Ice or frost on wings.

shall not attempt to take off if there be a coating of snow, frost or ice on the wings or control surfaces of said aircraft in sufficient amount as to reduce the performance of the aircraft and thereby endanger the occupants.

Section 6. For the purposes of this Act, the term "operate aircraft" means to use, navigate, pilot or taxi an aircraft in the airspace over this Territory, or upon the land or water within this Territory.

Penalties.

Section 7. PENALTIES. Any person, firm or corporation violating any of the provisions of this Act shall be guilty of a misdemeanor and upon conviction thereof, subject to a fine not exceeding five hundred dollars.

Approved March 26, 1949.

CHAPTER 129

AN ACT

[S. B. 53]

For the protection of public health by establishing standards of purity and cleanliness for food, drugs, devices and cosmetics; defining adulteration and misbranding of foods, drugs, devices and cosmetics; defining false advertising, providing for enforcement of this Act and penalties for violation, making an appropriation for carrying out the provisions of this Act, and fixing an effective date.

Be it enacted by the Legislature of the Territory of Alaska:

Title.

Section 1. SHORT TITLE. This Act may be cited as the Alaska Food, Drug and Cosmetic Act.

Section 2. DEFINITIONS. For the purposes of this Act— Definitions.

(a) The term "Commissioner of Health" means the chief executive of the Alaska Department of Health or his authorized representative.

(b) The term "Board" means the Board of Health of Alaska. Board.

(c) The term "person" includes individual, partnership, corporation, and association. Person.

(d) The term "food" means (1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article. Food.

(e) The term "drug" means (1) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (2) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (3) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (4) articles intended for use as a component of any article specified in clause (1), (2), or (3); but does not include devices or their components, parts, or accessories. Drug.

(f) The term "device" (except when used in paragraph (1) of this section and in Section 3 (j), 11 (f) and 15 (c) and 18 (c)) means instruments, apparatus, and contrivances, including their components, parts, and accessories, intended (1) for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; or (2) to affect the structure or any function of the body of man or other animals. Device.

)smetic.

(g) The term "cosmetic" means (1) articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and (2) articles intended for use as a component of any such articles; except that such term shall not include soap, intended for cleansing purposes only.

)fficial ompendium.

(h) The term "official compendium" means the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, official National Formulary, or any supplement to any of them.

Label.

(i) The term "label" means a display of written, printed or graphic matter upon the immediate container of any article; and a requirement made by or under authority of this Act, that any word, statement, or other information appearing on the label shall not be considered to be complied with unless such word, statement, or other information also appears on the outside container or wrapper, if any there be, of the retail package of such article, or is easily legible through the outside container or wrapper.

Immediate container.

(j) The term "immediate container" does not include package liners.

Labeling.

(k) The term "labeling" means all labels and other written, printed or graphic matter (1) upon an article or any of its containers or wrappers, or (2) accompanying such article.

Determination of misleading labels.

(l) If an article is alleged to be misbranded because the labeling is misleading, or if an advertisement is alleged to be false because it is misleading, then in determing whether the labeling or advertisement is misleading, there shall be taken into account (among other things) not only representations made or suggested by

statement, word, design, device, sound or any combination thereof, but also the extent to which the labeling or advertisement fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article to which the labeling or advertisement relates under the conditions of use prescribed in the labeling or advertisement thereof or under such condition of use as are customary or usual.

(m) The term "advertisement" means all representations disseminated in any manner or by any means, other than by labeling, for the purpose of inducing, or which are likely to induce, directly or indirectly, the purchase of food, drugs, devices or cosmetics. Advertisement.

(n) The representation of a drug, in its labeling or advertisement, as an antiseptic shall be considered to be a representation that it is a germicide, except in the case of a drug purporting to be, or represented as, an antiseptic for inhibitory use as a wet dressing, ointment, dusting powder, or such other use as involves prolonged contact with the body. When drug is germicide.

(o) The term "new drug" means (1) any drug the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety of drugs, as safe for use under the conditions prescribed, recommended, or suggested in the labeling thereof; or (2) any drug the composition of which is such that such drug, as a result of investigations to determine its safety for use under such conditions, has become so recognized, but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions. New drug.

(p) The term "contaminated with filth" applies to any food, drug, device, or cosmetic not securely protected

Contamination with filth.

from dust, dirt, and as far as may be necessary by all reasonable means, from all foreign or injurious contaminations.

What termed to be selling.

(q) The provisions of this Act regarding the selling of food, drugs, devices, or cosmetics, shall be considered to include the manufacture, production, processing, packing, exposure, offer, possession, and holding of any such article for sale; and the sale, dispensing, and giving of any such article, and the supplying or applying of any such articles in the conduct of any food, drug, or cosmetic establishment.

(r) The term "Federal Act" means the Federal Food, Drug, and Cosmetic Act (Title 21 U.S.C. 301 et seq.; 52 Stat. 1040 et seq.).

Prohibited acts.

Section 3. PROHIBITED ACTS. The following acts and the causing thereof within the Territory of Alaska are hereby prohibited:

(a) The manufacture, sale, or delivery, holding or offering for sale 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 receipt in commerce of any food, drug, device, or cosmetic that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise.

(d) The sale, delivery for sale, holding for sale, or offering for sale of any article in violation of Section 12 or 16.

(e) The dissemination of any false advertisement.

(f) The refusal to permit entry or inspection, or to permit the taking of a sample, as authorized by Section 21.

(g) The giving of a guaranty or undertaking, which guaranty or undertaking is false, except by a person who relied on a guaranty or undertaking to the same effect signed by, and containing the name and address of, the person residing in the Territory of Alaska from whom he received in good faith the food, drug, device, or cosmetic.

(h) The removal or disposal of a detained or embargoed article in violation of Section 6.

(i) 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 and results in such article being misbranded.

(j) Forging, counterfeiting, simulating, or falsely representing, or without proper authority using any mark, stamp, tag, label, or other identification device authorized or required by regulations promulgated under the provisions of this Act.

(k) The using, on the labeling of any drug or in any advertisement relating to such drug, of any representation or suggestion that an application with respect to such drug is effective under Section 16, or that such drug complies with the provisions of such section.

Section 4. INJUNCTION PROCEEDINGS. In addition to the remedies hereinafter provided the Commissioner of Health is hereby authorized to apply to the U. S. District Court for, and such court shall have jurisdiction upon hearing and for cause shown, to grant Injunction.

a temporary or permanent injunction restraining any person from violating any provision of Section 3.

Section 5. PENALTIES AND GUARANTY.

Penalties.

(a) Any person who violates any of the provisions of Section 3 shall be guilty of a misdemeanor and upon conviction thereof shall be punished by imprisonment in the Federal jail for not more than six months or by a fine of not more than $500.00, or by both such imprisonment and fine; but if the violation is committed after a conviction of such person under this section has become final, such person shall be subject to imprisonment in the Federal jail for not more than one year, or to a fine of not more than $500.00, or to both such imprisonment and fine.

Guaranty in good faith.

(b) No person shall be subject to the penalties of subsection (a) of this section, for having violated Section 3 (a) or (c) if he establishes a guaranty or undertaking signed by, and containing the name and address of, the person residing in the Territory of Alaska from whom he received in good faith the article, to the effect that such article is not adulterated or misbranded within the meaning of this Act, designating this Act.

Limitation on publisher or radio broadcast.

(c) No publisher, radio-broadcast licensee, or agency or medium for the dissemination of an advertisement, except the manufacturer, packer, distributor, or seller of the article to which a false advertisement relates, shall be liable under this section by reason of the dissemination by him of such false advertisement, unless he has refused, on the request of the Commissioner of Health to furnish the Commissioner of Health the name and post office address of the manufacturer, packer, distributor, seller, or advertising agency, residing in the Territory of Alaska who caused him to disseminate such advertisement.

Section 6. SEIZURE.

(a) Whenever the Commissioner of Health finds or has probable cause to believe, that any food, drug, device, or cosmetic is adulterated, or so misbranded as to be dangerous or fraudulent, within the meaning of this Act, he shall affix to such article a tag or other appropriate marking, giving notice that such article is, or is suspected of being, adulterated or misbranded and has been detained or embargoed, and warning all persons not to remove or dispose of such article by sale or otherwise until permission for removal or disposal is given by the Commissioner of Health or the court. It shall be unlawful for any person to remove or dispose of such detained or embargoed article by sale or otherwise without such permission. Seizure.

(b) When an article detained or embargoed under subsection (2) has been found by the Commissioner of Health to be adulterated, or misbranded, he shall petition the U. S. District Court in whose jurisdiction the article is detained or embargoed for a libel for condemnation of such article. When the Commissioner of Health has found that an article so detained or embargoed is not adulterated or misbranded, he shall remove the tag or other marking. Petition to court

(c) If the court finds that a detained or embargoed article is adulterated or misbranded, such article shall, after entry of the decree, be destroyed at the expense of the claimant thereof, under the supervision of the Commissioner of Health, and all court costs and fees, and storage and other proper expenses, shall be taxed against the claimant of such article or his agent; Provided, That when the adulteration or misbranding can be corrected by proper labeling or processing of the article, the court, after entry of the decree and after such costs, fees, and expenses have been paid and a good and sufficient bond, conditioned that such article shall be so labeled or pro- Destruction by court order. Relabeling or processing.

cessed, has been executed, may by order direct that such article be delivered to the claimant thereof for such labeling or processing under the supervision of the Commissioner of Health. The expense of such supervision shall be paid by the claimant. Such bond shall be returned to the claimant of the article on representation to the court by the Commissioner of Health that the article is no longer in violation of this Act, and that the expenses of such supervision have been paid.

Condemnation of food.

(d) Whenever the Commissioner of Health shall find in any room, building, vehicle of transportation or other structure, any meat, sea food, poultry, vegetable, fruit or other perishable articles which are unsound, or contain any filthy, decomposed, or putrid substance, or that may be poisonous or deleterious to health or otherwise unsafe, the same being hereby declared to be a nuisance, the Commissioner of Health shall forthwith condemn or destroy the same, or in any other manner render the same unsalable as human food.

Notice prior to criminal proceeding.

Section 7. HEARING BEFORE REPORT OF CRIMINAL VIOLATION. It shall be the duty of each United States attorney, to whom the Commissioner of Health reports any violation of this Act, to cause appropriate proceedings to be instituted in the proper court without delay and to be prosecuted in the manner required by law. Before any violation of this Act is reported to any such attorney for the institution of a criminal proceeding, the person against whom such proceeding is contemplated shall be given appropriate notice and an opportunity to present his views before the Commissioner of Health, either orally or in writing, in person, or by attorney, with regard to such contemplated proceeding.

Minor violations.

Section 8. REPORT OF MINOR VIOLATIONS. Nothing in this Act shall be construed as requiring the Commissioner of Health to report for prosecution, or for the institution of libel or injunction proceedings under

this Act, minor violations of this Act, whenever the Commissioner of Health believes that the public interest will be adequately served by a suitable written notice or warning.

Section 9. DEFINITIONS AND STANDARDS FOR FOOD. Whenever in the judgment of the Commissioner of Health such action will promote honesty and fair dealing in the interest of consumers, the Board shall promulgate regulations fixing and establishing for any food, or class of food, a reasonable definition and standard of identity, a reasonable standard of quality, and/or reasonable standards of fill of container. In prescribing a definition and standard of identity for any food or class of food in which optional ingredients are permitted, the Board shall, for the purpose of promoting honesty and fair dealing in the interest of consumers, designate the optional ingredients which shall be named on the label. The definitions and standards so promulgated shall conform as far as practicable to the definitions and standards promulgated under authority of the Federal Act.

Fixing of food standards.

Section 10. ADULTERATED FOOD. A food shall be deemed to be adulterated—

(a) (1) If it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health; or (2) if it bears or contains any added poisonous or added deleterious substance which is unsafe within the meaning of Section 13; or (3) if it consists in whole or in part of a diseased, contaminated, filthy, putrid, or decomposed substance, or if it is otherwise unfit for food; or (4) if it has been produced, prepared, packed, or held under insanitary conditions whereby it

Adulterated food how determined.

may have become contaminated with filth, or whereby it may have been rendered diseased, unwholesome, or injurious to health; or (5) if it is, in whole or in part, the product of a diseased animal or an animal which has died otherwise than by slaughter, or that has been fed upon the uncooked offal from a slaughterhouse; or (6) if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health.

(b) (1) If any valuable constituent has been in whole or in part omitted or abstracted therefrom; or (2) if any substance has been substituted wholly or in part therefor; or (3) if damage or inferiority has been concealed in any manner; or (4) if any substance has been added thereto or mixed or packed therewith so as to increase its bulk or weight, or reduce its quality or strength, or make it appear better or of greater value than it is.

(c) If it is confectionery, and it bears or contains any alcohol or non-nutritive article or substance except harmless coloring, harmless flavoring, harmless resinous glaze not in excess of four-tenths of 1 per centum, harmless natural wax not in excess of four-tenths of one per centum, harmless natural gum, and pectin; Provided, That this paragraph shall not apply to any confectionery by reason of its containing less than one-half of one per centum by volume of alcohol derived solely from the use of flavoring extracts, or to any chewing gum by reason of its containing harmless non-nutritive masticatory substances.

(d) If it bears or contains a coal-tar color other than one from a batch which has been certified under authority of the Federal Act.

Section 11. MISBRANDED FOODS. A food shall be deemed to be misbranded—

(a) If its labeling is false or misleading in any particular. Misbranded food how determined.

(b) If it is offered for sale under the name of another food.

(c) If it is an imitation of another food, unless its label bears, in type of uniform size and prominence, the word "imitation" and, immediately thereafter, the name of the food imitated.

(d) If its container is so made, formed, or filled as to be misleading.

(e) 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, or numerical count; Provided, That under clause (2) of this paragraph reasonable variations shall be permitted, and exemptions as to small packages shall be etsablished, by regulations prescribed by the Board.

(f) If any word, statement, or other information required by or under authority of this Act to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(g) If it purports to be or is represented as a food for which a definition and standard of identity has been prescribed by regulations as provided by Section 9, unless (1) is [it] conforms to such definition and standard, and (2) its label bears the name of the food specified in the definition and standard, and, insofar as may be required by such regulations, the common names of optional in-

gredients (other than spices, flavoring, and coloring) present in such food.

(h) If it purports to be or is represented as—

(1) a food for which a standard of quality has been prescribed by regulations as provided by Section 9, and its quality falls below such standard, unless its label bears, in such manner and form as such regulations specify, a statement that it falls below such standard; or

(2) a food for which a standard or standards of fill of container have been prescribed by regulation as provided by Section 9, and it falls below the standard of fill of container applicable thereto, unless its label bears, in such manner and form as such regulations specify, a statement that it falls below such standard.

(i) If it is not subject to the provisions of paragraph (g) of this section, unless it bears labeling clearly giving (1) the common or usual name of the food, if any there be, 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 Board. And provided further that the requirements of clause (2) of this paragraph shall not apply to food products which are packaged at the direction of purchasers at retail at the time of sale, the ingredients of which are disclosed to the purchasers by other means in accordance with regulations promulgated by the Board.

(j) If it purports to be or is represented for special dietary uses, unless its label bears such information concerning its vitamin, mineral, and other dietary properties as the Commissioner of Health determines to be, and by regulations prescribes as, necessary in order fully to inform purchasers as to its value for such uses.

(k) If it bears or contains any artificial flavoring, artificial coloring, or chemical preservative, unless it bears labeling stating that fact; Provided, That to the extent that compliance with the requirements of this paragraph is impracticable, exemption shall be established by regulations promulgated by the Board.

Section 12. EMERGENCY PERMIT CONTROL.

(a) Whenever the Board finds after investigation that the distribution in Alaska of any class of food may, by reason of contamination with microorganisms during the manufacture, processing, or packing thereof in any locality, be injurious to health, and that such injurious nature cannot be adequately determined after such articles have entered commerce, it then, and in such case only, shall promulgate regulations 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 introduce or deliver for introduction into commerce 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 Commissioner of Health as provided by such regulations.

Issuance of emergency permits.

(b) The Commissioner of Health is authorized to sus-

pend 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. The holder of a permit so suspended shall be privileged at any time to apply for the reinstatement of such permit, and the Commissioner of Health shall, immediately after prompt hearing and an inspection of the establishment, reinstate such permit if it is found that adequate measures have been taken to comply with and maintain the conditions of the permit, as originally issued or as amended.

Suspension of permit.

(c) Any officer or employee duly designated by the Commissioner of Health shall have access to any factory or establishment, the operator of which holds a permit from the Commissioner of Health, 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.

Access to premises.

Section 13. TOLERANCES FOR ADDED POISONOUS INGREDIENTS. Any poisonous or deleterious substance added to any food, except where such substance is required in the production thereof or cannot be avoided by good manufacturing practice, shall be deemed to be unsafe for purposes of the application of clause (2) of Section 10 (a); but when such substance is so required or cannot be so avoided, the Board shall promulgate regulations limiting the quantity therein or thereon to such extent as the Board finds necessary for the protection of public health, and any quantity exceeding the limits so fixed shall also be deemed to be unsafe for purposes of the application of clause (2) of Section 10 (a). While such a regulation is in effect limiting the quantity of any such substance in the case of any food, such food shall not, by reason of bearing or containing any added amount of such substance, be considered to be adulterated within the meaning of clause (1) Section 10 (a). In determining the quantity of such added

Poison tolerances.

substance to be tolerated in or on different articles of food, the Board shall take into account the extent to which the use of such substance is required or cannot be avoided in the production of each such article and the other ways in which the consumer may be affected by the same or other poisonous or deleterious substances.

Section 14. ADULTERATED DRUGS AND DEVICES.

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; or (2) if it has been produced, prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health, or (3) if it is a drug 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, a coal-tar other than one from a batch certified under the authority of the Federal Act. Adulterated drug how determined.

(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 quality or purity falls below the standard set forth in such compendium. Such determination as to strength, quality, or purity shall be made in accordance with the tests or methods of assay set forth in such compendium, or in the absence of or inadequacy of such tests or methods of assay, those prescribed under authority of the Federal Act . No drug defined in an official compendium shall be deemed to be adulterated under this paragraph because it differs from the standard of strength, quality, or purity therefor set forth in such compendium, if its difference in strength, quality, or purity from such standard is plainly stated on its label. Whenever a drug is recognized in both the

United States Pharmacopoeia and the Homoeopathic Pharmacopoeia of the United States it shall be subject to the requirements of the United States Pharmacopoeia unless it is labeled and offered for sale as a homoeopathic drug, in which case it shall be subject to the provisions of the Homoeopathic Pharmacopoeia of the United States and not to those of the United States Pharmacopoeia.

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

(d) If it is a drug and any substance has been (1) mixed or packed therewith so as to reduce its quality or strength; or (2) substituted wholly or in part therefor.

Misbranded drugs how determined.

Section 15. MISBRANDED DRUGS AND DEVICES. A drug or device shall be deemed to be misbranded—

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

(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, or 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 Board.

(c) If any word, statement, or other information required by or under authority of this Act to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and

understood by the ordinary individual under customary conditions of purchase and use.

(d) If it is for use by man and contains any quantity or the narcotic or hypnotic substance alpha-eucaine, barbituric acid, beta-eucaine, bromal, cannabis, carbromal, chloral, coca, cocaine, codeine, heroin, marihuana. morphine, opium, paraldehyde, peyete, or sulphonmethane, or any chemical derivative of such substance, which derivative has been by the Commissioner of Health, after investigation, found to be, and by regulations under this Act, designated as, habit forming; unless its label bears the name, and quantity or proportion of such substance or derivative and in juxtaposition wherewith 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 kind and quantity or proportion of any alcohol, and also including, whether active or not, the name and quantity or proportion of any bromides, ether, chloroform, acetanilid, acetphenetidin, amidopyrine, antipyrine, atropine, hyoscine, hyoscyamine, arsenic, digitalis glucosines, mercury, quabain, strophanthin. strychnine, thyroid, or any derivative or preparation of any such substances, contained therein; Provided, That to the extent that compliance with the requirements of clause (2) of this paragraph is impracticable, exemptions shall be established by regulations promulgated by the Board.

(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 (1) of this paragraph, as applied to any drug or device, is not necessary for the protection of the public health, the Board shall promulgate regulations exempting such drug or device from such requirements.

(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 Commissioner of Health. Whenever a drug is recognized in both the United States Pharmacopoeia and the Homoeopathic Pharmacopoeia of the United States, it shall be subject to the requirements of the United States Pharmacopoeia with respect to packaging and labeling unless it is labeled and offered for sale as a homoeopathic drug, in which case it shall be subject to the provisions of the Homoeopathic Pharmacopoeia of the United States, and not to those of the United States Pharmacopoeia.

(h) If it has been found by the Commissioner of Health 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 Board shall by regulations require as necessary for the protection of public health. No such regulation shall be established for any drug recognized in any official compendium until the Commissioner of Health shall have informed the appropriate body charged with the revision of such compendium of the need for such packaging or labeling requirements and such body shall have failed within a reasonable time to prescribe such requirements.

(i) If it is a drug and its container is so made, formed, or filled as to be misleading; or if it is an imitation of another drug; or if it is offered for sale under the name of another drug.

(j) If it is dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof.

(k) If (1) it is a drug sold at retail and contains any quantity of aminopyrine, barbituric acid, cincohophen, pituitary, thyroid, or their derivatives, or (2) it is a drug or device sold at retail and its label (as originally packed) bears a statement that it is to be dispensed or sold only by or on the prescription of a physician, dentist or veterinarian; unless it is sold on a written prescription signed by a member of the medical, dental, or veterinary profession who is licensed by law to administer such drug or device, and its label (as dispensed) bears the name and place of business of the seller, the serial number and date of such prescription, and the name of such member of the medical, dental or veterinary profession. Such prescription shall not be refilled except on the written authorization of the prescribing physician, dentist or veterinarian.

Section 16. EXEMPTIONS IN CASE OF DRUGS AND DEVICES. A drug sold on a written prescription signed by a member of the medical, dental, or veterinary profession (except a drug sold in the course of the conduct of a business of selling drugs pursuant to diagnosis by mail) shall be exempt from the requirements of Section 15 (b) and (e) if— Exemptions.

(1) Such member of the medical, dental, or veterinary profession is licensed by law to administer such drug, and (2) such drug bears a label containing the name and place of business of the seller, the serial number and date of such prescription, and the name of such member of the medical, dental, or veterinary profession.

Section 17. NEW DRUGS.

(a) No person shall sell, deliver, offer for sale, hold

Limitation on introduction of new drugs.

for sale or give way any new drug unless (1) an application with respect thereto has become effective under Section 355 of the Federal Act, or (2) when not subject to the Federal Act unless such drug has been tested and has not been found to be unsafe for use under the conditions prescribed, recommended, or suggested in the labeling thereof, and prior to selling or offering for sale such drug, there has been filed with the Commissioner of Health an application setting forth (a) full reports of investigations which have been made to show whether or not such drug is safe for use; (b) a full list of the articles used as components of such drug; (c) a full statement of the composition of such drug; (d) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug; (e) such samples of such drug and of the articles used as components thereof as the Commissioner of Health may require; and (f) specimens of the labeling proposed to be used for such drug.

(b) An application provided for in subsection (a) (2) shall become effective on the 60th day after the filing thereof, except that if the Commissioner of Health finds after due notice to the applicant and giving him an opportunity for a hearing, that the drug is not safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof, he shall, prior to the effective date of the application, issue an order refusing to permit the application to become effective.

(c) This section shall not apply — (1) to a drug intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety in drugs provided the drug is plainly labeled "For investigational use only"; or (2) to a drug sold in this Territory at any time prior to the enactment of this Act or introduced into interstate commerce at any time prior to the enactment of the Federal Act; or (3) to any drug

which is licensed under the virus, serum, and toxin Act of July 1, 1902 (U.S.C. 1934 ed. title 42, Chap. 4).

(d) An order refusing to permit an application under this section to become effective may be revoked by the Commissioner of Health.

Section 18. ADULTERATED COSMETICS. A cosmetic shall be deemed to be adulterated—

(a) If it bears or contains any poisonous or deleterious substance which may render it injurious to users under the conditions of use prescribed in the labeling or advertisement thereof, or under such conditions of use as are customary or usual; Provided, That this provision shall not apply to coal-tar hair dye, the label of which bears the following legend conspicuously displayed thereon: "Caution—This Product contains ingredients which may cause skin irritation on certain individuals and a preliminary test according to accompanying directions should first be made. This product must not be used for dyeing the eyelashes or eyebrows; to do so may cause blindness", and the labeling of which bears adequate directions for such preliminary testing. For the purposes of this paragraph and paragraph (e) the term "hair dye" shall not include eyelash dyes or eyebrow dyes.

Adulterated cosmetics how determined.

(b) If it consists in whole or in part of any filthy, putrid, or decomposed substance.

(c) If it has been produced, prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health.

(d) If its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health.

(e) If it is not a hair dye and it bears or contains a coal-tar color other than one from a batch which has been certified under authority of the Federal Act.

Section 19. MISBRANDED COSMETICS. A cosmetic shall be deemed to be misbranded—

Misbranded cosmetics how determined.

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

(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, or 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 Board.

(c) If any word, statement, or other information required by or under authority of this Act to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(d) If its container is so made, formed, or filled as to be misleading.

Section 20. FALSE ADVERTISING.

False advertising how determined.

(a) An advertisement of a food, drug, device, or cosmetic shall be deemed to be false if it is false or misleading in any particular.

(b) For the purpose of this Act the advertisement of a drug or device representing it to have any effect in albuminuria, appendicitis, arteriosclerosis, blood poison, bone disease, Bright's disease, cancer, carbuncles, cholecytitis, diabetes, diphtheria, dropsy, erysipelas, gallstones, heart and vascular diseases, high blood pressure, mastoiditis, measles, meningitis, mumps, nephritis, otitis media, paralysis, pneumonia, poliomyelitis (infantile paralysis), prostate gland disorders, pyelitis, scarlet fever, sexual impotence, sinus infection, smallpox, tuberculosis, tumors, typhoid, uremia, venereal disease, shall also be deemed to be false, except that no advertisement not in violation of subsection (a) shall be deemed to be false under this subsection if it is disseminated only to members of the medical, dental, or veterinary professions, or appears only in the scientific periodicals of these professions, or is disseminated only for the purpose of public health education by persons not commercially interested, directly or indirectly, in the sale of such drugs or devices; Provided, That whenever the Commissioner of Health determines that an advance in medical science has made any type of self-medication safe as to any of the diseases named above, the Board shall by regulation authorize the advertisement of drugs having curative or therapeutic effect for such disease, subject to such conditions and restrictions as the Commissioner of Health may deem necessary in the interests of public health: Provided, That this subsection shall not be construed as indicating that self-medication for diseases other than those named herein is safe or efficacious.

Section 21. REGULATIONS — HEARINGS.

Promulgation of regulations.

(a) The authority to promulgate regulations for the efficient enforcement of this Act is hereby vested in the Board. The Board is hereby authorized to make the regulations promulgated under this Act conform, in so far as practicable, with those promulgated under the Federal Act.

Hearings.

(b) Hearings authorized or required by this Act shall be conducted by the Commissioner of Health or such officer, agent, or employee as the Commissioner of Health may designate for the purpose.

Notice prior to promulgating rules.

(c) Before promulgating any regulations contemplated by Section 9; 11 (j); 12; 15 (d), (f), (g), (h), and (k), or 20 (b), the Board shall give appropriate notice of the proposal and of the time and place for a hearing. The regulation so promulgated shall become effective on a date fixed by the Commissioner of Health (which date shall not be prior to sixty days after its promulgation). Such regulation may be amended or repealed in the same manner as is provided for its adoption, except that in the case of a regulation amending or repealing any such regulation the Board, to such an extend [extent] as it deems necessary in order to prevent undue hardship, may disregard the foregoing provisions regarding notice, hearing, or effective date.

Access to premises.

Section 22. INSPECTIONS—EXAMINATIONS. The Commissioner of Health or his duly authorized agent shall have free access at all reasonable hours to any factory, warehouse, or establishment in which foods, drugs, devices, or cosmetics are manufactured, processed, packed, or held for introduction into commerce, or to enter any vehicle being used to transport or hold such foods, drugs, devices, or cosmetics in commerce, for the purpose:

(1) Of inspecting such factory, warehouse, establishment, or vehicle to determine if any of the provisions of this Act are being violated, and

Sampling.

(2) To secure samples or specimens of any food, drug, device, or cosmetic after paying or offering to pay for such sample. It shall be the duty of the Commissioner of Health to make or cause to be made examinations of samples secured under the provisions of this section to

determine whether or not any provision of this Act is being violated.

Section 23. PUBLICITY — REPORTS.

(a) The Commissioner of Health may cause to be published from time to time reports summarizing all judgments, decrees, and court orders which have been rendered under this Act, including the nature of the charge and the disposition thereof. Reports.

(b) The Commissioner of Health may also cause to be disseminated such information regarding food, drugs, devices, and cosmetics as he deems necessary in the interest of pubic health and the protection of the consumer against fraud. Nothing in this section shall be construed to prohibit the Commissioner of Health from collecting, reporting, and illustrating the results of his investigations.

Section 24. APPROPRIATION. The sum of ten thousand dollars ($10,000.00) is hereby appropriated out of any money in the Territorial Treasury not otherwise appropriated for the enforcement of this Act. Appropriation.

Section 25. SEVERABILITY. If any provision of this Act, or the application thereof to any person or circumstance is held invalid, the remainder of the Act and such application to other persons or circumstances shall not be affected thereby. Savings clause.

Section 26. EFFECTIVE DATE. This Act shall take effect October 1, 1949.

Approved March 28, 1949.