sgd) NEPTALI A. GONZALES
President of the Senate

This Act, which is a consolidation of Senate Bill NO. 1284 and House Bill No. 5666 was finally passed by the Senate and the House of Representatives on August 27, 1996 and August 22, 1996, respectively.

(Sgd) ROBERTO P. NAZARENO
Secretary General Secretary of the Senate

(Sgd) HEZEL P. GACUTAN
House of Representatives

Approved: September 4, 1996