H. No. 3052 / 59 OG No. 47, 8022 (November 25, 1963)

[REPUBLIC ACT NO. 3720, June 22, 1963]

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.

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

CHAPTER I.—*Title*

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

CHAPTER II.—*Declaration of Policy*

SEC. 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.

SEC. 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*

SEC. 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.

SEC. 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.

SEC. 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.

SEC. 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.

SEC. 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*

SEC. 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 or 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 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*

SEC. 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 does 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

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

(a) The manufacture, sale, offering for sale or transfer of any food, drug, device or cosmetics 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

SEC. 12.(a) Any person who violates any of the provision of Section eleven hereof shall, upon conviction, be subject to imprisonment of not less than six months 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.—*Definitions and Standards for Food*

SEC. 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.