83 OG No. 21, 2492 (May 25, 1987)

[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 a 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:

SECTION 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

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

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

SECTION 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."

SECTION 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."

SECTION 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 Drug 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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(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, efficacy, and quality 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 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, 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 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 new mode of administration; or (e) 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".

SECTION 6. Section 10 of 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 term 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 propagation, processing, compounding, formulating, filling, packing, repacking, altering, ornamenting, finishing and labeling with the ends in view of its storage, sale or distribution; Provided, That the term shall not apply to the compounding and filling of prescriptions in

drugstores and hospital pharmacies.

(w) "New veterinary drugs" means drugs intended for use for animals including any drug intended for use in animal feeds within the contemplation of the implementing rules and regulations."

SECTION 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 manufacturing, 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 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) Forgiving, 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 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 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.

SECTION 8. Section 11 of Republic Act No. 3720 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."

SECTION 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 therefore 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 documents, 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 establishes 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."

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