

P.L. 11-40



GOV. COMM.
(HOUSE)

11-298

COMMONWEALTH OF THE NORTHERN MARIANA ISLANDS

Pedro P. Tenorio
Governor

Jesus R. Sablan
Lt. Governor

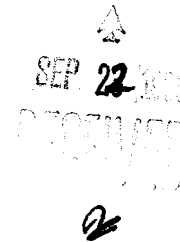
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SEP 22 1998

Honorable Diego T. Benavente
Speaker, House of Representatives
Eleventh Northern Marianas
Commonwealth Legislature

and

Honorable Paul A. Manglona
President of the Senate
Eleventh Northern Marianas
Commonwealth Legislature



Dear Mr. Speaker and Mr. President:

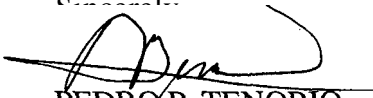
This is to inform you that I have signed into law House Bill No. 11- 101, HD 1, cited as the "Pure Food, Drug and Cosmetic Device Act of 1998," which was passed by the Eleventh Northern Marianas Commonwealth Legislature.

Currently the public faces a serious risk from imported foods, pharmaceuticals and cosmetics being sold in the CNMI without restrictions. This measure is important in that it will provide the Department of Public Health with the authority to investigate those firms or persons importing and selling harmful foods, drugs, cosmetics, as well as those using devices in an illegal manner. The Department of Public Health will work closely with the Attorney General in the prosecution of alleged violations.

Because this legislation is sorely needed, I have signed it into law. However, there are some technical and typographical concerns contained in the bill that need to be addressed. In addition, the Department of Public Health (DPH) has expressed enthusiasm in working with the Legislature to further improve the measure. I am attaching some of the suggestions from DPH for your consideration.

This bill becomes **Public Law No. 11-40**. Copies bearing my signature are forwarded for your reference.

Sincerely,


PEDRO P. TENORIO
EDR P. TENO

CC: Department of Public Health
Department of Finance
Department of Public Safety
Programs and Legislative Review

Analysis

I. Legal Considerations

As drafted, the Bill establishes basic standards for the sale, importation, labeling, and advertising of food, drugs, cosmetics, and devices in the CNMI. Articles 2-4. Although the standards established are not elaborate, the Bill delegates the responsibility for promulgating detailed regulations creating specific standards and limitations to the Secretary of Health. **This** delegation of authority is **consistent** with many other CNMI laws. Article 5 of the Bill sets forth the Department of Public Health's authority to enforce the law and establishes penalties for violations. The Inspection, Seizure, and Forfeiture provisions, Sections 501 through 513, provide **the necessary** due process protections for the alleged violator both with respect to inspections and forfeiture of assets. Section 518, which creates the penalties for violations, is reasonable and provides for increased penalties for repeat violations.

There are some aspects of the Bill that could be improved, however. First, the Bill could provide civil penalties as well as criminal penalties. If civil fines were included, the Civil Division of the Office of the Attorney General could act against an alleged violator without waiting for the filing of a criminal information with the Court. In the past, the Criminal Division of the Office of the Attorney General has been **overburdened** with the number of cases involving violent crimes, assault and battery, and domestic violence. Understandably, crimes that do not involve violence against an individual have had a lower priority for action. On the other hand, Section 513 of the Bill does enable an inspector to petition the court through a civil motion to have **the** violating articles forfeited. The risk to the public in having the violating articles enter **the** stream of commerce is therefore limited.

Second, Sections 521 through 527 create rules of procedure that are covered generally in Title 7 of the CNMI Code and the Superior Court Rules of Criminal Procedure. Although these Sections of the Bill may be duplicative of existing law, and therefore unnecessary, they do provide specific procedural guidelines for the prosecution of cases involving the sale, importation, labeling and advertising of food, drugs, cosmetics and devices. Their inclusion in the Bill does not render the Bill constitutionally defective.

Third, as drafted, Sections 203, 204, 303, 402, and 406 of the Bill are ambiguous in that they refer to "the regulations," when such regulations are neither defined in Article 1 nor identified in preceding sections. Sections 206 and 516 do authorize the Secretary of Public Health to promulgate regulations that will establish detailed standards and requirements for the sale, importation, labeling and

advertising of food, **drugs**, cosmetics, and devices. The Law Revision Commission can likely rectify this ambiguity in the Bill when they **codify it**'

Fourth, Section 208 ~~of~~ the Bill sets forth a policy ~~of~~ the Department ~~of~~ Public Health. Statutes set forth law as established by the Legislative and **Executive** Branches, not the policy of the **Department**. The wording of this **Section** is therefore unusual and should be reworded to read, "[In the interest of protecting the public health,] the sale of dogs and ~~cats~~ for human consumption is prohibited and shall be deemed a violation of this Act." Again, during codification of the Bill the Law Revision Commission could modify the wording ~~of~~ this Section and include an explanatory footnote.

Finally, Section 501(c), lines 3031 ~~of~~ the Bill contain a typographical error. Words are missing between the words "Act" and "the regulations."

These deficiencies in the Bill are not sufficient to render it constitutionally or legally defective. The problems can be corrected through the codification process or through future legislative refinement as implementation of the Bill uncovers other possible concerns.

HOUSE OF REPRESENTATIVES

**ELEVENTH NORTHERN MARIANAS COMMONWEALTH LEGISLATURE
FIRST REGULAR SESSION, 1998**

PUBLIC LAW NO. 11-40
HOUSE BILL NO. 11-101.HD1

AN ACT

To ensure that foods are pure, wholesome, safe to eat and produced under sanitary conditions; drugs and devices are safe and effective for their intended uses; cosmetics are safe and made from approved ingredients; and that all labeling and packaging must be informative and truthful; and for other purposes.

Offered by Representatives:
and Heinz S. Hofschneider

Melvin L. O. Faisao

Date: February 20, 1998

HOUSE ACTION

Standing Committee Report: None

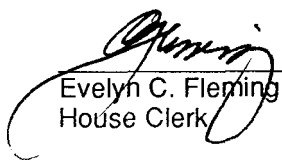
First and Final Reading: March 25, 1998

SENATE ACTION

Referred to: Committee on Health, Education, Welfare and Programs

Standing Committee Report: None

Second and Final Reading: July 31, 1998


Evelyn C. Fleming
House Clerk

ELEVENTH NORTHERN MARIANAS COMMONWEALTH LEGISLATURE

PUBLIC LAW NO. 11-40

H.B. NO. 11-101, HD1

FIRST REGULAR SESSION, 1998

AN ACT

To ensure that foods are pure, wholesome, safe to eat and produced under sanitary conditions; drugs and devices **are** safe and effective for their intended uses; cosmetics are safe and made from approved ingredients; and that all labeling and packaging must be informative and truthful; and for other purposes.

BE IT ENACTED BY THE ELEVENTH NORTHERN MARIANAS COMMONWEALTH
LEGISLATURE:

Section 1. Title. This act shall be cited as the "Pure Food, Drug and Cosmetic Device Act of 1998".

Section 2. Amendment. 3 CMC, Division 2, is hereby amended to add a new Chapter 7 entitled "Pure Food and Drug Control" to read as follows:

"CHAPTER 7

PURE FOOD AND DRUG CONTROL

Article 1.

General Provisions.

Section 101. Definitions.

(a) The term "adulterated" for the purposes of this act shall have the following meanings:

(1) If a food bears or contains any poisonous or deleterious substance which may render it injurious to health; unless the substance is not an added substance, but rather a naturally occurring substance the quantity of which does not ordinarily render it injurious to health; or

(2) If a food, drug, cosmetic, or device consists in whole or in part of any filthy, putrid, or decomposed substance, or in the case of food, if it is otherwise unfit for food; or

(3) If a food, drug, cosmetic, or device has been prepared, packed, or held under unsanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health; or

(4) If a food is in whole or in part, the product of a diseased animal or of an animal which has died otherwise than by slaughter at a facility licensed by the CNMI.

(b) The term "advertisement" includes any representation by any means whatever for the purpose of promoting directly or indirectly the sale or disposal of any foods, drugs, cosmetics, and devices.

(c) The term "Commonwealth" means the Commonwealth of the Northern Mariana Islands ("CNMI").

(d) The term "cosmetic" means 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 articles intended for use a component of any such articles.

(e) The term "Department" means the Department of Public Health.

(f) The term "device" means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory which is;

(1) recognized in an official compendium as defined in this Act, or any supplement to them; or

(2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or

(3) intended to affect the structure or any function of the body of man or other animals.

(g) The term "drug" means an article recognized in an official compendium as defined in this Act or any supplements to any of them; and includes any substance or mixture of substances manufactured, sold or represented for use in:

(1) the diagnosis, cure treatment, mitigation or prevention of a disease, disorder or abnormal physical or mental state, or its symptoms, in human beings or animals,

(2) restoring, correcting or modifying organic functions in human beings or animals, or

(3) articles intended for use as a component of any such articles as mentioned above.

This definition does not include any natural substances used as a traditional drug as defined in this Act.

(h) The term "food" includes any article manufactured, sold or represented for use as food or drink for human beings, chewing gum, and any ingredient that may be mixed with food for any purpose whatsoever.

(i) The term "foreign drug" shall mean a drug prescribed, purchased or manufactured in a jurisdiction other than the Commonwealth, the United States of America, its territories and possessions.

(j) The term "unsanitary conditions" means such conditions or circumstances as might contaminate with dirt or filth, or render injurious to health, a food, drug, cosmetic, or device.

(k) The term "inspector" means any person designated as an inspector for the purpose of the enforcement of this Act.

(l) The term "label" includes any legend, word or mark attached to, included in, belonging to, in close proximity to, or accompanying any food, drug, cosmetic, device, or package.

(m) The term "official compendium" means the most recent editions, including all errata, supplements, revisions and addenda of the following: Commonwealth Health Center Formulary, official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, official National Formulary, and Remington Pharmaceuticals.

(n) The term "package" includes anything in which any food, drug, cosmetic or device is wholly or partially contained, placed or packed.

(o) The term "prescribed" means required by the regulations.

(p) The term "Secretary" means the Secretary of the Department of Public Health for the Commonwealth of the Northern Mariana Islands.

(q) The term "sell" includes offer for sale, expose for sale, have in possession for sale and distribution, whether or not the distribution is made for compensation of any kind.

(r) The term "traditional drug" means natural substances used by the Chamorro and Carolinian people, or by any other people who reside in the Commonwealth, in the diagnosis, cure, treatment, mitigation or prevention of a disease, disorder or abnormal physical and mental state, or its symptoms, in human beings or animals.

Section **102. General Provisions Governing Advertising.**

(a) No person shall advertise any food, drug, cosmetic, or device to the general public as a treatment, preventative or cure for any of the diseases, disorders or abnormal physical states that are listed in Schedule A.

(b) Any food, drug, cosmetic, or device advertised to the general public as a treatment, preventative or cure for any disease, disorder or abnormal physical state shall be made in the English, or Carolinian or Chamorro languages. An advertisement made in any other language shall be accompanied by an accurate and full English translation.

Section **103. Prohibited label or advertisement where promotion for sale is made.**

(a) No person shall sell any food, drug, cosmetic or device

(1) that is not represented by label; or

(2) that the person advertises to the general public as a treatment, preventative or cure for any of the diseases, disorders or abnormal physical states listed in Schedule A.

(3) that the person advertises to the general public as a treatment, preventative or cure for any of the diseases, disorders or abnormal physical states in a language other than English, Chamorro or Carolinian unless accompanied by an accurate and full English translation.

1 Section 104. Construction with respect to the traditional art of healing.
2 Nothing in this Act shall be construed to inhibit the traditional art of healing as it is
3 practiced by the Chamorro and Carolinian people.

4 **Article 2.**

5 **Regulation of Food**

6 Section 201. Prohibited sales of food.

- 7 (a) No person shall sell an article of food for human consumption that;
8 (1) has in or on it any poisonous or harmful substance;
9 (2) is unfit for human consumption;
10 (3) consists in whole or in part of any filthy, putrid, disgusting,
11 rotten, decomposed or diseased animal or vegetable substance;
12 (4) is adulterated; or
13 (5) was manufactured, prepared, preserved, packaged,
14 distributed, or stored under unsanitary conditions.
15 (6) contains wholly or in part the flesh of cats or dogs.

16 Section 202. Deception regarding food.

17 No person shall label, package, treat, process, distribute, sell or advertise any
18 food in a manner that is false, misleading or deceptive or is likely to create an
19 erroneous impression regarding its character, value, quantity, composition, merit or
20 safety.

21 Section 203. Food labeled or packaged in contravention of regulations.

22 An article of food that is not labeled or packaged as required by, or is labeled or
23 packaged contrary to, the regulations shall be deemed to be labeled or packaged
24 contrary to subsection (1).

25 Section 204. Importation of food.

- 26 (a) Where a standard for a food has been prescribed, no person shall;
27 (1) import into the Commonwealth, or
28 (2) send, convey or receive for conveyance within the
29 Commonwealth, or
30 (3) have in possession for the purpose of sending or conveying
31 within the Commonwealth,

any article that is intended for sale and that is likely to be mistaken for the food for which the regulations prescribe a standard unless that article complies with the prescribed standard.

(b) Not applicable to carriers.

Paragraphs (a)(2) and (3) do not apply to an operator of a conveyance that is used to carry an article or to a carrier of an article whose sole concern, in respect of the article, is the conveyance of the article unless the operator or carrier could, with reasonable diligence, have ascertained that the conveying or receiving for conveyance of the article or the possession of the article for the purpose of conveyance would be in contravention of subsection (a).

Section 205. Labeling of food that is imported or moved within the Commonwealth.

(a) Where a standard for a food has been prescribed, no person shall label, package, sell or advertise any article that

(1) has been imported into Commonwealth

(2) has been sent or conveyed within the Commonwealth, or

(3) is intended to be sent or conveyed within the Commonwealth that it is likely to be mistaken for that food unless the article complies in such a manner with the prescribed standard.

Section 206. Authority of the Secretary to identify standard.

(a) The secretary may, by regulation, identify a standard prescribed for a food as being necessary to prevent injury to the health of the consumer or purchaser of the food.

(b) Where a standard prescribed for a food is identified by the secretary pursuant to subsection (a), no person shall label, package, sell or advertise any article in such a manner that it is likely to be mistaken for that food unless that article complies with the standard so identified.

Section 207. Unsanitary manufacture of food.

No person shall manufacture, prepare, preserve, package or store for sale any food under unsanitary conditions.

Section 208. Prohibition regarding slaughter of dogs and cats.

It is the policy of the Commonwealth Department of Public Health that the sale of dogs and cats for human consumption is prohibited and shall be deemed a violation of this Act.

Article 3.

Regulation of Drugs

Section 301. Prohibited sales of drugs.

No person shall sell any drug that

(a) was manufactured, prepared, preserved, packaged, distributed or stored under unsanitary conditions; or

(b) is adulterated.

Section 302. Deception regarding drugs.

No person shall label, package, treat, process, distribute, sell or advertise any drug in a manner that is false, misleading or deceptive or is likely to create erroneous impression regarding its character, value, quantity, composition, merit or safety.

Section 303. Drugs labeled or packaged in contravention of regulations.

A drug that is not labeled or packaged as required by, or is labeled or packaged contrary to the regulations shall be deemed to be labeled or packaged contrary to section 302.

Section 304. Where standard prescribed for drug.

Where a standard has been prescribed for a drug by the World Health Organization (WHO) or in official compendium as defined in this act, no person shall label, package, distribute, sell or advertise any substance in such a manner that it is likely to be mistaken for that drug, unless the substance complies with the prescribed standard.

Section 305. Unsanitary manufacture of drug.

No person shall manufacture, prepare, preserve, package, distribute, or store for sale any drug under unsanitary conditions.

Section 306. Drugs not to be sold unless safe manufacture indicated.

No person shall sell any drug described in Schedule B or C unless the Secretary has, in prescribed form and manner, indicated that the premises in which the drug was

manufactured and the process and conditions of manufacture therein are suitable to ensure that the drug will not be unsafe for use.

Section **307. Drugs not to be sold unless safe batch indicated.**

No person shall sell any drug described in Schedule D unless the Secretary has, in prescribed form and manner, indicated that the batch from which the drug was taken is not unsafe for use.

Section **308. Samples.**

(a) No person shall distribute or cause to be distributed any drug as a sample.

(b) Subsection (a) does not apply to the distribution, under prescribed conditions, of samples of drugs to physicians, dentists, veterinary surgeons or pharmacists.

Section **308. Importation of Drugs.**

No person shall import foreign drugs unless:

(a) the foreign drug was purchased or acquired for personal use;

(b) the intended use of the foreign drug is appropriately identified and such prescription or product shall not extend in excess of three months;

(c) the patient seeking to import or who imports the product(s) shall affirm in writing that it is for personal use and shall provide the name and address of the licensed physician in the U.S. or foreign countries responsible for such prescription and the name and telephone number of an authorized pharmaceutical business establishment where the foreign drug was purchased.

Article 4.

Regulation of Cosmetics and Devices.

Section **401. Prohibited sales of cosmetics.**

No person shall sell **any** cosmetic that

(a) has in or on it any substance that may cause injury to the health of the user when the cosmetic is used,

(1) according to the directions on the label or accompanying the cosmetic, or

(2) for such purposes and by such methods of use as are customary or usual therefore;

(b) consists in whole or in part of any filthy or decomposed substance or of any foreign matter; or

(c) was manufactured prepared, preserved, packaged, distributed, or stored under unsanitary conditions.

Section **402.** Where standard prescribed for cosmetic.

Where a standard has been prescribed under Commonwealth regulation for a cosmetic, no person shall label, package, sell or advertise any article in such a manner that it is likely to be mistaken for that cosmetic, unless the article complies with the prescribed standard.

Section **403.** Unsanitary conditions.

No person shall manufacture, prepare, preserve, package or store for sale any cosmetic under unsanitary conditions.

Section **404.** Prohibited sales of devices.

No person shall sell any device that, when used according to directions or under such conditions as are customary or usual, may cause injury to the health of the purchaser or use thereof.

Section **405.** Deception regarding devices.

No person shall label, package, treat, process, sell or advertise any device in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its design, construction, performance, intended use, quantity, character, value, composition, merit or safety.

Section **406.** Devices labeled or packaged in contravention of regulations.

A device that is not labeled or packaged as required by, or is labeled or packaged contrary to, the regulations shall be deemed to be labeled or packaged contrary to section **405.**

Section **407.** Where standard urescribed for device.

Where a standard has been prescribed by the World Health Organization (WHO) or in an official compendium as defined in this act, for a device, no person shall label, package, sell or advertise any article in such a manner that it is likely to be mistaken for that device, unless that article complies with the prescribed standard.

Administration and Enforcement,

(a) The Secretary may designate any person employed by the Department of Public Health as an inspector and, in coordination with the Secretary of Finance, request employees in Customs Service, to act on his or her behalf, as an inspector for the purpose of the enforcement of this Act.

(c) Subject to the limitation of section 502, an inspector may enter any place during any reasonable time of operations where the inspector believes on reasonable grounds any article to which this Act the regulations apply is manufactured, prepared, preserved, packaged, distributed, or stored, and may

(2) enter any conveyance that the inspector believes on reasonable grounds is used to carry any article to which section 204 applies and examine any such article found therein and take samples thereof.

(4) examine and make copies of, or extracts from, any books, documents or other records found in any place referred to in this subsection that the inspector believes on reasonable grounds contains any information relevant to the enforcement of this Act with respect to any article to which this Act or the regulations apply; and

(5) seize and detain for such time as may be necessary any article by means of or in relation to which the inspector believes on reasonable grounds any provision of this Act or any regulations promulgated thereunder has been contravened.

Section 502. Warrant required to enter into any dwelling-house.

Where any place mentioned in section 501 (c) is a dwelling-house, an inspector may not enter that dwelling-house without the consent of the occupant except under the authority of a warrant issued under section 503.

Section 503. Authority to issue warrant.

Where on ex parte application of the Department, a judge of the Commonwealth is satisfied by information on oath

(a) that the conditions for entry described in section 501 (c) exist in relation to a dwelling-house,

(b) that entry to the dwelling-house is necessary for any reasonable purpose relating to the administration or enforcement of this Act, and

(c) that entry to the dwelling-house has been refused or that there are reasonable grounds for believing that entry thereto will be refused;

The judge may issue a warrant under his or her hand authorizing the inspector named therein to enter that dwelling-house subject to such conditions as may be specified in the warrant.

Section 504. Use of force. In executing a warrant issued under section 503, the inspector named therein shall not use force unless the inspector is accompanied by a Department of Public Safety police officer, and the use of force has been specifically authorized in the warrant.

Section 505. Definition of "article to which this Act or the regulations apply:"

(a) In section 501 (c), "article to which this Act or the regulations apply" includes;

(1) any food, drug, cosmetic, or device;

(2) anything used for the manufacture, preparation, preservation, packaging or storing thereof; and

(3) any labeling or advertising material.

1 Section **506.** Assistance and information to be given inspector. The owner or
2 person in charge of a place entered by an inspector pursuant to section **501** (c) and
3 every person found therein shall give the inspector all reasonable assistance and furnish
4 the inspector with any information he or she may reasonably require.

5 Section **507.** Obstruction and false statement. No person shall obstruct or
6 hinder, or knowingly make any false or misleading statement either orally or in writing
7 to an inspector while the inspector is engaged in carrying out his or her duties or
8 functions under this Act or the regulations.

9 Section **508.** Interference. Except with the authority of an inspector, no person
10 shall remove, alter or interfere in any way with anything seized under this Act or the
11 regulations.

12 Section **509.** Storage and removal. Any article seized under this Article 5 may,
13 at the option of an inspector, be kept or stored in the building or place where it was
14 seized or, at the direction **of** an inspector, the article may be removed to any other
15 proper place.

16 Section **510.** Release of seized articles. An inspector who has seized any
17 article under this Article 5 shall release it when he or she is satisfied that all the
18 provisions of this Act and the regulations with respect thereto have been complied with.

19 Section **511.** Destruction with consent. Where an inspector has seized an
20 article under this Article 5 and its owner or the person in whose possession the article
21 was at the time of seizure consents to its destruction, the article is thereupon forfeited to
22 the Commonwealth and may be destroyed or otherwise disposed of as the Secretary
23 may direct.

24 Section **512.** Forfeiture on conviction.

25 Where a person has been convicted of a contravention of this Act or the
26 regulations, the court or judge may order that any article by means of or in relation to
27 which the offense was committed, and anything of a similar nature belonging to or in
28 the possession of the accused or found with the article, be forfeited and, on the making
29 **of** the order, the article and thing are forfeited to the Commonwealth and may be
30 disposed of as the Secretary may direct.

31 Section **513.** Order for forfeiture on application of inspector. Without
32 prejudice to section **512**, a judge of a court of the Commonwealth under this Article 5

1 may, on the application of ~~an~~ inspector and on such notice to such persons as the judge
2 directs, order that the article and anything of a similar nature found therewith be
3 forfeited to Commonwealth, to be disposed of as the Secretary may direct, if the judge
4 finds, after making such inquiry as the judge considers necessary, that the article is one
5 by means of or in relation to which any of the provisions of this Act or the regulations
6 have been contravened.

7 Section **514. Designation of Analysts.** The Secretary may designate any person
8 as an analyst for the purpose of the enforcement of this Act.

9 Section **515. Analysis and examination**

10 (a) An inspector may submit to an analyst, for analysis or examination,
11 any article seized by the inspector, or any sample taken by the inspector.

12 (b) An analyst who has made an analysis or examination may issue a
13 certificate or report setting out the results of the analysis or examination.

14 Section **516. Authority to make regulations.** The Secretary may make
15 regulations for carrying the purposes and provisions of this Act into effect, and, in
16 particular, but without restricting the generality of the foregoing, may make
17 regulations:

18 (a) declaring that any food, drug, cosmetic, or device or class of foods,
19 **drugs**, cosmetics, or devices are adulterated if any prescribed substance or class
20 of substances is present therein or has been added thereto or extracted or
21 omitted there from;

22 (b) respecting:

23 (1) the labeling and packaging and the offering, exposing and
24 advertising for sale of a food, drug, cosmetic, or device

25 (2) the size, dimensions fill and other specifications of packages
26 of a food, drug, cosmetic, or device

27 (3) the sale or the conditions of sale of any food, drug, cosmetic,
28 or device and

29 (4) the use of any substance as an ingredient or component in
30 any food, drug, cosmetic, or device to prevent the purchaser or
31 consumer thereof from being deceived or misled in respect of the
32 design, construction, performance, intended use, quantity, character,

1 value, composition, merit or safety thereof, or to prevent injury to the
2 health of the purchaser or consumer;

3 (c) prescribing standards of composition, strength, potency, purity,
4 quality or other property of any article of food, drug, cosmetic or device;

5 (d) respecting the importation of foods, drugs, cosmetics, devices in
6 order to ensure compliance with this Act and regulations;

7 (e) respecting the method of manufacture, preparation, preserving,
8 packing, storing and testing of any food, drug, cosmetic, device in the interest
9 of, or for the prevention of injury to, the health of the purchaser or consumer;

10 (f) requiring persons who sell drugs and devices to register their place
11 of business and list their products, and maintain such books and records as the
12 Secretary considers necessary for the proper enforcement and administration of
13 this Act and regulations;

14 (g) respecting the form and manner of the Secretary's indication under
15 section **306**, including the fees payable therefor, and prescribing what premises
16 or what processes or conditions of manufacture, including qualifications of
17 technical staff, shall or shall not be deemed to be suitable for the purposes of
18 that section;

19 (h) requiring manufacturers of any drugs described in Schedule D to
20 submit test portions of any batch of those drugs and respecting the form and
21 manner of the Secretary's indication under section **307**, including the fees
22 payable therefor;

23 (i) respecting the powers and duties of inspectors and analysts and the
24 taking of samples and the seizure, detention, forfeiture and disposition of
25 articles;

26 (j) exempting any food or drug from all or any of the provisions of this
27 Act and prescribing the conditions of the exemption;

28 (k) prescribing forms for the purposes of this Act **and** the regulations;

29 (l) providing for the analysis of a food, drug, cosmetic, or device other
30 than for the purposes of this Act and prescribing a tariff of fees to be paid for
31 that analysis.

(m) adding anything to any of the schedules, in the interest of, or for the prevention of injury to, the health of the purchaser or consumer, or deleting anything therefrom;

(n) respecting the distribution or the conditions of distribution of samples of any drug;

(o) respecting

(1) the method of manufacture, preparation, preserving, packing, labeling, storing, holding, and testing of any new drug, and

(2) the sale or the conditions of sale of any new drug, and defining for the purposes of this Act the expression "new drug".

Section 517. Regulations respecting drugs manufactured outside the United States. Without limiting or restricting the authority conferred by any other provisions of this Act or any part thereof for carrying into effect the purposes and provisions of this Act or any part thereof, the Secretary may make such regulations governing, regulating or prohibiting:

(a) the importation into the Commonwealth of any drug or device or class of drugs or devices manufactured outside the United States, or

(b) the distribution or sale in the Commonwealth, or the offering, exposing or having in possession for sale in the Commonwealth, of any drug or device or class of drugs or devices manufactured outside the United States, as the Secretary deems necessary for the protection of the public in relation to the safety and quality of any such drug or device or class of drugs devices.

Section 518. Offenses and Punishment: Contravention of Act or regulations. Every person who contravenes any of the provisions of this Act, or of the regulations made pursuant to sections 516 and 517, is guilty of an offense and liable:

(a) on conviction for a first offense to a fine not exceeding five hundred dollars (\$500) or to imprisonment for a term not exceeding three (3) months or to both and for a subsequent offense, to a fine not exceeding one thousand dollars (\$1,000) or to imprisonment for a term not exceeding six months, or both; and

(b) on conviction for a subsequent offense to a fine not exceeding five thousand dollars (\$5,000) or to imprisonment for a term not exceeding three (3) years, or both.

Section 519. Limitation period. A prosecution under paragraph section 518 may be instituted at any time within but not later than twelve months from the time the subject-matter of the prosecution arose.

Section 520. Certificate of analyst. Subject to this section, in any prosecution for an offense under section 518, a certificate purporting to be signed by an analyst and stating that an article, sample or substance has been submitted to, and analyzed or examined by, the analyst and stating the results of the analysis or examination is admissible in evidence and, in the absence of evidence to the contrary, is proof of the statements contained in the certificate without proof of the signature or official character of the person appearing to have signed the certificate.

Section 521. Requiring attendance of analyst. The party against whom a certificate of an analyst is produced pursuant to section 520 may, with leave of the court, require the attendance of the analyst for the purposes of cross-examination.

Section 522. Notice of intention to produce certificate. No certificate shall be admitted in evidence pursuant to section 520 unless, before the trial, the party intending to produce the certificate has given reasonable notice of that intention, together with a copy of the certificate, to the party against whom it is intended to be produced.

Section 523. Proof of service. For the purposes of this Act, service of any certificate referred to in section 520 may be proved by oral evidence given under oath by, or by the affidavit or solemn declaration of, the person claiming to have served it.

Section 524. Requirement to appear before court. Notwithstanding section 523, the court may require the person who appears to have signed an affidavit or solemn declaration referred to in that subsection to appear before it for examination or cross-examination in respect of the issue of proof of service.

Section 525. Proof as to manufacturer or packer. In a prosecution for a contravention of this Act, or of the regulations made pursuant to it, proof that a package containing any article to which this Act or the regulations apply bore a name or address purporting to be the name or address of the person by who it was manufactured or packaged is, in the absence of evidence to the contrary, proof that the article was

manufactured or packaged, as the case may be, by the person whose name or address appeared on the package.

Section 526. Offense by employee or agent. In a prosecution for a contravention described in section 525, it is sufficient proof of the offense to establish that it was committed by an employee or agent of the accused whether or not the employee or agent is identified or has been prosecuted for the offense.

Section 527. Certified copies and extracts. In a prosecution for a contravention described in section 525, a copy of a record or an extract therefrom certified to be a true copy by the inspector who made it pursuant to section 501 (c) (4) is admissible in evidence and is, in the absence of evidence to the contrary, proof of its contents.

Section 528. Where accused had adulterating substances. Where a person is prosecuted under this Article for having manufactured an adulterated food or drug for sale, and it is established that the person had in his or her possession or on his or her premises any substance the addition of which to that food or drug has been declared by regulation to cause the adulteration of the food or drug, the onus of proving that the food or drug was not adulterated by the addition of that substance lies on the accused.

SCHEDULE A

Alcoholism
Alopecia
Anxiety state
Appendicitis
Arteriosclerosis
Arthritis
Asthma
Bladder Disease
Cancer
Convulsions
Depression
Diabetes
Disease of the prostate
Prostate (maladies)
Disorder of menstrual flow

1	Dysentery
2	Edematous state
3	Epilepsy
4	Gall bladder disease
5	Gangrene
6	Glaucoma
7	Gout
8	Heart disease
9	Hernia
10	Hypertension
11	Hyportension
12	Impetigo
13	Kidney disease
14	Leukemia
15	Liver disease
16	Nausea and vomiting of pregnancy
17	Pleurisy
18	Rheumatic fever
19	Septicemia
20	Sexual Impotence
21	Thrombotic and Embolic disorders
22	Thyroid disease
23	Tumor
24	Ulcer of the gastro intestinal tract
25	Venereal disease

SCHEDULE B

Drugs, other than radionuclides, sold or represented for use in the preparation of
radiopharmaceuticals
Radiopharmaceuticals

SCHEDULE C

Allergenic substances used for the treatment or diagnoses of allergic or
immunological diseases

1 Substances...
2 Anterior pituitary extracts
3 Aprotinin
4 Aprotinine
5 Blood and blood derivatives
6 Cholecystokinin
7 Cholecystokinine
8 Drugs obtained by recombinant DNA procedures
9 Drugs, other than antibiotics, prepared from micro-organisms
10 Glucagon
11 Gonadotrophins
12 Gonadotrophines
13 Human plasma collected by plasmapheresis
14 Plasma...
15 Immunizing agents
16 Insulin
17 Interferon
18 Monoclonal antibodies, their conjugates and derivatives
19 Secretin
20 Sensitivity Discs and Sensitivity Tablets
21 Snake Venom
22 Urokinase

23 **SCHEDULE D**

24 Any drugs intended for use in the treatment, prevention, or cure of any diseases,
25 disorders, or abnormal physical states listed in Schedule A, or any drugs listed in
26 Schedule B and C.”


27 Section 3. Severability. If any provision of this Act or the application of any such
28 provision to any person or circumstance should be held invalid by a court of competent
29 jurisdiction, the remainder of this Act or the application of its provisions to persons or
30 circumstances other than those to which it is held invalid shall not be affected thereby.

31 Section 4. Savings Clause. This Act and any repealer contained herein shall not be
32 construed as affecting any existing right acquired under contract or acquired under statutes

1 repealed or under any rule, regulation or order adopted under the statutes. Repealers contained
2 in this Act shall not affect any proceeding instituted under or pursuant to prior law. The
3 enactment of this Act shall not have the effect of terminating, or in any way modifying, any
4 liability, civil or criminal, which shall already be in existence at the date this Act becomes
5 effective.

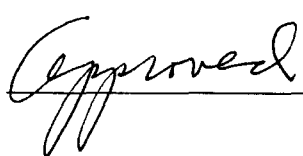
6 Section 5. Effective Date. This Act shall take effect upon its approval by the Governor
7 or upon its becoming law without such approval.


CERTIFIED BY:


DIEGO T. BENAVENTE
Speaker
House of Representatives

ATTESTED BY:


EVELYN C. FLEMING
House Clerk

 Approved this 22nd day of September, 1998


PEDRO P. TENORIO
Governor
Commonwealth of the Northern Mariana Islands