ASSEMBLY, No. 245

STATE OF NEW JERSEY

INTRODUCED FEBRUARY 20, 1939

By Mr. PALESE

Referred to Committee on Judiciary

AN ACT concerning food, drugs and cosmetics, amending sections 24:1–1, 24:1–2, 24:3–1, 24:3–2, 24:3–3, 24:3–4, 24:3–6, 24:4–1, 24:4–2, 24:4–8, 24:4–9, 24:5–1, 25:5–2, 24:5–5, 24:5–6, 24:5–8, 24:5–9, 24:5–10, 24:5–11, 24:5–13, 24:5–16, 24:5–17, 24:5–18, 24:6–1, 24:6–2, 24:6–3 and 24:17–2 of the Revised Statutes; supplementing Title 24 by the addition of two new sections to be known as 24:5–11.1 and 24:5–18.1; and further supplementing Title 24 by the addition of a chapter to be known as chapter six-A.

BE IT ENACTED *by the Senate and General Assembly of the State of New Jersey:*

1. Section 24:1–1 of the Revised Statutes is hereby amended to read as follows:

24:1–1. As used in this Title:

a. "State department," "department of health" and "department" mean the "Department of Health of the State of New Jersey."

b. "State board" means the State Board of Health which is the governing head of the department.

c. "Local board" or "local board of health" means the board of health of any municipality, or the boards, bodies, or officers in such municipality lawfully exercising the powers of a local board of health under the laws governing such municipality.

d. ["Food" includes every article used for food or drink by man or animal, and every ingredient of such article, and all confectionery and

condiments.] "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.

e. ["Drug" includes all medicines and preparations recognized in the United States Pharmacopœia or National Formulary for internal or external use, and any substance or mixture of substances intended to be used internally or externally for the care, mitigation or prevention of disease of man or animal.] "Drug" means (1) articles recognized in the official United States Pharmacopœia, official Homeopathic Pharmacopœia 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.

f. "Package" or "container" [includes] means wrapper, case, basket, hamper, can, bottle, jar, tube, cask, vessel, tub, firkin, keg, jug, barrel, or other receptacles [of a like nature].

g. "Device" 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.

h. "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).

i. "New drugs" 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, and (2) any drug the composition of which is such that such drug, as a result of investigation 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.

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

k. "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 or associated with such article.

l. "Official compendium" means the official United States Pharmacopœia, official Homeopathic Pharmacopœia of the United States, official National Formulary, or any supplement to any of them.

m. If an article is alleged to be misbranded because the labeling is misleading, then in determining whether such labeling is misleading there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, or any combination thereof, but also the extent to which such labeling 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 such labeling relates under the conditions of use prescribed in the labeling thereof or under such conditions of use as are customary or usual.

n. The representation of a drug 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 power, or such other use as involves prolonged contact with the body.

o. 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 away of any such article and the supplying or applying of any such articles in the conduct of any food, drug or cosmetic establishment.

2. Section 24:1–2 of the Revised Statutes is hereby amended to read as follows:

24:1–2. [The book printed and published under the authority of the United States Pharmacopœial convention, known as the United States Pharmacopœia, or any of the printed copies of such book, shall in any action or proceeding brought under any of the provisions of this subtitle be received as evidence of the contents thereof in any court or before any magistrate.] The books printed and published and known as the official United States Pharmacopœia, official Homeopathic Pharmacopœia of the United States, official National Formulary, or any supplement to any of them, or any of the printed copies of such books, shall in any action or proceeding brought under any of the provisions of this subtitle be received as evidence of the contents thereof, in any court or before any magistrate.

The court or magistrate may determine whether the [book] books offered as such [was] were so printed and published, either from inspection or the knowledge of the judge or magistrate, or from testimony.

No error shall be assigned or judgment reversed because of the admission of such [book] books unless it be shown that the [book] books so offered in evidence [was] were not, in fact, printed and published as such official United States Pharmacopœia [under the authority of such convention or was not, in fact, the edition of such United States Pharmacopœia which it purported to be], official Homeopathic Pharmacopœia of the United States, official National Formulary.

3. Section 24:3–1 of the Revised Statutes is hereby amended to read as follows:

24:3–1. The State Department and the local board, and any officer or employee thereof, in the performance of any duty imposed by this subtitle, shall have full access to any place, container or conveyance used in the production, preparation, manufacture, packing, storage, transportation, handling, distribution or sale of any food, [or] drug, cosmetic or device, and may examine and open any package or container which is believed to contain any food, [or] drug, cosmetic or device manufactured, sold, exposed for sale or had in possession with intent to sell in violation of any provision of this subtitle and inspect the contents thereof and take therefrom samples for analysis.

4. Section 24:3–2 of the Revised Statutes is hereby amended to read as follows:

24:3–2. Every person who shall distribute or sell, or offer for distribution or sale, or have in his possession with intent to distribute or sell, any food, [or] drug, cosmetic or device, shall, on request and tender of the value by the State Department, deliver so much thereof to the department as it may request as a sample.

5. Section 24:3–3 of the Revised Statutes is hereby amended to read as follows:

24:3–3. If such request is not immediately complied with, the department may demand and take so much of the food, [or] drug, cosmetic or device as it may think necessary, tendering to the person in charge what it deems to be the reasonable value.

6. Section 24:3–4 of the Revised Statutes is hereby amended to read as follows:

24:3–4. At the time of the delivery or taking of the sample excepting in the case where the article is a device, it shall be divided in the presence of the person of whom the request or demand was made, or before a witness, into two or more parts and each part shall be sealed in a suitable package. One part shall be tendered and, if accepted, shall be delivered to the person

of whom the request or demand was made with a statement in writing that such sample is taken for the purpose of examination, issued in the name of the department and signed by the person taking the same.

7. Section 24:3–6 of the Revised Statutes is hereby amended to read as follows:

24:3–6. In any prosecution for the sale of food, [or] drug or cosmetic in violation of any provision of this subtitle, proof of the analysis of the article so sold may be given in evidence on the part of the prosecutor, notwithstanding the fact that the article may have been purchased by some person other than a representative of the department, if such article shall immediately after such sale be delivered by the purchaser to the department.

The department shall, in the presence of the person from whom the request or demand was made, or of a witness who may be the purchaser, divide the article into two or more parts and preserve the sample in the same manner as prescribed by section 24:3–4 of this title.

8. Section 24:4–1 of the Revised Statutes is hereby amended to read as follows:

24:4–1. Any food, [or] drug, cosmetic or device, if not in transit from one state to another, that is offered or exposed for sale, or had in possession with intent to distribute or sell or is intended for distribution or sale in violation of any provision of this subtitle, [or in any condition which renders it unwholesome or unfit for use as food, whether it is in the custody of a common carrier or of any other person,] may be confiscated by a summary proceeding.

9. Section 24:4–2 of the Revised Statutes is hereby amended to read as follows:

24:4–2. The circuit court, court of common pleas, or district court having jurisdiction in the county in which such food, [or] drug, cosmetic or device is found or any judge of any such court, or any justice of the peace in such county shall have jurisdiction to hear and determine such proceeding.

10. Section 24:4–8 of the Revised Statutes is hereby amended to read as follows:

24:4–8. Any person who appears and claims the food, [or] drug, cosmetic or device seized under the warrant shall be required to file a claim [in writing] under oath.

11. Section 24:4–9 of the Revised Statutes is hereby amended to read as follows:

24:4–9. If upon the hearing it shall appear that the article was offered or exposed for sale, or had in possession with intent to distribute or sell, or was intended for distribution or sale in violation of any provision of this subtitle, [or in any condition which rendered it unwholesome or unfit for food,] it shall be confiscated and disposed of by destruction or sale as the court, judge, or justice of the peace may direct, but no such article shall be sold contrary to any provision of this subtitle.

The proceeds of any sale, less the legal costs and charges, shall be paid to the State Department which shall pay the same into the State treasury, or to the local board for the use of the municipality.

12. Section 24:5–1 of the Revised Statutes is hereby amended to read as follows:

24:5–1. No person shall distribute or sell, or manufacture for distribution or sale, or have in his possession with intent to distribute or sell, any food, [or] drug, cosmetic or device which under any of the provisions of this subtitle is adulterated or misbranded.

13. Section 24:5–2 of the Revised Statutes is hereby amended to read as follows:

24:5–2. No dealer shall be prosecuted for a violation of any provision of this subtitle regulating the adulteration or misbranding of any food, [or] drug, cosmetic or device if he distributes or sells it or has it in his possession with intent to distribute or sell it in the original, unbroken package in which it was received by him, and he can establish a guarantee signed by the person from whom he purchased the same;

a. If a resident of the State, that the article is not adulterated or misbranded within the meaning of this subtitle, designating it; or

b. If a nonresident of the State residing in the United States, that the article is not adulterated or misbranded within the meaning of an Act of Congress entitled [“An act for preventing the manufacture, sale, or transportation of adulterated or misbranded, or poisonous or deleterious foods, drugs, medicines and liquors, and for regulating traffic therein, and for other purposes,” approved June thirtieth, one thousand nine hundred and six,] “An act to prohibit the movement in interstate commerce of adulterated or misbranded food, drug, cosmetic or device, and for other purposes,” approved June twenty-fifth, one thousand nine hundred and thirty-eight, and the supplements and amendments thereto.

14. Section 24:5–5 of the Revised Statutes is hereby amended to read as follows:

24:5–5. No guarantee that any food, [or] drug, cosmetic or device is not adulterated or misbranded within the meaning of the federal legislation specified in section 24:5–2 of this Title shall be effective to exempt any dealer from prosecution under this subtitle unless the requirements of the Federal legislation and of this subtitle covering the adulteration and misbranding of the guaranteed article are identical.

15. Section 24:5–6 of the Revised Statutes is hereby amended to read as follows:

24:5–6. No food, [or] drug, cosmetic or device shall be deemed adulterated or misbranded within the meaning of this subtitle when specially prepared for export to any foreign country:

a. If the article shall be prepared and packed according to the directions of the foreign purchaser; and

b. If no substance is used in the preparation or packing of the article which is prohibited by the laws of the foreign country to which the article was prepared for export.

If such food, [or] drug, cosmetic or device shall later be sold or offered for sale within the United States, then all the provisions of this subtitle with regard to adulteration and misbranding shall apply thereto.

16. Section 24:5–8 of the Revised Statutes is hereby amended to read as follows:

24:5–8. For the purposes of this subtitle food shall be deemed adulterated:

[a. If any substance has been mixed or packed with it so as to reduce or lower or injuriously affect its quality or strength;

b. If any substance has been substituted wholly or in part for it;

c. If any valuable constituent of the food has been wholly or in part abstracted;

d. If it has been mixed, colored, powdered, coated or stained in a manner whereby damage or inferiority is concealed;

e. If it contain any added poisonous or other added deleterious ingredient which may render it injurious to health; provided that when in the preparation of food products for shipment they are preserved by any external application applied in such manner that the preservative is necessarily removed mechanically or by maceration in water, or otherwise, and directions for the removal of the preservative are printed on the covering or package, the provisions of this subtitle shall be construed as applying only to a food ready for consumption; or

f. If it consists in whole or in part of a filthy, decomposed or putrid animal or vegetable substance, or any portion of an animal unfit for food, whether manufactured or not, or if it is the product of a diseased animal or one that has died otherwise than by slaughter.]

a. 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 substances 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 regulations promulgated by the Department of Health of the State of New Jersey limiting the quantity therein or thereon to such extent as the Department of Health of the State of New Jersey finds necessary for the protec-

tion of the public health; or (3) if it consists in whole or in part of any 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 may have become contaminated with filth, or whereby it may have been rendered injurious to health; or (5) if it is in whole or in part the product of a diseased animal or of an animal which has died otherwise than by slaughter; 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 falls below the standard of purity, quality or strength which it purports or is represented to possess.

16. Section 24:5–9 of the Revised Statutes is hereby amended to read as follows:

24:5–9. For the purposes of this subtitle, confectionery shall be deemed adulterated if it [contains terra alba, barytes, talc, chrome yellow or other mineral substance, or poisonous color or flavor, or other ingredient deleterious or detrimental to health, or any vinous, malt or spiritous liquor, or compound or narcotic drug] bears or contains any alcohol, or non-nutritive article or substance except harmless coloring and harmless flavoring; *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.

17. Section 24:5–10 of the Revised Statutes is hereby amended to read as follows:

24:5–10. For the purposes of this subtitle a drug shall be deemed adulterated:

[a. If when sold under or by a name recognized in the United States Pharmacopœia, or National Formulary, or when contained in a package or container bearing a name recognized in the United States Pharmacopœia or National Formulary, it differs from the standard of strength, quality or purity laid down in such Pharmacopœia or Formulary which is official at the time of investigation; or

b. If its strength or purity falls below the professed standard or quality under which it is sold.]

a. (1) If it consists in whole or in part of any filthy, putrid, or decomposed substance; or (2) if it has been 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 color other than one from a batch which has been certified by the United States Department of Agriculture.

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 tests or methods of assay set forth in such compendium.

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 strength, quality, or purity; or (2) substituted wholly or in part therefor.

e. 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.

18. Section 24:5–11 of the Revised Statutes is hereby amended to read as follows:

24:5–11. [No drug sold under or by a name recognized in the United States Pharmacopœia or National Formulary, or contained in a package or container bearing a name recognized in such Pharmacopœia or Formulary, except any drug sold under or by the name of any preparation of opium, iodine, camphor, ginger or peppermint, or contained in a package or container bearing the name of any such preparation, shall be deemed to be adulterated within the meaning of section 24:5–10 of this Title if the standard of strength, quality or purity is plainly and correctly stated upon the package or container, although the standard may differ from that laid down in such Pharmacopœia or Formulary.] 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.

19. Chapter five of Title 24 of the Revised Statutes is hereby supplemented by the addition of the following section to be known as section 24:5–11.1.

24:5–11.1. For the purpose of this subtitle 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 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 purpose of this paragraph and paragraph (e) the term "hair dye" shall not include eyelash dyes or eyebrow dyes.

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 that has been certified by the United States Department of Agriculture.

20. Section 24:5–13 of the Revised Statutes is hereby amended to read as follows:

24:5–13. No person shall sell or offer or expose for sale, or have in his possession with intent to distribute or sell, any food, drug, cosmetic, preparation or mixture of any kind, intended for internal use, which contains methyl or wood alcohol; nor shall any person sell, or offer or expose for sale, or have in his possession with intent to distribute or sell, or use upon or apply to the body of another, any drug, hair tonic, bay rum or similar preparation, intended for external use, which contains methyl or wood alcohol.

Any person who shall violate any of the provisions of this section shall be liable to a penalty of one hundred dollars for the first offense, two hundred dollars for the second offense, and three hundred dollars for the third and each subsequent offense.

21. Section 24:5–16 of the Revised Statutes is hereby amended to read as follows:

24:5–16. The term "misbranded" as used in this subtitle shall apply to all drugs or articles of food, or articles which enter into the composition of food, or cosmetic, or device, the package or label of which shall bear any statement [,] or design [or device] regarding such article or the ingredients or substances contained therein, which shall be false or misleading in any particular, and to any food or drug product, or cosmetic, or device which is falsely branded as to the state, territory or country in which it is manufactured or produced.

22. Section 24:5–17 of the Revised Statutes is hereby amended to read as follows:

24:5–17. For the purposes of this subtitle a food shall also be deemed to be misbranded:

[a. If it be an imitation of or offered for sale under the distinctive name of another article;

b. If it be labeled or branded so as to deceive or mislead the purchaser, or purport to be a foreign product when not so, or if the contents of the package as originally put up shall have been removed, in whole or in part, and other contents shall have been placed in such package, or if it fails to bear a statement on the label of the quantity or proportion of any morphine, opium, cocaine, heroin, alpha or beta eucaine, chloroform, cannabis indica, chloral hydrate, acetanilide, acet-phenetidine, phenacetin or antipyrin, or any derivative or preparation of any such substances contained therein; or

c. If the package containing the food, or its label, shall bear any statement, design or device regarding the ingredients or substances contained therein which is false or misleading in any particular.]

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

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.

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, or designs, 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 adopted by the Department of Health of the State of New Jersey, unless (1) it conforms to such definition and standard, and (2) its label bears the name of the food specified in the definition and standard and, in so far as may be required by such regulations, the common names of optional ingredients (other than spices, flavoring and coloring) present in such food.

h. If it purports to be or is represented as a food for which a standard of quality has been prescribed by the Department of Health of the State of New Jersey, and its quality falls below such standard, unless such label bears, in such manner and form as specified by the Department of Health of the State of New Jersey that it falls below such standard.

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 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 impractical, or results in deception, exemptions shall be established by regulations promulgated by the Department of Health of the State of New Jersey.

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 Department of Health of the State of New Jersey 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, exemptions shall be established by regulations promulgated by the Department of Health of the State of New Jersey.

23. Section 24:5–18 of the Revised Statutes is hereby amended to read as follows:

24:5–18. For the purposes of this subtitle a drug or device shall [also] be deemed to be misbranded:

[a. If it be an imitation of or offered for sale under the name of another article;

b. If the contents of the package as originally put up shall have been removed, in whole or in part, and other contents shall have been placed in such package, or if the package fails to bear a statement on the label of the quantity or proportion of alcohol, morphine, opium, cocaine, heroin, alpha or beta eucaine, chloroform, cannabis indica, chloral hydrate, acetanilide, acetphenetidine, phenacetin or antipyrin, or any derivative or preparation of any such substances contained therein; but nothing in this paragraph contained shall be construed to apply to preparations specified and recognized by the United States Pharmacopœia or National Formulary which are in accordance therewith, or to the compounding of family or domestic recipes, or the filling of prescriptions furnished by practicing physicians, dentists or veterinarians, the original of which recipes and prescriptions are retained and filed by the druggists compounding or filling the same; or

c. If the package containing the drug, or its label shall bear or contain any statement, design or device regarding the curative or therapeutic effect of the drug or any ingredients or substances contained therein which is false or fraudulent.]

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

b. If in package form unless it bears a label containing the name and place of business of the manufacturer, packer, or distributor.

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 or designs in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

d. If it is for use by man and contains any quantity of (1) the narcotic or hypnotic substance alpha-eucaine, barbituric acid, beta-eucaine, bromal, cannabis, carbromal, chloral, coca, cocaine, codeine, heroin, marihuana, morphine, opium paraldehyde, peyote, or sulphonmethane; or any chemical derivative of such substance, which derivative has been found by the Department of Health of the State of New Jersey to be habit forming; unless its label bears the name, quantity, and percentage 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 (23) 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, acetphenetidin, amidopyrine, antipyrine, atropine, hyoscine, hyoscyamine, arsenic, digitalis, digitalis glucosides, mercury, onabain, strophanthin, strychnine, thyroid, or any derivative or preparation of any such substances, contained therein.

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 Department of Health of the State of New Jersey may 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.

h. If it has been found by the Department of Health of the State of New Jersey 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 Department of Health of the State of New Jersey may by regulations require as necessary for the protection of the public health.

i. If it is a drug and its container is so made, formed or filled as to be misleading; or (2) if it is an imitation of another drug; or (3) if it is offered for sale under the name of another drug.

24. Chapter five of Title 24 of the Revised Statutes is hereby supplemented by the addition of the following section to be known as section 24:5–18.1.

24:5–18.1. For the purposes of this subtitle a cosmetic 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 the name and place of business of the manufacturer, packer, or distributor.

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 or designs 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.

25. Section 24:6–1 of the Revised Statutes is hereby amended to read as follows:

24:6–1. If the standard of purity, quality, or strength of a particular food, [or] drug, cosmetic or device has not been fixed by any law of this State, but such standard has been or may hereafter be established and published by the Secretary of Agriculture of the United States, the State Board of Health may adopt by resolution duly passed at a regular meeting of the board the standard so established and published.

If such standard shall be changed at any time by the Secretary of Agriculture of the United States, after the adoption of the resolution, it shall not continue in effect in this State after such change has become operative.

26. Section 24:6—2 of the Revised Statutes is hereby amended to read as follows:

24:6–2. Such resolution shall be certified to the Secretary of State by the secretary of the board, and shall be published at the end of the first volume of the session laws of the Legislature published after the adoption of the resolution. The standard of purity, quality or strength of a food, [or] drug, cosmetic or device fixed in the resolution shall take effect when so published.

27. Section 24:6–3 of the Revised Statutes is hereby amended to read as follows:

24:6–3. No person shall distribute or sell, or offer or expose for sale, or have in his possession with intent to sell, or manufacture for distribution or sale, any food, [or] drug, cosmetic or device which differs in purity, quality or strength from the standards adopted and published in accordance with sections 24:6–1 and 24:6–2 of this Title.

28. Section 24:17–2 of the Revised Statutes is hereby amended to read as follows:

24:17–2. The production, preparation, manufacture, distribution, sale, offering or exposing for sale or having in possession with intent to distribute or sell of any food, [or] drug, cosmetic or device in different places on the same day, or in the same place on different days, in violation of any provision of this subtitle, or of any rule or regulation of the State Department made pursuant thereto, or of any lawful order or direction of the department given thereunder, shall each be deemed to be a separate violation.

29. Title 24 of the Revised Statutes is hereby supplemented by the addition of the following chapter to be known as chapter six-A.

24:6–A. a. No person shall introduce or deliver for introduction into intrastate commerce in the State of New Jersey any new drug unless an application filed pursuant to subsection (b) is effective with respect to such drug.

b. Any person may file with the Department of Health of the State of New Jersey an application with respect to any new drug subject to the provisions of subsection (a). Such person shall submit to the Department

of Health of the State of New Jersey as a part of the application (1) full reports of investigations which have been made to show whether or not such drug is safe for use; (2) a full list of the articles used as components of such drug; (3) a full statement of the composition of such drug; (4) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing and packing of such drug; (5) such samples of such drugs and of the articles used as components thereof as the Department of Health of the State of New Jersey may require; and (6) specimens of the labeling proposed to be used for such drug.

c. The application provided for in subsection (b) shall become effective on the sixtieth day after the filing thereof unless prior to such day the Department of Health of the State of New Jersey by notice to the applicant in writing postpones the effective date of the application to such time (not more than one hundred eighty days after the filing thereof) as the Department of Health of the State of New Jersey deems necessary to enable it to study and investigate the application.

d. If the Department of Health of the State of New Jersey finds, after due notice to the applicant and giving him an opportunity for a hearing that (1) the investigations, reports of which are required to be submitted to the Department of Health of the State of New Jersey pursuant to subsection (b), do not include adequate tests by all methods reasonably applicable to show whether or not such drug is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof; (2) the results of such tests show that such drug is unsafe for use under such conditions or do not show that such drug is safe for use under such conditions; (3) the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug, are inadequate to preserve its identity, strength, quality, and purity; or (4) upon the basis of the information submitted to the Department of Health of the State of New Jersey as part of the application, or upon the basis of any other information before the Department of Health of the State of New Jersey with respect to such drug, the Department of Health of the State of New Jersey has

insufficient information to determine whether such drug is safe for use under such conditions, the Department of Health of the State of New Jersey may, prior to the effective date of the application, issue an order refusing to permit the application to become effective.

30. This act shall take effect immediately.

STATEMENT

The Federal Food and Drugs Act, passed in 1906, was changed in June, 1938, by the passage of an act which extended the regulation of the interstate traffic in foods and drugs to include "new drugs," appliances used in treating the human body, and cosmetics. It seems necessary to bring the State Food and Drug Act, governing the production, sale and distribution of food and drugs into conformity with the Federal act.

The death of approximately ninety persons in southern and midwestern states, resulting from the taking of a new drug which had not been tested, aroused public opinion throughout the country and resulted in the passage of new Federal Food and Drugs Law. Similar action is requested by the Legislature of this State to regulate the intrastate traffic in "new drugs". This proposed law will govern such "new drugs" in New Jersey.

At the present time there is no legislation or regulation in this State governing the composition of cosmetics. Serious injury to human beings has resulted from the use of certain hair dyes and cosmetic preparations containing poisonous ingredients throughout the country. This proposed law will govern these preparations.

Legislation is also needed to regulate the manufacture and sale in New Jersey of appliances and devices intended for use in the treatment of human ailments. This proposed law will govern these appliances.

[OFFICIAL COPY REPRINT]

SENATE AMENDMENTS TO
COMMITTEE SUBSTITUTE FOR

ASSEMBLY, No. 245

STATE OF NEW JERSEY

ADOPTED JULY 12, 1939

Amend section 19, on page 10, at lines 38, 39 and 40, by striking out the following after the word "animal" where it first appears in line 38: "or of an animal which has died otherwise than by slaughter, or that has been fed upon uncooked garbage or upon uncooked offal from a slaughterhouse;"

Amend subsection E, of section 26, on page 14, at line 25, by inserting after the word "label" and before the word "containing" the words "or tag."

Amend section 35, on page 22, at line 63, by adding a new subsection before section 36 as follows: "(5) to meat and meat food products which have passed inspection in accordance with the Federal Meat Inspection Act, approved March fourth, one thousand nine hundred and seven, as amended (U. S. C., 1934 ed., Title 21, secs. 71-91; 34 Stat. 1260 et seq.), and such meat and meat food products as have been inspected and passed as fit for food by official meat inspectors, either State or local.

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FURTHER SENATE AMENDMENTS TO

COMMITTEE SUBSTITUTE FOR

ASSEMBLY, No. 245

STATE OF NEW JERSEY

ADOPTED AUGUST 3, 1939

Amend section 19, on page 10, by inserting after the word "animal" in line 38 the following words: "Unless such animal has at the time of slaughter been inspected and the meat of such animal has been passed as fit for food by an official Federal inspector or an inspector of the Bureau of Animal Industry of the New Jersey Department of Agriculture, or if it is in whole or in part the product of an animal which has died otherwise than by slaughter."

Amend section 35, page 22, line 63, by striking out the new subsection before section 36, which reads as follows: "(5) to meat and meat food products which have passed inspection in accordance with the Federal Meat Inspection Act, approved March fourth, one thousand nine hundred and seven, as amended (U. S. C., 1934 ed., Title 21, secs. 71-91; 34 Stat. 1260 et seq.), and such meat and meat food products as have been inspected and passed as fit for food by official meat inspectors, either State or local."

[SECOND OFFICIAL COPY REPRINT]

COMMITTEE SUBSTITUTE FOR

ASSEMBLY, No. 245

STATE OF NEW JERSEY

ADOPTED JUNE 8, 1939

AN ACT concerning food, drugs, devices and cosmetics, amending sections 24:1–1, 24:1–2, 24:2–1, 24:3–1, 24:3–2, 24:3–3, 24:3–4, 24:3–6, 24:4–1, 24:4–2, 24:4–8, 24:4–9, 24:5–1, 24:5–2, 24:5–5, 24:5–6, 24:5–8, 24:5–9, 24:5–10, 24:5–11, 24:5–13, 24:5–16, 24:5–17, 24:5–18, 24:5–19, 24:6–1, 24:6–2, 24:6–3 and 24:17–2 of the Revised Statutes; supplementing Title 24 by the addition of five new sections to be known as 24:1–4, 24:4–12, 24:5–11.1, 24:5–18.1 and 24:5–18.2; and further supplementing Title 24 by the addition of a chapter to be known as chapter six-A.

BE IT ENACTED *by the Senate and General Assembly of the State of New Jersey:*

1. Section 24:1–1 of the Revised Statutes is hereby amended to read as follows:

24:1–1. As used in this Title:

a. "State department," "department of health" and "department" mean the "Department of Health of the State of New Jersey."

b. "State board" means the State Board of Health which is the governing head of the department.

c. "Local board" or "local board of health" means the board of health of any municipality, or the boards, bodies, or officers in such municipality lawfully exercising the powers of a local board of health under the laws governing such municipality.

d. "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.

e. "Drug" means (1) articles recognized in the official United States Pharmacopœia, official Homeopathic Pharmacopœia 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.

f. "Package" or "container" means wrapper, case, basket, hamper, can, bottle, jar, tube, cask, vessel, tub, firkin, keg, jug, barrel, or other receptacles, but the word, "package" shall not include open containers which permit a visual and physical inspection by the purchaser at retail, nor bags and other receptacles which are filled in the presence of the purchaser at retail.

g. "Device" 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.

h. "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.

i. "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, and (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.

j. "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 subtitle that any word, statement or other information appear 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. The term "immediate container" does not include package liners.

k. "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.

l. "Official compendium" means the official United States Pharmacopœia, official Homeopathic Pharmacopœia of the United States, official National Formulary, or any supplement to any of them.

m. If an article is alleged to be misbranded because the labeling is misleading, then in determining whether such labeling is misleading there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, or any combination thereof, but also the extent to which such labeling 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 such labeling relates under the conditions of use prescribed in the labeling thereof or under such conditions of use as are customary or usual.

n. The representation of a drug 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.

o. 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 away of any such article and the supplying or applying of any such articles in the conduct of any food, drug or cosmetic establishment.

p. 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.).

2. Section 24:1-2 of the Revised Statutes is hereby amended to read as follows:

24:1-2. The books printed and published and known as the official United States Pharmacopœia, official Homeopathic Pharmacopœia of the United States, official National Formulary, or any supplement to any of them, or any of the printed copies of such books, shall in any action or proceeding brought under any of the provisions of this subtitle be received as evidence of the contents thereof, in any court or before any magistrate.

The court or magistrate may determine whether the books offered as such were so printed and published, either from inspection or the knowledge of the judge or magistrate, or from testimony.

No error shall be assigned or judgment reversed because of the admission of such books unless it be shown that the books so offered in evidence were not, in fact, printed and published as such official United States Pharmacopœia, official Homeopathic Pharmacopœia of the United States, or official National Formulary.

3. Chapter one of Title 24 of the Revised Statutes is hereby supplemented by the addition of the following section to be known as section 24:1-4:

24:1-4. No food, drug, device, or cosmetic, which is established to the satisfaction of the State Department to be subject to, and to comply with, regulations promulgated under the Federal Act shall be deemed to be in violation of this subtitle because of its failure to comply with regulations pro-

mulgated hereunder, insofar as the same are in conflict with the regulations under the Federal Act.

4. Section 24:2–1 is hereby amended to read as follows:

24:2–1. The State Department shall execute and enforce the provisions of this subtitle and make and publish all necessary rules and regulations providing for the enforcement and carrying into effect of any provision of this subtitle and for the government of its officers and employees. The State Department is hereby authorized to adopt, insofar as applicable, the regulations from time to time promulgated by the Secretary of Agriculture of the United States under the Federal Act.

5. Section 24:3–1 of the Revised Statutes is hereby amended to read as follows:

24:3–1. The State Department and the local board, and any officer or employee thereof, in the performance of any duty imposed by this subtitle, shall have full access to any place, container or conveyance used in the production, preparation, manufacture, packing, storage, transportation, handling, distribution or sale of any food, drug, cosmetic or device, and may examine and open any package or container which is believed to contain any food, drug, cosmetic or device manufactured, sold, exposed for sale or had in possession with intent to sell in violation of any provision of this subtitle and inspect the contents thereof and take therefrom samples for analysis.

6. Section 24:3–2 of the Revised Statutes is hereby amended to read as follows:

24:3–2. Every person who shall distribute or sell, or offer for distribution or sale, or have in his possession with intent to distribute or sell, any food, drug, cosmetic or device, shall, on request and tender of the value by the State Department, deliver so much thereof to the department as it may request as a sample.

7. Section 24:3–3 of the Revised Statutes is hereby amended to read as follows:

24:3–3. If such request is not immediately complied with, the department may demand and take so much of the food, drug, cosmetic or device as

it may think necessary, tendering to the person in charge what it deems to be the reasonable value.

8. Section 24:3–4 of the Revised Statutes is hereby amended to read as follows:

24:3–4. At the time of the delivery or taking of the sample excepting in the case where the article is a device, it shall be divided in the presence of the person of whom the request or demand was made, or before a witness, into two or more parts and each part shall be sealed in a suitable package. One part shall be tendered and, if accepted, shall be delivered to the person of whom the request or demand was made with a statement in writing that such sample is taken for the purpose of examination, issued in the name of the department and signed by the person taking the same.

9. Section 24:3–6 of the Revised Statutes is hereby amended to read as follows:

24:3–6. In any prosecution for the sale of food, drug or cosmetic in violation of any provision of this subtitle, proof of the analysis of the article so sold may be given in evidence on the part of the prosecutor, notwithstanding the fact that the article may have been purchased by some person other than a representative of the department, if such article shall immediately after such sale be delivered by the purchaser to the department.

The department shall, in the presence of the person from whom the request or demand was made, or of a witness who may be the purchaser, divide the article into two or more parts and preserve the sample in the same manner as prescribed by section 24:3–4 of this Title.

10. Section 24:4–1 of the Revised Statutes is hereby amended to read as follows:

24:4–1. Any food, drug, cosmetic or device, if not in transit from one state to another, that is offered or exposed for sale, or had in possession with intent to distribute or sell or is intended for distribution or sale in violation of any provision of this subtitle, may be confiscated by a summary proceeding.

11. Section 24:4–2 of the Revised Statutes is hereby amended to read as follows:

24:4–2. The circuit court, court of common pleas, or district court having jurisdiction in the county in which such food, drug, cosmetic or device is found or any judge of any such court, or any justice of the peace in such county shall have jurisdiction to hear and determine such proceeding.

12. Section 24:4–8 of the Revised Statutes is hereby amended to read as follows:

24:4–8. Any person who appears and claims the food, drug, cosmetic or device seized under the warrant shall be required to file a claim under oath.

13. Section 24:4–9 of the Revised Statutes is hereby amended to read as follows:

24:4–9. If upon the hearing it shall appear that the article was offered or exposed for sale, or had in possession with intent to distribute or sell, or was intended for distribution or sale in violation of any provision of this subtitle, it shall be confiscated and disposed of by destruction or sale as the court, judge, or justice of the peace may direct, but no such article shall be sold contrary to any provision of this subtitle.

The proceeds of any sale, less the legal costs and charges, shall be paid to the State Department which shall pay the same into the State treasury, or to the local board for the use of the municipality.

14. Chapter four of Title 24 is hereby supplemented by the addition of the following section to be known as 24:4–12:

24:4–12. Whenever an agent of the State Department or of a local board 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 subtitle, 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

such agent 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.

15. Section 24:5–1 of the Revised Statutes is hereby amended to read as follows:

24:5–1. No person shall distribute or sell, or manufacture for distribution or sale, or have in his possession with intent to distribute or sell, any food, drug, cosmetic or device which under any of the provisions of this subtitle is adulterated or misbranded.

16. Section 24:5–2 of the Revised Statutes is hereby amended to read as follows:

24:5–2. No dealer shall be prosecuted for a violation of any provision of this subtitle regulating the adulteration or misbranding of any food, drug, cosmetic or device if he distributes or sells it or has it in his possession with intent to distribute ~~or~~ sell it in the original, unbroken package in which it was received by him, and he can establish a guarantee signed by the person from whom he purchased the same;

a. If a resident of the State, that the article is not adulterated or misbranded within the meaning of this subtitle, designating it; or

b. If a nonresident of the State residing in the United States, that the article is not adulterated or misbranded within the meaning of an Act of Congress entitled "An act to prohibit the movement in interstate commerce of adulterated and misbranded food, drugs, devices and cosmetics, and for other purposes," approved June twenty-fifth, one thousand nine hundred and thirty-eight, and the supplements and amendments thereto.

17. Section 24:5–5 of the Revised Statutes is hereby amended to read as follows:

24:5–5. No guarantee that any food, drug, cosmetic or device is not adulterated or misbranded within the meaning of the federal legislation specified in section 24:5–2 of this Title shall be effective to exempt any dealer from prosecution under this subtitle unless the requirements of the Federal

legislation and of this subtitle covering the adulteration and misbranding of the guaranteed article are identical.

18. Section 24:5–6 of the Revised Statutes is hereby amended to read as follows:

24:5–6. No food, drug, cosmetic or device shall be deemed adulterated or misbranded within the meaning of this subtitle when specially prepared for export to any foreign country:

a. If the article shall be prepared and packed according to the specifications of the foreign purchaser; and

b. If no substance is used in the preparation or packing of the article which is prohibited by the laws of the foreign country to which the article was prepared for export; and

c. If the article is labeled on the outside of the shipping package to show that it is intended for export.

If such food, drug, cosmetic or device shall later be sold or offered for sale within the United States, then all the provisions of this subtitle with regard to adulteration and misbranding shall apply thereto.

19. Section 24:5–8 of the Revised Statutes is hereby amended to read as follows:

24:5–8. For the purposes of this subtitle food shall be deemed adulterated:

a. 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 regulations promulgated by the Department of Health of the State of New Jersey limiting the quantity therein or thereon to such extent as the Department of Health of the State of New Jersey finds necessary for the protection of the public health; or (3) if it consists in whole or in part of any 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 con-

ditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health; or (5) if it is in whole or in part the product of a diseased animal, unless such animal has at the time of slaughter been inspected and the meat of such animal has been passed as fit for food by an official Federal inspector or an inspector of the Bureau of Animal Industry of the New Jersey Department of Agriculture, or if it is in whole or in part the product of an animal which has died otherwise than by slaughter; 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 packaged 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 falls below the standard of purity, quality or strength which it purports or is represented to possess.

d. If it bears or contains a coal-tar color other than one from a batch that has been certified by the United States Department of Agriculture.

20. Section 24:5–9 of the Revised Statutes is hereby amended to read as follows:

24:5–9. For the purposes of this subtitle, confectionery shall be deemed adulterated if it bears or contains any alcohol, or non-nutritive article or substance except harmless vegetable coloring, or if a coal-tar color one from a batch which has been certified by the United States Department of Agriculture, harmless flavoring, harmless resinous glaze not in excess of four-tenths of one per centum, 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.

21. Section 24:5–10 of the Revised Statutes is hereby amended to read as follows:

24:5–10. For the purposes of this subtitle a drug or device shall be deemed adulterated:

a. (1) If it consists in whole or in part of any filthy, putrid, or decomposed substance; or (2) if it has been 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 color other than one from a batch which has been certified by the United States Department of Agriculture.

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 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 by the United States Department of Agriculture. Whenever a drug is recognized in both the United States Pharmacopœia and the Homeopathic Pharmacopœia of the United States it shall be subject to the requirements of the United States Pharmacopœia unless it is labeled and offered for sale as a homeopathic drug, in which case it shall be subject to the provisions of the Homeopathic Pharmacopœia of the United States and not to those of the United States Pharmacopœia.

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 strength, quality, or purity; or (2) substituted wholly or in part therefor.

e. 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.

22. Section 24:5–11 of the Revised Statutes is hereby amended to read as follows:

24:5–11. No drug defined in an official compendium shall be deemed to be adulterated under section 24:5–10 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.

23. Chapter five of Title 24 of the Revised Statutes is hereby supplemented by the addition of the following section to be known as section 24:5–11.1.

24:5–11.1. For the purpose of this subtitle 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 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 purpose of this paragraph and paragraph e the term "hair dye" shall not include eyelash dyes or eyebrow dyes.

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 that has been certified by the United States Department of Agriculture.

24. Section 24:5–13 of the Revised Statutes is hereby amended to read as follows:

24:5–13. No person shall sell or offer or expose for sale, or have in his possession with intent to distribute or sell, any food, drug, cosmetic, preparation or mixture of any kind, intended for internal use, which contains methyl or wood alcohol; nor shall any person sell, or offer or expose for sale, or have in his possession with intent to distribute or sell, or use upon or apply to the body of another, any drug, hair tonic, bay rum or similar preparation, intended for external use, which contains methyl or wood alcohol.

Any person who shall violate any of the provisions of this section shall be liable to a penalty of one hundred dollars for the first offense, two hundred dollars for the second offense, and three hundred dollars for the third and each subsequent offense.

25. Section 24:5–16 of the Revised Statutes is hereby amended to read as follows:

24:5–16. The term "misbranded" as used in this subtitle shall apply to all drugs, articles of food, cosmetics and devices and to articles which enter into the composition of foods, drugs, cosmetics or devices, the package or label of which shall bear any statement or design regarding such article or the ingredients or substances contained therein, which shall be false or misleading in any particular, and to any food or drug product, or cosmetic, or device which is falsely branded as to the State, territory or country in which it is manufactured or produced.

26. Section 24:5–17 of the Revised Statutes is hereby amended to read as follows:

24:5–17. For the purposes of this subtitle a food shall also be deemed to be misbranded:

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

b. If it is offered for sale or distributed 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 or tag containing the name and place of business of the manufacturer, packer, or distributor.

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, or designs, 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 is established in this subtitle or has been adopted by the Department of Health of the State of New Jersey pursuant to section 24:6–1 unless (1) it conforms to such definition and standard, and (2) its label bears the name of the food specified in the definition and standard and, in so far as may be required by such definition and standard, the common names of optional ingredients (other than spices, flavoring and coloring) present in such food.

h. If it purports to be or is represented as a food for which a standard of quality has been prescribed by the Department of Health of the State of New Jersey, pursuant to section 24:6–1, and its quality falls below such standard, unless such label bears, in such manner and form as specified by the Department of Health of the State of New Jersey a statement that it falls below such standard.

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 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 impractical, or results in deception, exemptions shall be established by regulations promulgated by the Department of Health of the State of New Jersey; *provided, further,* that the requirements of clause (2) of this paragraph shall not apply to any carbonated beverage the ingredients of which have been fully and correctly disclosed, to the extent prescribed by said clause (2), to the Department of Health of the State of New Jersey in an affidavit.

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 Department of Health of the State of New Jersey 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, exemptions shall be established by regulations promulgated by the Department of Health of the State of New Jersey. The provisions of this paragraph and paragraphs g and i with respect to artificial coloring shall not apply in the case of butter, cheese, or ice cream.

27. Section 24:5–18 of the Revised Statutes is hereby amended to read as follows:

24:5–18. For the purposes of this subtitle a drug or device shall also 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 the name and place of business of the manufacturer, packer, or distributor.

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

d. If it is for use by man and contains any quantity of the narcotic or hypnotic substance alpha-eucaine, barbituric acid, beta-eucaine, bromal, cannabis, carbromal, chloral, coca, cocaine, codeine, heroin, marihuana, morphine, opium, paraldehyde, peyote, or sulphonmethane; or any chemical derivative of such substance, which derivative has been by the Department of Health of the State of New Jersey after investigation found to be, and by regulations under this subtitle 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 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, digitalis glucosides, mercury, ouabain, 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 may be e tablished by regulations promulgated by the State Department.

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 Department of Health of the State of New Jersey may 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 State Department. Whenever a drug is recognized in both the United States Pharmacopœia and the Homeopathic Pharmacopœia of the United States it shall be subject to the requirements of the United States Pharmacopœia unless it is labeled and offered for sale as a homeopathic drug, in which case it shall be subject to the provisions of the Homeopathic Pharmacopœia of the United States and not to those of the United States Pharmacopœia.

h. If it has been found by the Department of Health of the State of New Jersey 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 Department of Health of the State of New Jersey may by regulations require as necessary for the protection of the public health. No such regulation shall be established for any drug recognized in an official compendium until the State Department 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. (1) If it is a drug and its container is so made, formed or filled as to be misleading; or (2) if it is an imitation of another drug; or (3) if it is offered for sale under the name of another drug.

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

28. Chapter five of Title 24 of the Revised Statutes is hereby supplemented by the addition of the following section to be known as section 24:5–18.1.

24:5–18.1. For the purposes of this subtitle a cosmetic shall also 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 the name and place of business of the manufacturer, packer, or distributor.

c. If any word, statement, or other information required by or under authority of this subtitle to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements or designs 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.

29. Chapter five of Title 24 is hereby supplemented by the addition of the following section to be known as section 24:5–18.2.

24:5–18.2. Foods, drugs, devices, and cosmetics 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 shall be exempted from the labeling and packaging requirements of this subtitle on such conditions as the State Department by regulations shall specify; *provided,* that such food, drugs, devices and cosmetics are not adulterated or misbranded under the provisions of this subtitle upon removal from such processing, labeling or repacking establishment.

30. Section 24:5–19 is hereby amended to read as follows:

24:5–19. Nothing contained in this subtitle, except the provisions of section 24:5–10, shall be construed to apply to (1) any drug personally dispensed by any legally licensed physician, dentist or veterinarian in the course of his practice, or (2) any drug dispensed on a written prescription signed by a physician, dentist, or veterinarian (except a drug dispensed in the course

of the conduct of a business of dispensing drugs pursuant to diagnosis by mail), if (a) such physician, dentist, or veterinarian is licensed by law to administer such drug, and (b) such drug bears a label containing the name and place of business of the dispenser, the serial number and date of such prescription, and the name of such physician, dentist, or veterinarian.

31. Section 24:6–1 of the Revised Statutes is hereby amended to read as follows:

24:6–1. If the definition or standard of identity, purity, quality, or strength of a particular food, drug, cosmetic or device has not been fixed by any law of this State, but such definition or standard has been or may hereafter be established and published by the Secretary of Agriculture of the United States, the State Board of Health may adopt by resolution duly passed at a regular meeting of the board the definition or standard so established and published.

If such definition or standard shall be changed at any time by the Secretary of Agriculture of the United States, after the adoption of the resolution, it shall not continue in effect in this State after such change has become operative.

32. Section 24:6–2 of the Revised Statutes is hereby amended to read as follows:

24:6–2. Such resolution shall be certified to the Secretary of State by the secretary of the board, and shall be published at the end of the first volume of the session laws of the Legislature published after the adoption of the resolution. The definition or standard of identity, purity, quality or strength of a food, drug, cosmetic or device fixed in the resolution shall take effect when so published.

33. Section 24:6–3 of the Revised Statutes is hereby amended to read as follows:

24:6–3. No person shall distribute or sell, or offer or expose for sale, or have in his possession with intent to sell, or manufacture for distribution or sale, any food, drug, cosmetic or device which differs in purity, quality

or strength from the standards adopted and published in accordance with sections 24:6–1 and 24:6–2 of this Title.

34. Section 24:17–2 of the Revised Statutes is hereby amended to read as follows:

24:17–2. The production, preparation, manufacture, distribution, sale, offering or exposing for sale or having in possession with intent to distribute or sell of any food, drug, cosmetic or device in different places on the same day, or in the same place on different days, in violation of any provision of this subtitle, or of any rule or regulation of the State Department made pursuant thereto, or of any lawful order or direction of the department given thereunder, shall each be deemed to be a separate violation.

35. Title 24 of the Revised Statutes is hereby supplemented by the addition of the following chapter to be known as chapter six-A.

24:6–A. a. No person shall introduce or deliver for introduction into intrastate commerce in the State of New Jersey any new drug unless (1) an application with respect thereto has become effective under the Federal Act, or (2) an application filed pursuant to subsection b is effective with respect to such drug.

b. Any person may file with the Department of Health of the State of New Jersey an application with respect to any new drug subject to the provisions of subsection a. Such person shall submit to the Department of Health of the State of New Jersey as a part of the application (1) full reports of investigations which have been made to show whether or not such drug is safe for use; (2) a full list of the articles used as components of such drug; (3) a full statement of the composition of such drug; (4) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing and packing of such drug; (5) such samples of such drug and of the articles used as components thereof as the Department of Health of the State of New Jersey may require; and (6) specimens of the labeling proposed to be used for such drug.

c. The application provided for in subsection b shall become effective on the sixtieth day after the filing thereof unless prior to such day the Department of Health of the State of New Jersey by notice to the applicant in writing postpones the effective date of the application to such time (not more than one hundred eighty days after the filing thereof) as the Department of Health of the State of New Jersey deems necessary to enable it to study and investigate the application.

d. If the Department of Health of the State of New Jersey finds, after due notice to the applicant and giving him an opportunity for a hearing that (1) the investigations, reports of which are required to be submitted to the Department of Health of the State of New Jersey pursuant to subsection b, do not include adequate tests by all methods reasonably applicable to show whether or not such drug is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof; (2) the results of such tests show that such drug is unsafe for use under such conditions or do not show that such drug is safe for use under such conditions; (3) the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug, are inadequate to preserve its identity, strength, quality, and purity; or (4) upon the basis of the information submitted to the Department of Health of the State of New Jersey as part of the application, or upon the basis of any other information before the Department of Health of the State of New Jersey with respect to such drug, the Department of Health of the State of New Jersey has insufficient information to determine whether such drug is safe for use under such conditions, the Department of Health of the State of New Jersey may, prior to the effective date of the application, issue an order refusing to permit the application to become effective.

e. This chapter shall not apply

(1) to a drug intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety of drugs provided the drug is plainly labeled "For investigational use only"; or

(2) to a drug sold in this State at any time prior to the enactment of this subtitle 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); or

(4) to a drug dispensed on a written prescription signed by a physician, dentist, or veterinarian (except a drug dispensed in the course of conduct of a business of dispensing drugs pursuant to diagnosis by mail) if (1) such physician, dentist, or veterinarian is licensed by law to administer such drug, and (2) such drug bears a label containing the name and place of business of the dispenser, the serial number and date of such prescription, and the name of such physician, dentist, or veterinarian.

36. This act shall take effect on the first day of January one thousand nine hundred and forty.