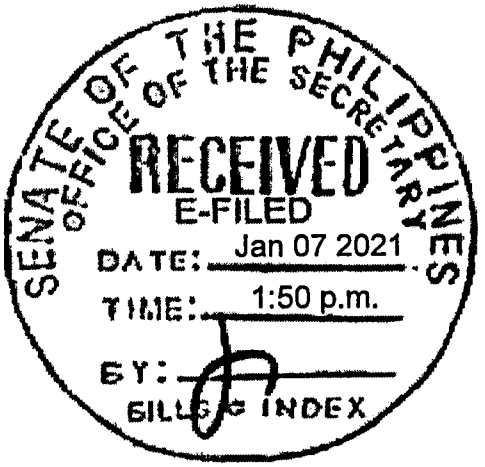


EIGHTEENTH CONGRESS OF THE)
REPUBLIC OF THE PHILIPPINES)
Second Regular Session)

SENATE

S. No. 1974

Introduced by SENATOR RAMON BONG REVILLA, JR.

AN ACT
INSTITUTING THE FOOD AND DRUG ADMINISTRATION AS AN INDEPENDENT AGENCY, AMENDING CERTAIN SECTIONS OF REPUBLIC ACT NO. 3720, AS AMENDED, AND REPUBLIC ACT NO. 9711

EXPLANATORY NOTE

Article XIII Section 12 of the 1987 Constitution provides 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 needs and problems."

The Food and Drug Administration (FDA) was created by virtue of Republic Act No. 3720, otherwise known as the "Food, Drug, and Cosmetic Act" which was approved on 22 June 1963. It was created as a regulatory agency under the Department of Health (DOH) mandated to ensure the safety, efficacy and quality of health products to ensure the protection and promotion of the people's right to health and to establish and maintain an effective health products regulatory system that is responsive to the health needs and problems of the country.

Republic Act No. 3720 was amended by Executive Order No. 175 which was approved on 22 May 1987 and subsequently by Republic Act No. 9711 or the "Food and Drug Administration (FDA) Act of 2009" which was signed into law on 18 August

2009. The law was amended to strengthen the agency and rationalize its regulatory capacity. Since its creation, though, the FDA has always been under the DOH.

Recognizing the fact that the FDA plays an important role in maintaining an efficient and responsive health system of the country, it should be given the authority and independence that will enable it to fully utilize its capacity, fulfill its duties and exercise its powers with utmost responsibility.

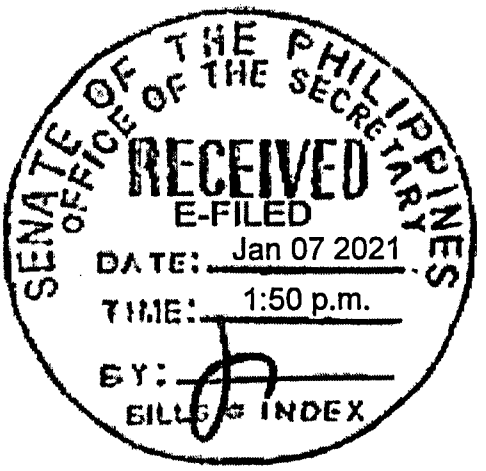
This measure seeks to separate the FDA from the DOH by making it an independent and autonomous office attached to the Office of the President. By doing so, bureaucratic processes will be lessened wherein decisions and actions can be implemented swiftly and timely, especially during such times of health emergencies and pandemic that we are in today.

Through this bill, the FDA is envisioned to be further strengthened and empowered to fully achieve its mandate to ensure the safety, efficacy, quality and purity of health products.

In this light, the immediate passage of this bill is highly recommended.

RAMON BONG REVILLA, JR.

EIGHTEENTH CONGRESS OF THE)
REPUBLIC OF THE PHILIPPINES)
Second Regular Session)



S E N A T E

S. No. 1974

Introduced by SENATOR RAMON BONG REVILLA, JR.

AN ACT
INSTITUTING THE FOOD AND DRUG ADMINISTRATION AS AN INDEPENDENT AGENCY, AMENDING CERTAIN SECTIONS OF REPUBLIC ACT NO. 3720, AS AMENDED, AND REPUBLIC ACT NO. 9711

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

Section 1. Section 4 of Republic Act No. 3720, as amended, is hereby further amended to read as follows:

"Sec. 4. To carry out the provisions of this Act, there is hereby created an office to be called the Food and Drug Administration (FDA) [~~in the Department of Health (DOH). Said Administration shall be under the Office of the Secretary and shall have the following functions, powers and duties:~~]. THE FDA SHALL BE AN INDEPENDENT AND AUTONOMOUS AGENCY ATTACHED TO THE OFFICE OF THE PRESIDENT AND SHALL EXERCISE THE FOLLOWING FUNCTIONS, POWERS AND DUTIES:

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

"x x x"

Sec. 2. Section 6 of Republic Act No. 3720, as amended, is hereby further amended to read as follows:

"Sec. 6. (a) The FDA shall be headed by a director-general, with the rank of undersecretary, who shall be tasked, among others, to determine the needed personnel and, to appoint personnel, below the assistant director level [~~in coordination with the Secretary of Health~~].

" x x x

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

"x x x"

Sec. 3. Section 7 of Republic Act No. 3720, as amended, is hereby further amended to read as follows:

"Sec. 7. The FDA shall review its staffing pattern and position titles subject to the approval of the [~~Secretary of Health~~] PRESIDENT."

Sec. 4. Section 11 of Republic Act No. 3720, as amended, is hereby further amended to read as follows:

"Sec. 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.

"x x x

"(f) The using by any person to his own advantage, or revealing, other than to the [~~Secretary~~] DIRECTOR GENERAL 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.

"x x x"

Sec. 5. Section 12 of Republic Act No. 3720, as amended, is hereby further amended to read as follows:

"Sec. 12. (a) x x x

"(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~~] FDA or an officer or employee duly designated by the [~~Secretary~~] DIRECTOR GENERAL, 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~~] DIRECTOR GENERAL 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~~] DIRECTOR GENERAL under this Act."

Sec. 6. Section 13 of Republic Act No. 3720, as amended, is hereby amended to read as follows:

"Sec. 13. Whenever in the judgment of the [~~Secretary~~] DIRECTOR GENERAL 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."

Sec. 7. Section 15 of Republic Act No. 3720, as amended, is hereby amended to read as follows:

"Sec. 15. A food shall be deemed to be misbranded:

"(a)

"x x x

"(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, numerical 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~~] DIRECTOR GENERAL.

"x x x

"(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~~] DIRECTOR GENERAL."

Sec. 8. Section 16 of Republic Act No. 3720, as amended, is hereby amended to read as follows:

"Sec. 16. (a) Whenever the [~~Secretary~~] DIRECTOR GENERAL 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~~] DIRECTOR GENERAL as provided by such regulations.

"(b) The [~~Secretary~~] DIRECTOR GENERAL 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~~] DIRECTOR GENERAL shall have access to any factory or establishment, the operator of which holds a permit from the [~~Secretary~~] DIRECTOR GENERAL, 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."

Sec. 9. Section 17 of Republic Act No. 3720, as amended, is hereby amended to read as follows:

"Sec. 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~~] DIRECTOR GENERAL 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 indifferent articles of food the [Secretary] DIRECTOR GENERAL 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~~] DIRECTOR GENERAL 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."

Sec. 10. Section 18 of Republic Act No. 3720, as amended, is hereby further 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 substance which may affect 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~~] DIRECTOR GENERAL, 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~~] DIRECTOR GENERAL, insufficient for the making of such determination the [~~Secretary~~] DIRECTOR GENERAL 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.

"x x x"

Sec. 11. Section 19 of Republic Act No. 3720, as amended, is hereby further 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~~] DIRECTOR GENERAL.

"x x x

"(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, carbromal, 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~~] DIRECTOR GENERAL, 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, strophantin, 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~~] DIRECTOR GENERAL.

"(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 are necessary for the protection of users: *Provided*, That where any requirement of clause (I) of this paragraph, as applied to any drug or device, is not necessary for the protection of the public health, the [~~Secretary~~] DIRECTOR GENERAL 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~~] DIRECTOR GENERAL.

"(h) If it has been found by the [~~Secretary~~] DIRECTOR GENERAL 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~~] DIRECTOR GENERAL shall by regulations require as necessary for the protection of the public health.

"X X X"

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

"Sec. 20. (a) The [~~Secretary~~] DIRECTOR GENERAL 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) x x x

"(2) x x x

"(3) The [~~Secretary~~] DIRECTOR GENERAL may by regulation remove drugs subject to Section nineteen (d) and Sections twenty-one and twenty-one-B from the requirements of subsection (b)(1) of this Section, when such requirements are not necessary for the protection of the public health.

"x x x"

Sec. 13. Section 21 of Republic Act No. 3720, as amended, is hereby further amended to read as follows:

"Sec. 21. (a) x x x

"(b) Any person may file with the [~~Secretary~~] DIRECTOR GENERAL[~~, 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~~] DIRECTOR GENERAL: (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~~] DIRECTOR GENERAL 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~~] DIRECTOR GENERAL and the applicant, the [~~Secretary~~] DIRECTOR GENERAL 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~~] DIRECTOR GENERAL under subsection (d) on the question whether such application is approvable.

"(d) If the [~~Secretary~~] DIRECTOR GENERAL finds, after due notice to the applicant and giving him an opportunity for a hearing, that (1) the reports of the investigations which are required to be submitted to the [~~Secretary~~] DIRECTOR GENERAL pursuant to 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 and controls used for the manufacture 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) 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 or device, there is a 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~~] DIRECTOR GENERAL be suspended if the [~~Secretary~~] DIRECTOR GENERAL 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 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~~] DIRECTOR GENERAL 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.

"x x x"

Sec. 14. Section 21-A of Republic Act No. 3720, as amended, 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 without first securing a license to operate from the [~~Bureau~~] FDA after due compliance with technical requirements in accordance with the rules and regulations promulgated by the [~~Secretary~~] DIRECTOR GENERAL pursuant to this Act."

Sec. 15. Section 21-B of Republic Act No. 3720, as amended, is hereby amended to read as follows:

"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~~] DIRECTOR GENERAL pursuant to this Act. The provisions of Section 21(b), (d) and (e), to the extent applicable, shall govern the registration of such drugs and devices."

Sec. 16. Section 21-C of Republic Act No. 3720, as amended, is hereby amended to read as follows:

"Sec. 21-C. The [~~Secretary~~] DIRECTOR GENERAL 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. 17. Section 22 of Republic Act No. 3720, as amended, is hereby further amended to read as follows:

"Sec. 22. (a) The [~~Secretary~~] DIRECTOR GENERAL, 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~~] DIRECTOR GENERAL 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~~] DIRECTOR GENERAL, 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 "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~~] DIRECTOR GENERAL, 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~~] DIRECTOR GENERAL shall promulgate regulations exempting such drug or class of drugs from such requirements.

"(c) The [~~Secretary~~] DIRECTOR GENERAL 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. Section 24 of Republic Act No. 3720, as amended, is hereby amended to read as follows:

"Sec. 24. A cosmetic shall be deemed to be misbranded:

"(a) x x x

"(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~~] DIRECTOR GENERAL.

"x x x"

Sec. 19. Section 25 of Republic Act No. 3720, as amended, is hereby amended to read as follows:

"Sec. 25. The [~~Secretary~~] DIRECTOR GENERAL 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."

Sec. 20. Section 26 of Republic Act No. 3720, as amended, is hereby further amended to read as follows:

"Sec. 26. (a) Except as otherwise provided in this section, the [~~Secretary of Health~~] DIRECTOR GENERAL 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~~] DIRECTOR GENERAL 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~~] DIRECTOR GENERAL shall determine.

"x x x

"(e) When any violation of any provisions of this Act comes to the knowledge of the Director GENERAL 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~~] FDA, or other documentary evidence on which the charge is based.

"(f) The [~~Secretary~~] DIRECTOR GENERAL 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. 21. Section 27 of Republic Act No. 3720, as amended, is hereby amended to read as follows:

"Sec. 27. (a) For purposes of enforcement of this Act, officers or employees duly designated by the [~~Secretary~~] DIRECTOR GENERAL, 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.

Sec. 22. Section 29 of Republic Act No. 3720, as amended, is hereby further amended to read as follows:

"Sec. 29. (a) The [~~Secretary~~] DIRECTOR GENERAL may cause to be disseminated information regarding foods, drugs, devices, or cosmetics in situations involving, in the opinion of the [~~Secretary~~] DIRECTOR GENERAL, imminent danger to health, or gross deception to the consumer. Nothing in this Section shall be construed to prohibit the [~~Secretary~~] DIRECTOR GENERAL from collecting, reporting,

and illustrating the results of the investigations of the [~~Department~~] FDA.

"(b) The [~~Bureau~~] FDA 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~~] FDA is hereby authorized to sell the Drug Reference Manual at cost."

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

"Sec. 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~~] DIRECTOR GENERAL. 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~~] DIRECTOR GENERAL 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~~] FOOD AND DRUG SUPERVISOR 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~~] DIRECTOR GENERAL 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~~] DIRECTOR GENERAL 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~~] DIRECTOR GENERAL'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 Food and Drug Administration.

"x x x"

Sec. 24. A new Section 30-A is hereby added to Republic Act No. 3720, as amended, which shall read as follows:

"SEC. 30 (A). IN ANY ACTION TO ENFORCE THE PROVISIONS OF THIS ACT RESPECTIN A FOOD, DRUG, DEVICE, OR COSMETIC REGULATION, FDA'S JURISDICTION SHALL BE PRESUMED TO EXIST."

Sec. 25. Section 32 of Republic Act No. 3720, as amended, is hereby amended to read as follows:

"Sec. 32. The orders, rulings or decisions of the FDA shall be appealable to the [~~Secretary of Health~~] OFFICE OF THE PRESIDENT. An appeal shall be deemed perfected upon filing of the notice of appeal and posting of the corresponding appeal bond.

"An appeal shall not stay the decision appealed from unless an order from the [~~Secretary of Health~~] OFFICE OF THE PRESIDENT is issued to stay the execution thereof."

Sec. 26. Section 34 of Republic Act No. 3720, as amended, is hereby further amended to read as follows:

"Sec. 34. Fees and Other Income. –

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

"(b) x x x

"(c) The Director-General of the FDA[~~, upon the approval of the Secretary,~~] shall be authorized to promulgate rules and regulations governing the collection of the 'other related regulatory fees'. [~~Upon approval of the Secretary, t~~]

These fees shall likewise be reviewed periodically and any proposed increase shall be published in two (2) leading newspapers of general circulation."

Sec. 27. Section 35 of Republic Act No. 3720, as amended, is hereby further amended to read as follows:

"Sec. 35. x x x

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

Sec. 28. Section 37 of Republic Act No. 3720, as amended, is hereby further amended to read as follows:

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

Sec. 29. Section 18 of Republic Act No. 9711, is hereby amended to read as follows:

"Sec. 18. X x x

"x x x

"The retention, use and application of this fund shall not be delayed, amended, altered or modified, or affected in any way by an order or directive from any executive office, but will be subject only to the general accounting rules and

guidelines by the Commission on Audit (COA). The primary purpose of the fund as herein stated shall prevail over any other purpose that may be pursued by the FDA on its own initiative or through an order or directive by any higher office. The FDA shall submit to the [~~Secretary of Health~~] PRESIDENT, the Secretary of Budget and Management and the Congressional Oversight Committee, created under Section 23 of this Act, a report on how the funds were utilized, including its accomplishments.

"x x x"

Sec. 30. *Separability Clause.* – If any provision or part hereof is held invalid or unconstitutional, the remainder of the law or the provision or part not otherwise affected shall remain valid and subsisting.

Sec. 31. *Repealing Clause.* – All laws, decrees, orders, rules and regulations or parts thereof inconsistent with this Act are hereby repealed or amended accordingly.

Sec. 32. *Effectivity.* – This Act shall take effect fifteen (15) days after its publication in the *Official Gazette* or in two (2) newspapers of general circulation.

Approved,