

EXECUTIVE ORDER NO. 175 May 22, 1987

FURTHER AMENDING REPUBLIC ACT NO. 3720, ENTITLED "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", AS AMENDED, AND FOR OTHER PURPOSES

WHEREAS, it is State policy, under Article II, Section 15, of the 1987 Constitution to "protect and promote the right to health of the people and instill health consciousness among them";

WHEREAS, the 1987 Constitution also provides, in its Article XIII, Section 12, that: "The State shall establish and maintain an effective food and drug regulatory system and undertake appropriate health manpower development and research, responsive to the country's health needs and problems";

NOW, THEREFORE, I, CORAZON C. AQUINO, President of the Philippines, do hereby order:

Sec. 1. The title of Republic Act No. 3720 is hereby amended to read as follows:

"An Act to Ensure The Safety And Purity of Foods and Cosmetics, And The Purity, Safety, Efficacy and Quality of Drugs and Devices Being Made Available To the Public, Vesting The Bureau of Food and Drugs with Authority To Administer And Enforce the Laws Pertaining Thereto, And For Other Purposes"

Sec. 2. Section 1 of the Republic Act No. 3720 is hereby amended to read as follows:

"Sec. 1. This Act shall be known as the Foods, Drugs and Devices, and Cosmetics Act".

Sec. 3. The headnote of Chapter II of Republic Act No. 3720 is hereby amended to read as follows: "Declaration Of Policies" and Section 2 thereof is likewise amended as follows:

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

Sec. 4. Section 3 of Republic Act No. 3720 is hereby amended to read as follows:

"Sec. 3. In the implementation of the foregoing policies, the Government, through the Department of Health, shall, in accordance with the provisions of this Act:

- (a) Establish standards and quality measures for foods, drugs and devices and cosmetics.
- (b) Adopt measures to ensure pure and safe supply of foods and cosmetics, and pure, safe, efficacious and good quality drugs and devices in the country.
- (c) Adopt measures to ensure the rational use of drugs and devices, such as, but not limited to, banning, recalling or withdrawing from the market drugs and devices which are not registered, unsafe, inefficacious or of doubtful therapeutic value, the adoption of an official National Drug Formulary, and the use of generic names in the labeling of drugs.

(d) Strengthen the Bureau of Food and Drugs."

Sec. 5. Section 10 of Republic Act No. 3720 is hereby amended to read as follows:

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

(a) "Bureau" means the Bureau of Food and Drugs.

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(f) "Drugs" mean (1) articles recognized in the current official United States Pharmacopeia National Formulary (USP-NF), official Homeopathic Pharmacopeia of the United States, official National Drugs 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 do not include devices or their components, parts or accessories.

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(1) "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, efficacy, and quality of drugs as safe, efficacious and of good quality for use under the conditions prescribed, recommended, or suggested in labelling thereof.

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

(3) "New drugs" shall include drugs (a) containing a newly discovered active ingredient; (b) containing a new fixed combination of drugs, either by molecular or physical combination; (c) intended for new indications; (d) in an additional dosage or strength of the dosage form, which meets the conditions as defined under the new drug.

The definition of "new drugs" covers, to the extent applicable "new devices".

Sec. 6. Section 10 of the Republic Act No. 3720 is hereby amended by adding thereto the following subsections:

"(o) "Batch" means a quantity of any drug or device produced during a given cycle of manufacture.

(p) "Batch number" means a designation printed on the label of a drug or device that identifies the batch, and permits the production history of the batch including all stages of manufacture and control, to be traced and reviewed.

(q) "Director" means Director of the Bureau of Food and Drugs.

(r) "Distribute" means the delivery or sale of any drug or device for purposes of distribution in commerce, except that such terms does not include a manufacturer or retailer of such product.

(s) "Expiry or expiration date" means the date stated in the label of a drug or device after which the drug is not expected to retain its claimed safety, efficacy and quality or potency or after which it is not permissible to sell the drug or device.

(t) "Export" means to bring out of the Philippines by sea, land or air.

(u) "Import" means to bring into the Philippines by sea, land or air.

(v) "Manufacture", in relation to a drug, or device where applicable, means any and all operations involved in the production of a drug or device including preparation, processing, compounding, formulating, filling, packing, repacking, altering, ornamenting, finishing and labeling with the ends of view of its storage, sale or distribution; Provided, That the term shall not apply to the compounding and filling of prescriptions in drugstores and hospital pharmacies.

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

Sec. 7. Section 11 of Republic Act No. 3720 is hereby amended to read as follows:

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

(a) The manufacture, importation, exportation, sale, offering for sale, distribution 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 guarantor 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 and employees of the Department or to the courts when relevant in any judicial proceeding under this Act, any information 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 result 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 Sections twenty-one and twenty-one-B hereof, or that such drug complies with the provisions of such sections.

(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.

Sec. 8. Section 11 of Republic Act No. 7320 is hereby amended by adding thereto the following subsections:

"(j) The manufacture, importation, exportation, sale, offering for sale, distribution, or transfer of any drug or device which is not registered with the Bureau pursuant to this Act.

(k) The manufacture, importation, exportation, sale, offering for sale, distribution, or transfer of any drug or device by any person without the license from the Bureau required under this Act.

(l) The sale or offering for sale of any drug or device beyond its expiration or expiry date.

(m) The release for sale or distribution of a batch of drugs without batch certification when required under Section twenty-two hereof."

Sec. 9. Section 12 of Republic Act No. 3720 is hereby amended to read as follows:

"Sec. 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 one year but not more than five years, or a fine of not less than five thousand pesos but not more than ten thousand pesos, or both such imprisonment and fine, in the discretion of the Court.

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

(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 Bureau 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 document, if any there be, pertaining to the delivery of the article to him; (2) for having violated Section 11 (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 color other than the permissible one under regulations promulgated by the Secretary under this Act, if such person established a guaranty or undertaking signed by, and containing the name and address, of the manufacturer of the color, to the effect that such color is permissible, under applicable regulations promulgated by the Secretary under this Act."

Sec. 10. Section 18 of Republic Act No. 3720 is hereby amended to read as follows:

"Sec. 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, or decomposed substances which may affects its safety, efficacy or good quality or (2) if it has been manufactured, prepared or held under unsanitary conditions whereby it may have been contaminated with dirt or filth or whereby it may have been rendered injurious to health; or (3) if it is a drug or device 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, any color other than a permissible one as determined by the Secretary, taking into consideration standards of safety, efficacy or good quality.

(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 safety, efficacy, quality or purity falls below the standards 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 Director, regulations prescribing appropriate tests or methods of assay in accordance with which such determination as to strength, safety, efficacy, 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 standards of strength, safety, efficacy, quality, or purity therefor set forth in such compendium, if its difference in strength, safety, efficacy, quality or purity from such standards is plainly stated in its label and approved for registration as such.

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

(d) If it is a drug or device and any substance has been mixed or packed therewith, or any substance has been substituted wholly or in part thereof, so as to reduce its safety, efficacy, quality, strength or purity.

(e) If the methods used in, or the facilities or controls used for its manufacture or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that such drug meets the requirements of this Act as to safety, quality and efficacy, and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess."

Sec. 11. Section 19 of Republic Act No. 3720 is hereby amended to read as follows:

"Sec. 19. A drug or device shall be deemed to be misbranded:

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

(b) If it is in package form unless it bears a label containing (1) the name and place of business of the manufacturer, importer, 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, marijuana, 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 or proportion of any bromides, ether, chloroform, acetanilid, acetophenetidin, amidopyrine, antipyrine, atropine, hyoscine, hyoscyamine, arsenic, digitalis, digitalis glycosides, mercury, ouabain, strophanthine, strychnine, thyroid, or any derivative or preparation of any such substances, contained therein: Provided, That where compliance with this paragraph is impracticable, exemptions shall, upon recommendation of the Director, be established by regulations promulgated by the Secretary.

(f) Unless its labeling bears (1) adequate directions for uses; 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 are 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 Director, 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 deterioration, 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, cephalosporins, amino glycosides, tetracycline, chloramphenicol, erythromycin, or any other antibiotic 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-two (a), (b) and (c)."

Sec. 12. Section 20 of Republic Act No. 3720 is hereby amended to read as follows:

"Sec. 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 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 their toxicity or other potentiality for harmful effect, or the method of their use is not safe for use except under the supervision of practitioner licensed by law to administer such drug:

(C) are new drugs whose applications 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 an 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 its filling, the name of the prescriber, and, if stated in the prescription the name of the patient, and the directions for use and cautionary statements, if any, contained in such prescription.

(3) The Secretary may by regulation remove drugs subject to Section nineteen (d) and Sections twenty-one and twenty-one-B from the requirements of subsection (b) (d) 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: Foods, Drugs and Devices, 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."

Sec. 13. The headnote "NEW DRUGS" before Section 21 hereof is hereby amended to read as follows: "LICENSING AND REGISTRATION"

Sec. 14. Section 21 of Republic Act No. 3720 is hereby amended to read as follows:

"Sec. 21. (a) No person shall manufacture, sell, offer for sale, import, export, distribute or transfer any drug or device, unless an application filed pursuant to subsection (b) hereof is effective with respect to such drug or device.

(b) Any person may file with the Secretary, thru the Bureau, an application under oath with respect to any drug or device subject to the provisions of subsection (a) hereof. Such persons shall submit to the Secretary thru the Bureau: (1) full reports of investigations which have been made to show whether or not such drug or device is safe, efficacious and of good quality for use based on clinical studies conducted in the Philippines; (2) a

full list of the articles used as components of such drug or device; (3) a full statement of the composition of such drug or device; (4) a full description of the methods used in and the facilities and controls used for the manufacture of such drug or device; (5) such samples of such drug or device and of the articles used as components thereof as the Secretary may require; (6) specimens of the labeling proposed to be used for such drug or device; and (7) such other requirements as may be prescribed by regulations to ensure the safety, efficacy and good quality of such drug or device.

(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 the 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 the opportunity for a hearing, that (1) the reports of the investigations which are required to be submitted to the Secretary pursuant to the subsection (b) hereof, do not include adequate tests by all methods reasonably applicable to show whether or not such drug or device is safe, efficacious and of good quality for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof; (2) the results of such test show that such drug or device is unsafe, inefficacious or of doubtful therapeutic value for use under such conditions or do not show that such drug or device is safe, efficacious or of good quality for use under such conditions; (3) the methods used in, and the facilities of such drug or device 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 or device, he has insufficient information to determine whether such drug or device is safe, efficacious or of good quality for use under such conditions; or (5) on evaluation 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 or device, there is lack of substantial evidence that the drug or device 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 disapproving the application.

(e) The effectiveness of an application with respect to any drug or device 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, test by new methods, or tests by methods not deemed reasonably applicable when such application became effective show that such drug or device is unsafe or ineffective 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) The Secretary shall promulgate regulations for exempting from the operation of this section drugs and devices intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety and effectiveness of drugs and devices.

(g) The procedure herein prescribed applies likewise to "new veterinary drugs".

Sec. 15. New sections, to be known as Sections 21-A, 21-B and 21-C, are hereby added to Republic Act No. 3720 to read as follows:

"Sec. 21-A. No person shall manufacture, sell, offer for sale, import, export, distribute or transfer any drug or device without first securing a license to operate from the Bureau after due compliance with technical requirements in accordance with rules and regulations promulgated by the Secretary pursuant to this Act."

"Sec. 21-B. No drug or device shall be manufactured, sold, offered for sale, imported, exported, distributed or transferred, unless registered by the manufacturer, importer or distributor thereof in accordance with rules and regulations promulgated by the Secretary pursuant to this Act. The provision of Section 21 (b), (d) and (e), to the extent applicable, shall govern the registration of such drugs and devices."

"Sec. 21-C. The Secretary shall promulgate a schedule of fees for the issuance of the certificate of product registration and the license to operate provided for under Sections 21, 21-A, and 21-B."

Sec. 16. The title of Chapter IX of Republic Act No. 3720 is hereby amended to read as follows:

"Certification of Drugs Containing Antibiotics

Sec. 17. Section 22 of Republic Act No. 3720 is hereby amended to read as follows:

"Sec. 22. (a) The Secretary, pursuant to regulations promulgated by him, shall provide for the certification of batches of drugs composed wholly or partially of any kind of antibiotic. 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 insure adequately safety and efficacy of use and good quality, 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 on 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 "antibiotic drug" means any drug intended for use by man containing any quantity of any chemical substance which is produced by a micro-organism and which has the capacity to inhibit or destroy micro-organisms 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 and good quality, the Secretary shall promulgate regulations exempting such drug or class of drugs from such requirements.

(c) The Secretary shall promulgate regulations exempting from any 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."

Sec. 18. The headnote of Chapter XI of Republic Act No. 3720 is hereby amended to read as follows:

"General Administration Provisions, Administrative Sanctions, Regulations, Hearing and Institution of Criminal Action."

Sec. 19. Section 26 of Republic Act No. 3720 is hereby amended to read as follows:

"Sec. 26. (a) Except as otherwise provided in this section, the Secretary of Health shall, upon recommendation of the Director, issue rules and regulations as may be necessary to enforce effectively the provisions of this Act. The rules and regulations shall provide for, among others, the banning, recalling or withdrawing from the market drugs and devices which are not registered, unsafe, inefficacious or of doubtful therapeutic value, the adoption of an official National Drug Formulary, and the use of generic names in the labeling of drugs.

(b) The Commissioner of Customs 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 Director and shall take effect at such time, after due notice, as the Secretary of Health shall determine.

(c) Hearing authorized or required by this Act shall be conducted by the Bureau which shall submit its recommendation to the Secretary.

(d) When it appears to the Director that the report of the Bureau that any article of food or any drug, device, or cosmetic secured pursuant to Section twenty-eight of this Act is adulterated, misbranded, or not registered, 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 Bureau and to submit evidence impeaching the correctness of the finding or charge in question.

(e) When any violation of any provisions of this Act comes to the knowledge of the Director, 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 laboratory report, the findings of the Bureau, or other documentary evidence on which the charge is based.

(f) The Secretary is hereby authorized to call on the assistance of any Department, Office or Agency for the effective implementation of the provisions of this Act."

Sec. 20. The headnote before Section 29 of Republic Act No. 3720 is hereby amended to read as follows:

"PUBLICITY AND PUBLICATION"

Sec. 21. Section 29 of Republic Act No. 3720 is hereby amended to read as follows:

"Sec. 29. (a) The Secretary may cause to be disseminated information regarding foods, drugs, devices, or cosmetics in situations involving, in the opinion of the Secretary, imminent danger to health, or gross deception to 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.

(b) The Bureau shall publish a Drug Reference Manual and Drug Bulletin to serve as reference by manufacturers, distributors, physicians, consumers and such other groups as may be deemed necessary. The Bureau is hereby authorized to sell the Drug Reference Manual at cost."

Sec. 22. A new headnote, "ADMINISTRATIVE SACTIONS", and a new section, Section 29-A, are hereby added to Republic Act No. 3720, to read as follows:

"Sec. 29-A. In addition to the administrative sanctions provided for under Letter of Instructions No. 1223, the Secretary is hereby authorized to impose, after notice and hearing, administrative fines of not less than one thousand pesos nor more than five thousand pesos for any violation of this Act."

Sec. 23. Section 30 of Republic Act No. 3720 is hereby amended to read as follows:

"Sec. 30. (a) The Commissioner of Customs shall cause to be delivered to the Bureau 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 quality of such samples shall be fixed by regulation issued by the Secretary. If it appear from the examination of such samples or otherwise that (1) such article has been manufactured under unsanitary conditions, or (2) such article is forbidden or restricted from sale in the country in which it was produced or from which it was exported, or (3) such article is adulterated, misbranded, or in violation of Sections twenty-one and twenty-one-B, then the Director shall so inform the Commissioner 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 foods, drugs, devices, and cosmetics being imported or offered for import into the Philippines arrives at port of entry other than Manila, the collection of such samples shall be the responsibility of the Regional Food and Drug Supervisor having jurisdiction over the port of entry and such samples shall be forwarded to the Bureau.

(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 of 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 officer or employee of the Bureau of Customs designated by the Commissioner of Customs and a duly authorized representative of the Bureau.

(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 specification of the foreign purchaser, (2) is not in connection with laws of the country to which it is intended for export, and (3) is labeled 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."

Sec. 24. All laws, orders, issuances, rules and regulations or parts thereof inconsistent with this Executive Order are hereby repealed or modified accordingly.

Sec. 25. This Executive Order shall take effect fifteen days after publication in the Official Gazette.

Done in the City of Manila, this 22nd day of May, in the year of Our Lord, nineteen hundred and eighty-seven.