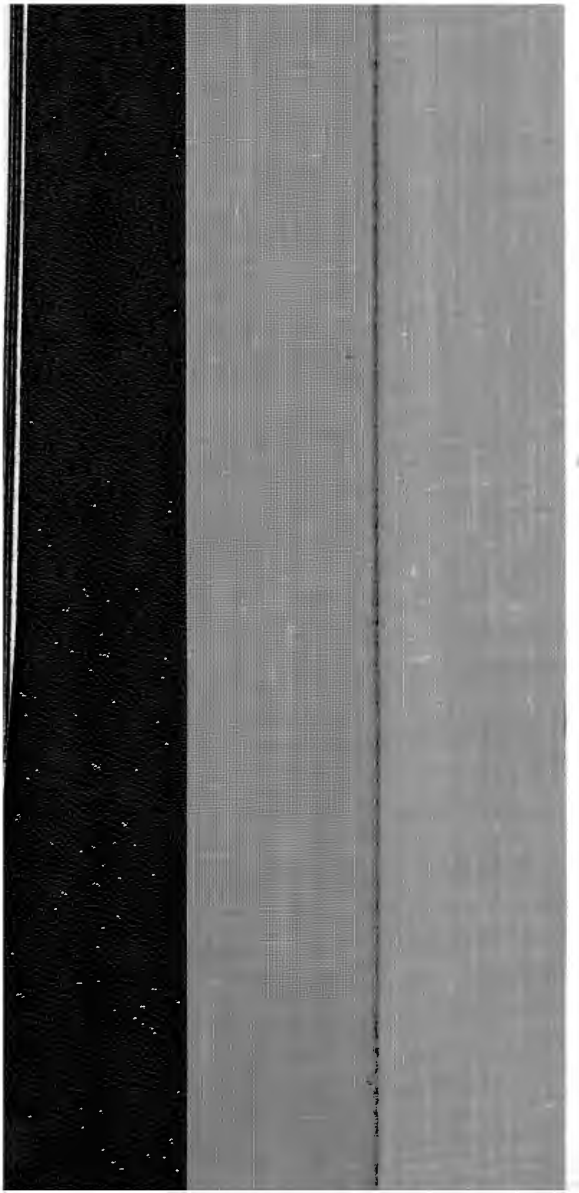

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New Jersey (State) Department of Health

Title 24. FOOD AND DRUGS.

Subtitle 1. FOOD, DRUGS AND COSMETICS.

Chapter 1. DEFINITIONS AND CONSTRUCTION.

24:1-1. Definitions. As used in this title:

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

b. "Council" means the Public Health Council in the State Department of Health.

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, and includes any consolidated local board of health or county local board of health created and established pursuant to law.

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 Pharmacopoeia, official Homeopathic 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.

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, pro-

moting 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.

Regulation. Newness of a drug may arise by reason (among other reasons) of—

(1) the newness for drug use of any substance which composes such drug, in whole or in part, whether it be an active substance or a menstruum, excipient, carrier, coating, or other component;

(2) the newness for drug use of a combination of two or more substances, none of which is a new drug;

(3) the newness for drug use of the proportion of a substance in a a combination, even though such combination containing such substance in other proportion is not a new drug;

(4) the newness of use of such drug in diagnosing, curing, mitigating, treating, or preventing a disease, or to affect a structure or function of the body, even though such drug is not a new drug when used in another disease or to affect another structure or function of the body; or

(5) the newness of a dosage, or method or duration of administration or application, or other condition of use prescribed, recommended, or suggested in the labeling of such drug, even though such drug when used in other dosage, or other method or duration of administration or application, or different condition, is not a new drug.

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.

Regulation. Labeling includes all written, printed, or graphic matter accompanying an article at any time while such article is held in possession with intent to distribute or sell.

l. "Official compendium" means the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia 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 mis-

leading 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 to 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.

Regulation. The existence of a difference of opinion, among experts qualified by scientific training and experience, as to the truth of a representation made or suggested in the labeling is a fact (among other facts) the failure to reveal which may render the labeling misleading, if there is a material weight of opinion contrary to such representation.

n. The representation of a drug as an anticeptic 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.)

24:1-2. United States Pharmacopoeia, Homeopathic, Pharmacopoeia, National Formulary. The books printed and published and known as the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia 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 judgment shall be 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 Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, or official National Formulary.

24:1-3. Responsibility for acts of officers and agents. When construing and enforcing any provision of this subtitle, the act, ommision or failure, within the scope of his employment or offiice, of any officer, agent or other person acting for or employed by another person, shall be deemed to be the act, omission or failure of the person so represented as well as that of the person acting in a representative capacity.

24:1-4 No violation if article complies with federal act. 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 promulgated hereunder, insofar as the same are in conflict with the regulations under the federal act.

Chapter 2 ENFORCEMENT AGENCIES.

24:2-1 Enforcement by state department; rules and regulations. 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 under the Federal Act.

24:2-2. Enforcement by local board. The local board of health shall enforce the provisions of this subtitle within its jurisdiction.

24:2-3. State inspectors, analysts and employees. The state board may appoint such analysts, chemists, chief inspectors and other inspectors and employees as may be authorized by law, and the persons thus appointed shall perform such duties as may be assigned to them by the state department. The state board shall fix the salaries of all such officers and employees subject to the provisions of Title 11, Civil Service except when otherwise provided by statute.

24:2-4 Local food and drug inspectors and analysts. The local board of health may designate from among its sanitary inspectors one or more inspectors who shall be known as local food and drug inspectors. The local board may also appoint one or more food and drug analysts.

24:2-5. Powers and duties of local food and drug inspectors. The local food and drug inspector shall have, within the jurisdiction of the local board appointing him, all the power and authority given an inspector appointed by the state board under the authority of section 24:2-3 of this title. He shall, in addition to the usual duties of a sanitary inspector, aid in the enforcement of the provisions of this subtitle.

24:2-6. Interference with officials. No person shall obstruct or interfere with the state department or the local board, or any officer or employee thereof, in the performance of any duty imposed by this subtitle. Any person who shall violate the provisions of this section shall be liable to a penalty of not more than:

a. $100.00 for each first offense.

b. $300.00 for each second and subsequent offense.

Chapter 3. INSPECTION—SAMPLES.

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 premises or 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 inspect any of the aforesaid premises, places or conveyances to determine if it meets the sanitary requirements set forth in this subtitle, 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, whether or not the container or package be sealed or locked and whether or not it be in transit.

24:3-2. Procuring sample of food, drug, cosmetic or device. 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.

24:3-3. Taking sample without consent of owner. 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.

24:3-4. Preservation of sample. 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.

24:3-5. Proof of analysis as evidence. In a prosecution for the violation of any provision of this subtitle no proof of an analysis shall be given in evidence by the prosecutor unless the sample shall have been sealed up and tenderd as provided in section 24:3-4 of this title, except as provided in section 24:3-6 of this title.

24:3-6. Proof of analysis on purchase by other than department representative. 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 prospector, 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.

24:3-7. Repealed. Laws of 1966, Chapter 74.

24:3-8. Repealed. Laws of 1966, Chapter 74.

24:3-9. Composite sample of milk seized in transit. When the department shall seize or take for inspection any milk in transit from a dairy to a receiving station or creamery, it shall proceed with the same to such place and cause all of the milk so seized to be poured in one vessel and thoroughly mixed and take a composite sample for analysis.

24:3-10. Repealed. Laws of 1966, Chapter 74.

Chapter 4. CONDEMNATION AND DESTRUCTION OF FOOD, DRUG, COSMETIC OR DEVICE.

24:4-1. Confiscation; summary proceeding. 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 as hereinafter provided.

24:4-2. Venue of proceeding. The County Court, or county district court or municipal court having jurisdiction in the county or municipality, as the case may be, in which such food, drug, cosmetic or device is found shall have jurisdiction to hear and determine such proceeding.

24:4-3. Repealed. Laws of 1953, Chapter 24.

24:4-4. Repealed. Laws of 1953, Chapter 24.

24:4-5. Issuance of warrant. Upon the filing of a verified complaint the court may issue a warrant directed to the sheriff or a constable of the county or other peace officer, commanding such officer to seize and take in his possession the article described in the complaint, and bring the same before the court which issued the warrant and to summon the person named in the warrant, and any other person who may be found in possession of the article, to appear at the time and place therein specified.

24:4-6. Repealed. Laws of 1953, Chapter 24.

24:4-7. Repealed. Laws of 1953, Chapter 24.

24:4-8. Claims under oath. 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.

24:4-9. Sale or destruction of condemned article. 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 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.

24:4-10. Return of goods; bond. In case the article seized is not injurious to health and is of such a character that when properly marked or branded its sale is not prohibited by this subtitle, the court may order such article delivered to the owner upon the payment of the costs of the proceeding and the execution and delivery to the state department or local board instituting the proceedings, as obligee, of a good and sufficient bond to the effect that such article shall not be sold or otherwise disposed of contrary to the provisions of this subtitle or the laws of any state, territory, district of the United States, or of the United States.

24:4-11. Summary destruction of perisable food. The state department or the local board shall condemn any food of a perishable nature and cause it to be destroyed or disposed of in such a manner as to make it impossible to be thereafter used for human food, whenever found:

a. Exposed or offered for sale, or had in possession with intent to sell, in violation of any provision of this subtitle; or

b. In a state of rottenness or putrefaction, or in any condition which renders it unwholesome or unfit for use for human food.

24:4-12. Marking condemned article. 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, adultered 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.

Chapter 5. GENERAL ADULTERATION AND MISBRANDING OF FOODS, DRUGS, COSMETICS AND DEVICES.

Article 1. IN GENERAL

24:5-1. Sale, distribution or manufacture of adulterated or misbranded articles. 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.

24:5-2. Certain dealers excepted from operation of law, guarantee of seller. 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.

Regulation. (a) A guaranty or undertaking referred to in section 24:5-2 of the act shall be limited to a specific shipment or other delivery of an article, in which case it may be a part of or attached to the invoice or bill of sale covering such shipment or delivery.

(b) No representation or suggestion that an article is guaranteed under the act shall be made in labeling.

(c) The following form of guaranty or undertaking is suggested: (Name of person giving the guaranty or undertaking) hereby guarantees that no article listed herein is adulterated or misbranded within the meaning of the Food, Drug, and Cosmetic Laws of New Jersey; or is an article which may not, under the provisions of section 24:6A of the act, be introduced into commerce.

Signature and post-office address of person giving the guaranty or undertaking.)

24:5-3. Content of guaranty; liability of resident seller. Such guaranty to afford protection, shall contain the name and address of the person making the sale of such article to the dealer. In case the seller is a resident of this state, he shall be amenable to the prosecution, fines, and penalties which would attach to the dealer under any provision of this subtitle.

24:5-4. Guaranty by nonresident. If the guaranty is signed by a person who resides outside of the state, the state department shall report the facts in the case to the proper officer appointed for the enforcement of the federal legislation specified in section 24:5-2 of this title.

24:5-5. Extent of protection of dealer. No guarantee that any food drug, cosmetic or device is not adultered 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.

24:5-6. Article for foreign market. 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.

24:5-7. Sale of patent medicines not authorized. Nothing contained in this subtitle shall be construed as authorizing the sale, gift, furnishing or disposition of any article, substance, admixture or patent or proprietary remedy, the sale, gift, furnishing or disposition of which is prohibited, except upon prescription by any statute of this state.

Article 2. ADULTERATION.

24:5-8. General food adulterations. For the purposes of this subtitle food shall be deemed 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 regulations promulgated by the Department of Health 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 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 an animal which has not been inspected, and the meat of such animal passed as fit for food, (a) by an official federal inspector, or (b) by such officer or person as shall be qualified for such purpose in accordance with, and in such manner as shall be prescribed by regulations adopted by the state department, if such inspection is required by such regulations, 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 under the Federal Act.

24:5-9. Confectionery adulterations. 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 coloring or if a coal-tar color one from a batch which has been certified under the Federal Act, 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.

24:5-10. General drug or device adulterations. 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 under the Federal Act.

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 agency enforcing the Federal Act. Whenever a drug is recognized in both the United States Pharmacopoeia and the Homeopathic 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 homeopathic drug, in which case it shall be subject to the provisions of the Homeopathic Pharmacopoeia of the United States and not to those of the United States Pharmacopoeia.

Regulation. (a) The name by which a drug is designated shall be clearly distinguishing and differentiating from any name recognized in an official compendium unless such drug complies in identity with the identity prescribed in an official compendium under such recognized name.

(b) The term "drug defined in an official compendium" means a drug having the identity prescribed for a drug in an official compendium.

(c) A statement that a drug defined in an official compendium differs in strength, quality, or purity from the standard of strength, quality, or purity set forth for such drug in an official compendium shall show all the respects in which such drug so differs, and the extent of each such difference.

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.

24:5-11. Exceptions to drug adulterations. 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.

24:5-11.1. General cosmetic adulterations. 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.

Regulation. 1. The term "coal-tar hair dye" includes all articles containing any coal-tar color or intermediate which color or intermediate alters the color of the hair when such articles are applied to the hair under the conditions of use prescribed in the labeling thereof, or under such conditions of use as are customary or usual.

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 under the Federal Act.

24:5-12. Repealed. Laws of 1966, Chapter 74.

24:5-13. Use of wood or methyl alcohol prohibited; penalty. 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.

24:5-14. Meat and meat products. No person shall distribute or sell or have in his possession with intent to distribute or sell any meat or meat product to which any sodium sulphite, sodium bisulphite, or any drug, chemical, chemical compound or preservative, from which sulphur dioxide can be liberated, has been added thereto or mixed therewith.

24:5-15. Repealed: Laws of 1966, Chapter 74.

Article 3. MISBRANDING.

24:5-16. "Misbranded" defined. 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.

24:5-17. Food misbrandings. 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.

Regulation. (a) Among representations in the labeling of a food which render such food misbranded is a false or misleading representation with respect to another food or a drug, device, or cosmetic.

(b) The labeling of a food which contains two or more ingredients may be misleading by reason (among other reasons) of the designation of such food in such labeling by a name which includes or suggests the name of one or more but not all such ingredients even though the names of all such ingredients are stated elsewhere in the labeling.

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.

Regulation. (a) If a food is not manufactured by the person whose name appears on the label, the name shall be qualified by a phrase which reveals the connection such person has with such food, such as "Manufactured for and Packed by .....", "Distributed by .....", or other similar phrase which expresses the facts.

(b) The statement of the place of business shall include the street address, if any, of such place, unless such street address is shown in a current city directory or telephone directory.

(c) Where a person manufactures, packs, or distributes a food at a place other than his principal place of business, the label may state the principal place of business in lieu of the actual place where each package of such food was manufactured or packed or is to be distributed, if such statement is not misleading in any particular.

(d) The requirement that the label shall contain the name and place of business of the manufacturer, packer, or distributor shall not be considered to relieve any food from the requirement that its label shall not be misleading in any particular.

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.

Regulation. (a) A word, statement, or other information required by or under authority of the act to appear on the label may lack that prominence and conspicuousness required by reason (among other reasons) of—

(1) the failure of such word, statement, or information to appear on the part or panel of the label which is presented or displayed under customary conditions of purchase;

(2) the failure of such word, statement, or information to appear on two or or more parts or panels of the label, each of which has sufficient space therefor and each of which is so designed as to render it likely to be, under customary conditions of purchase, the part or panel displayed;

(3) the failure of the label to extend over the area of the container or package available for such extension, so as to provide sufficient label space for the prominent placing of such word, statement, or information;

(4) insufficiency of label space (for the prominent placing of such word, statement, or information) resulting from the use of label space for any word, statement, or design which is not required by or under authority of the Act to appear on the label;

(5) insufficiency of label space (for the prominent placing of such word, statement, or information) resulting from the use of label space to give materially greater conspicuousness to any other word, statement, or information, or to any design; or

(6) smalless or style of type in which such word, statement, or information appears, insufficient background contrast, obscuring designs or vignettes, or crowding with other written, printed, or graphic matter.

(b) No exemption depending on insufficiency of label space shall apply if such insufficiency is caused by—

(1) the use of label space for any word, statement, design, or device which is not required by or under authority of the Act to appear on the label;

(2) the use of label space to give greater conspicuousness to any word, statement, or other information than is required by the Act.

(3) the use of label space for any representation in a foreign language.

(c) (1) All words, statements, and other information required by or under authority of the Act to appear on the label or labeling shall appear thereon in the English language.

(2) If the label contains any representation in a foreign language, all words, statements, and other information required by or under authority of the Act to appear on the label shall appear thereon in the foreign language.

(3) If the labeling contains any representation in a foreign language, all words, statements, and other information required by or under authority of the Act to appear on the label or labeling shall appear on the labeling in the foreign language.

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 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, 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 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; provided, further, that the requirements of clause (2) of this paragraph shall not apply to any carbonated non-alcoholic drink the ingredients of which have been fully and correctly disclosed, to the extent prescribed by said clause (2) to the Department of Health in an affidavit.

Regulation. (a) The name of an ingredient (except a spice, flavoring, or coloring which is an ingredient of a food other than one sold as a spice, flavoring, or coloring), required to be borne on the label of a food, shall be a specific name and not a collective name. But if an ingredient (which itself contains two or more ingredients) conforms to a definition and standard of identity prescribed by the department of health of the state of New Jersey, such ingredient may be designated on the label of such food by the name specified in the

definition and standard, supplemented, in case such regulations require the naming of optional ingredients present in such ingredient, by a statement showing the optional ingredients which are present in such ingredient.

(b) No ingredient shall be designated on the label as a spice, flavoring, or coloring unless it is a spice, flavoring, or coloring, as the case may be, within the meaning of such term as commonly understood by consumers. The term "coloring" shall not include any bleaching substance.

(c) An ingredient which is both a spice and a coloring, or both a flavoring and a coloring, shall be designated as spice and coloring, or flavoring and coloring, as the case may be, unless such ingredient is designated by its specific name.

(d) A label may be misleading by reason (among other reasons) of—

(1) the order in which the names of ingredients appear thereon, or the relative prominence othewise given such names; or

(2) its failure to reveal the proportion of, or other fact with respect to, an ingredient, when such proportion or other fact is material in the light of the representation that such ingredient was used in fabricating the food.

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 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 Department of Health. 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.

Regulation. (a) (1) The term "artificial flavoring" means a flavoring containing any sapid or aromatic constituent, which constituent was manufactured by a process of synthesis or other similar artifice.

(2) The term "artificial coloring" means a coloring containing any dye or pigment, which dye or pigment was manufactured by a process of synthesis or other similar artifice, or a coloring which was manufactured by extracting a natural dye or natural pigment from a plant or other material in which such dye or pigment was naturally produced.

(3) The term "chemical preservative" means any chemical which, when added to food, tends to prevent or retard deterioration thereof; but does not include common salt, sugars, vinegars, spices or oils extracted from spices, or substances added to food by direct exposure thereof to wood smoke.

(b) A food which is subject to the requirements of section 24:5-17 k of the Act shall bear labeling, even though such food is not in package form.

(c) A statement of artificial flavoring, artificial coloring, or chemical preservative shall be placed on the food, or on its container or wrapper, or on any two or all of these, as may be necessary to render such statement likely to be read by the ordinary individual under customary conditions of purchase and use of such food.

24:5-18. Misbranded drugs or devices; exceptions. 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.

Regulation. (a) Among representations in the labeling of a drug or device which render such drug or device misbranded is a false or misleading representation with respect to another drug or device or a food or cosmetic.

(b) The labeling of a drug which contains two or more ingredients may be misleading by reason (among other reasons) of the designation of such drug in such labeling by a name which includes or suggests the name of one or more but not all such ingredients, even though the names of all such ingredients are stated elsewhere in the labeling.

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

Regulation. (a) If a drug or device is not manufactured by the person whose name appears on the label, the name shall be qualified by a phrase which reveals the connection such person has with such drug or device, such as "Manufactured for and Packed by .....," "Distributed by .....," or other similar phrase which expresses the facts.

(b) The statement of the place of business shall include the street address, if any, of such place, unless such street address is shown in a current city directory or telephone directory.

(c) Where a person manufactures, packs, or distributes a drug or device at a place other than his principal place of business, the label may state the principal place of business in lieu of the actual place where each package of such drug or device was manufactured or packed or is to be distributed, if such statement is not misleading in any particular.

(d) The requirement that the label shall contain the name and place of business of the manufacturer, packer, or distributor shall not be considered to relieve any drug or device from the requirement that its label shall not be misleading in any particular.

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.

Regulation. (a) A word, statement, or other information required by or under authority of the Act to appear on the label may lack that prominence and conspicuousness required by section 24:5-18 c of the Act by reason (among other reasons) of—

(1) the failure of such word, statement, or information to appear on the part or panel of the label which is presented or displayed under customary conditions of purchase;

(2) the failure of such word, statement, or information to appear on two or more parts or panels of the label, each of which has sufficient space therefor, and each of which is so designed as to render it likely to be, under customary conditions of purchase, the part or panel displayed;

(3) the failure of the label to extend over the area of the container or package available for such extension, so as to provide sufficient label space for the prominent placing of such word, statement, or information;

(4) insufficiency of label space (for the prominent placing of such word, statement, or information) resulting from the use of label space for any word, statement, or design which is not required by or under authority of the Act to appear on the label;

(5) insufficiency of label space (for the prominent placing of such word, statement, or information) resulting from the use of label space to give materially greater conspicuousness to any other word, statement, or information, or to any design; or

(6) smallness or style of type in which such word, statement, or information appears, insufficient background contrast, obscuring designs or vignettes, or crowding with other written, printed, or graphic matter.

(b) No exemption depending on insufficiency of label space, as prescribed in regulations promulgated under section 24:5-18 e of the Act, shall apply if such insufficiency is caused by—

(1) the use of label space for any word, statement, design, or device which is not required by or under authority of the Act to appear on the label;

(2) the use of label space to give greater conspicuousness to any word, statement, or other information than is required by section 24:5-18 c of the Act; or

(3) the use of label space for any representation in a foreign language.

(c) (1) All words, statements, and other information required by or under authority of the Act to appear on the label or labeling shall appear thereon in the English language.

(2) If the label contains any representation in a foreign language, all words, statements, and other information required by or under authority of the Act to appear on the label shall appear thereon in the foreign language.

(3) If the labeling contains any representation in a foreign language, all words, statements, and other information required by or under authority of the Act to appear on the label or labeling shall appear on the labeling in the foreign language.

d. If it is for use by man and contains any quantity of the narcotic or hypnotic substance alpha-eucaine, barbituric acid, beta-eucanine, 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."

Regulation. (a) (1) The name of a substance or derivative required by or under authority of section 24:5-18 (d) of the Act to be borne on the label of a drug shall be the name by which such substance is designated in such section 24:5-18 (d), or such derivative is designated in regulations promulgated thereunder.

(2) A statement on the label of a drug of the name of a constituent, which constituent is a chemical derivative of a substance named in section 24:5-18 (d) of the Act, shall show the substance from which such constituent is derived and that such constituent is a derivative thereof.

(b) (1) If the drug is in tablet, capsule, ampul, or other unit form, the statement of the quantity or proportion of such substance or derivative contained therein shall express the weight or measure of such substance or derivative in each such unit. If the drug is not in such unit form, the statement shall express the weight or measure of such substance or derivative in a specified unit of weight or measure of the drug. Such statement shall be in terms which are informative to the ordinary consumer and user of the drug.

(2) The statement of the percentage of such substance or derivative contained in a drug shall express the percentage by weight; except that, if both the substance or derivative and the drug are liquid, the statement may express the percentage by volume at 68° Fahrenheit (20° Centigrade), but in such case the statement shall be so qualified as to show definitely that the percentage is expressed by volume.

(c) The names, and quantities or proportions of all such substances and derivatives, and the statement "Warning—May be habit forming," shall immediately follow (without intervening written, printed, or graphic matter) the name by which such drug is titled in the part or panel of the label thereof which is presented or displayed under customary conditions of purchase.

(d) A drug shall not be considered to be misbranded under section 24:5-18 (d) of the Act by reason of failure of its label to bear the statement "Warning—May be habit forming," if such drug is not suitable for internal use and is distributed and sold exclusively for such external use as involves no possibility of habit formation.

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, either, chloroform, acetanilid, acetophenetidin, amidopyrine, antipyrine, atropine, hyoscine, hyoscyamine, arsenic, digitalis, digitalis glucosides, mercury, ouabain, strophanthin, strychnine, thyroid, or any derviative 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 established by regulations promulgated by the state department.

Regulation. (a) (1) The name of an ingredient, substance, derivative, or preparation required by section 24:5-18 e (2) of the Act to be borne on the label of a drug shall be the name thereof which is listed in such section 24:5-18 e (2) of the Act, or, if not so listed, shall be a specific name and not a collective name. But if an ingredient is an article the name of which is recognized in an official compendium and such article complies with the specifications set forth therefor in such compendium, such ingredient may be designated on the label of such drug by the common or usual name under which such specifications are so set forth.

(2) Where an ingredient contains a substance the quantity or proportion of which is required by section 24:5-18 e (2) of the Act to appear on the label, and such ingredient is not a derivative or preparation of such substance as defined in paragraph (b) (1) of this regulation, the label shall bear, in conjunction with the name of the ingredient, a statement of the quantity or proportion of such substance in such drug.

(3) An abbreviation or chemical formula shall not be considered to be a common or usual name. The name "acetophenetidin" shall be considsidered to be the same as the name "acetophenetidin", "aminopyrine" the same as "amidopyrine." The name "alcohol", without qualification, means ethyl alcohol.

(b) (1) A derivative or preparation of a substance named in section 24:5-18 e (2) of the Act is an article which is derived or prepared from such substance by any method, including actual or theoretical chemical action.

(2) A statement on the label of a drug of the name of an ingredient thereof, which ingredient is a derivative or preparation of a substance named in section 24:5-18 e (2) of the Act, shall show the substance from which such ingredient is derived or prepared and that such ingredient is a derivative or preparation thereof.

(c) (1) If the drug is in tablet, capsule, ampul, or other unit form, the statement of the quantity or proportion of a substance, derivative, or preparation contained therein shall express the weight or measure of such substance, derivative or preparation in each such unit. If the drug is not in such unit form the statement shall express the

weight or measure of such substance, derivative, or preparation in a specified unit of weight or measure of the drug, or the percentage of such substance, derivative, or preparation in such drug. Such statement shall be in terms which are informative to the ordinary consumer and user of the drug.

(2) A statement of the percentage of alcohol shall express the percentage of absolute alcohol at 60° Fahrenheit (15.56° Centigrade). A statement of the percentage of a substance, derivative, or preparation other than alcohol shall express the percentage by weight; except that, if both the substances, derivative, or preparation and the drug containing it are liquid, the statement may express the percentage by volume at 68° Fahrenheit (20° Centigrade), but in such case the statement shall be so qualified as to show definitely that the percentage is expressed by volume.

(d) In case a statement of the quantity or proportion of a derivative or preparation in a drug is not as informative, to consumers or users of such drug, of the activity or consequences of use thereof as a statement of the quantity of proportion of the substance from which such derivative or preparation is derived or prepared, the quantity or proportion of such substance shall also be stated on the label of such drug.

(e) A label of a drug may be misleading by reason (among other reasons) of:

(1) the order in which the names of ingredients, substances, derivatives. or preparations appear thereon, or the relative prominence otherwise given such names; or

(2) its failure to reveal the proportion of, or other fact with respect to, an ingredient, substance, derivative, or preparation, when such proportion or other fact is material in the light of the representation that such ingredient, substance, derivative, or preparation is a constituent of such drug.

(f) A drug shall be exempt from the requirements of clause (2) of section 24:5-18 e of the Act with respect to the alkaloids atropine, hyoscine or hyoscyamine contained in such drug, if such alkaloid is contained therein as a constituent of belladonna, hyoscyamus, acopola, stramonium, or other plant material, or any preparation thereof, which was used as an ingredient of such drug, and no practical and accurate method of analysis exists for the quantitative determination of each such alkaloid in such ingredient. But such exemption shall be on the condition that the label of such drug shall state the quantity or proportion of total alkaloids contained therein as constituents of such ingredient.

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.

Regulation. (a) Directions for use may be inadequate by reason (among other reasons) of omission, in whole or in part, or incorrect specifications of—

(1) directions for use in all conditions for which such drug or device is prescribed, recommended, or suggested in its labeling, or in its advertising disseminated or sponsored by or on behalf of its manufacturer or packer, or in such other conditions, if any there be, for which such drug or device is commonly and effectively used;

(2) quantity of dose (including quantities for persons of different ages and different physical conditions);

(3) frequency of administration or application;

(4) duration of administration or application;

(5) time of administration or application (in relation to time of meals, time of onset of symptoms, or other time factor);

(6) route or method of administration or application; or

(7) preparation for use (shaking, dilution, adjustment of temperature, or other manipulation or process).

(b) A shipment or other delivery of a drug or device shall be exempt from compliance with the requirements of clause (1) of section 24:5-18 f of the Act—

(1) with respect to directions for common uses, adequate directions for which are known by the ordinary individual;

(2) if the label of such drug or device bears the statement "Caution: To be used only by or on the prescription of a ....." (the blank to be filled in by the "Physician", "Dentist" or "Veterinarian", or any combination of such words), and all representations or suggestions contained in the labeling thereof with respect to the conditions for which such drug or device is to be used appear only in such medical terms as are not likely to be understood by the ordinary individual, and if such shipment or delivery is made for use exclusively by, or on the prescription of, physicians, dentists, or veterinarians licensed by law to administer or apply such drug or device; but such exemption shall expire when such shipment or delivery, or any part thereof, is offered or sold or otherwise disposed of for any use other than by or on the prescription of such a physician, dentist, or veterinarian, except such use as renders the article not a drug or device within the meaning of section 24:1-1 e and g of the Act; or

(3) if the label of such drug or device bears the statement "For manufacturing use only", and the labeling thereof contains no representation or suggestion with respect to the effect of such drug or device, and of such shipment or delivery is made for use exclusively in the manufacture of another drug or device; but such exemption shall expire when such shipment or delivery, or any part thereof, is offered or sold or otherwise disposed of for any use other than in such manufacture, except such use as renders the article not a drug or device within the meaning of section 24:1-1 e and g of the Act.

(c) The expiration of an exemption under paragraph (b) of this regulation shall not be considered to render invalid the exemption existing up to the time of expiration. The causing by any person of such exemption so to expire shall be considered to be an act of misbranding for which such person shall be liable.

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 Pharmacopoeeia and the Homeopathic 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 homepathic drug, in which case it shall be subject to the provisions of the Homeopathic Pharmacopoeia of the United States and not to those of the United States Pharmacopoeia.

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.

24:5-18.1. Cosmetic misbrandings. 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.

Regulation. (a) Among representations in the labeling of a cosmetic which render such cosmetic misbranded is a false or misleading representation with respect to another cosmetic or a food, drug, or device.

(b) The labeling of a cosmetic which contains two or more ingredients may be misleading by reason (among other reasons) of the designation of such cosmetic in such labeling by a name which includes or suggests the name of one or more but not all such ingredients, even though the names of all such ingredients are stated elsewhere in the labeling.

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

Regulation. (a) If a cosmetic is not manufactured by the person whose name appears on the label, the name shall be qualified by a phrase which reveals the connection such person has with such cosmetic, such as "Manufactured for and Packed by .....," "Distributed by .....," or other similar phrase which expresses the facts.

(b) The statement of the place of business shall include the street address, if any, of such place, unless such street address is shown in a current city directory or telephone directory.

(c) Where a person manufactures, packs, or distributes a cosmetic at a place other than his principal place of business, the label may state the principal place of business in lieu of the actual place where each package of such cosmetic was manufactured or packed or is to be distributed, if such statement is not misleading in any particular.

(d) The requirement that the label shall contain the name and place of business of the manufacturer, packer, or distributor shall not be considered to relieve any cosmetic from the requirement that its label shall not be misleading in any particular.

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.

Regulation. (a) A word, statement, or other information required by or under authority of the Act to appear on the label may lack that prominence and

conspicuousness required by section 24:5-18.1 c of the Act by reason (among other reasons) of—

(1) the failure of such word, statement, or information to appear on the part or panel of the label which is presented or displayed under customary conditions of purchase;

(2) the failure of such word, statement, or information to appear on two or more parts or panels of the label, each of which has sufficient space therefor, and each of which is so designed as to render it likely to be, under customary conditions of purchase, the part or panel displayed;

(3) the failure of the label to extend over the area of the container or package available for such extension, so as to provide sufficient label space for the prominent placing of such word, statement, or information;

(4) insufficiency of label space (for the prominent placing of such word, statement, or information) resulting from the use of label space for any word, statement, design, or device which is not required by or under authority of the Act to appear on the label;

(5) insufficiency of label space (for the prominent placing of such word, statement, or information) resulting from the use of label space to give materially greater conspicuousness to any other word, statement, or information, or to any design or device; or

(6) smallness or style of type in which such word, statement, or information appears, insufficient background contrast, obscuring designs or vignettes, or crowding with other written, printed or graphic matter.

(b) (1) All words, statements, and other information required by or under authority of the Act to appear on the label or labeling shall appear thereon in the English language.

(2) If the label contains any representation in a foreign language, all words, statements, and other information required by or under authority of the Act to appear on the label shall appear thereon in the foreign language.

(3) If the labeling contains any representation in a foreign language, all words, statements, and other information required by or under authority of the Act to appear on the label or labeling shall appear on the labeling in the foreign language.

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

24:5-18.2. Foods, drugs, devices and cosmetics which are to be repacked. 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.

Regulation. (a) Except as provided by paragraphs (b) and (c) of this regulation, a shipment or other delivery of a food, drug, cosmetic, or device which is, in accordance with the practice of the trade, to be processed, labeled, or repacked in substantial quantity at an establishment other than that where originally processed or packed, shall be exempt, during the time of introduction into and movement in intrastate commerce and the time of holding in such establishment, from compliance with the labeling and packaging requirements of section 24:5-17 c, e, g, h, i, j and k and of section 24:5-10 b and of section 24:5-18 b, d, e, f and g and of section 24:5-11.1 a and of section 24:5-18.1 b of the Act if—

(1) The person who introduced such shipment or delivery into intrastate commerce is the operator of the establishment where such food, drug, cosmetic or device is to be processed, labeled, or repacked; or

(2) in case such person is not such operator, such shipment or delivery is made to such establishment under a written agreement, signed by and containing the post-office addresses of such person and such operator, and containing such specifications for the processing, labeling, or repacking, as the case may be of such food, drug, cosmetic or device in such establishment as will insure, if such specifications are followed, that such food, drug, cosmetic or device will not be adulterated or misbranded within the meaning of the Act upon completion of such processing, labeling, or repacking. Such person and such operator shall keep a copy of such agreement until all such shipment or delivery has been removed from such establishment, and shall make such copies available for inspection at any reasonble hour to any officer or employee of the department who requests them.

(b) An exemption of a shipment or other delivery of a food, drug, cosmetic, or device under clause (1) of paragraph (a) of this regulation shall, at the beginning of the act of removing such shipment or delivery, or any part thereof, from such establishment, become void ab initio if the food, drug, cosmetic or device comprising such shipment, delivery, or part is adulterated or misbranded within the meaning of the Act when so removed.

(c) An exemption of a shipment or other delivery of a food, drug, cosmetic or device under clause (2) of paragraph (a) of this regulation shall become void ab initio with respect to the person who introduced such shipment or delivery into intrastate commerce upon refusal by such person to make available for inspection a copy of the agreement, as required by such clause.

(d) An exemption of a shipment or other delivery of a food, drug, cosmetic or device under clause (2) of paragraph (2) of this regulation shall expire—

(1) at the beginning of the act of removing such shipment or delivery, or any part thereof, from such establishment if the food, drug, cosmetic or device comprising such shipment, delivery, or part is adulterated or misbranded within the meaning of the Act when so removed; or

(2) upon refusal by the operator of the establishment where such food, drug, cosmetic or device is to be processed, labeled, or repacked, to make available for inspection a copy of the agreement, as required by such clause.

24:5-19. Drugs or medicines personally dispensed or on written prescriptions by physicians, etc. 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.

24:5-20. Repealed. Laws of 1966, Chapter 74.

24:5-21. Horse flesh; labeling; penalties for violations. No person other than a common carrier shall transport nor shall any person, sell, or offer or expose for sale, or in anywise aid in the selling or offering or exposing for sale, any horse flesh unless every carcass, piece and parcel thereof shall have conspicuously attached thereto a

label or tag not less than three inches wide and four inches long, on which shall be printed or stamped, in letters not less than one inch in height the word "horse flesh."

Any person who shall violate the provisions of this section shall be liable to the following penalties:

a. For each first offense, a penalty of five hundred dollars ($500.00),

b. For each second and subsequent offense, a penalty of one thousand dollars ($1,000.00), which penalties shall be recovered and enforced pursuant to chapter seventeen of this title.

24:5-22. Defacement or removal of label. No person shall erase, cancel, obliterate, deface, cover, remove or alter any brand, tag, label or other marking required by any provision of this subtitle to be attached or affixed to any package or container.

Chapter 6. STANDARDS OF PURITY, QUALITY AND STRENGTH.

24:6-1. Establishment of standards. 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 under the Federal Act, the state department of health may adopt the definition or standard so established and published.

If such definition or standard shall be changed at any time by the agency administering the Federal Act, after the adoption of the definition or standard, it shall not continue in effect in this state after such change has become operative.

24:6-2. Publication; time of taking effect. Such definition or standard shall be filed with 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 filing of the definition or standard and shall take effect when so published.

24:6-3. Sale or manufacture of nonstandard articles prohibited. 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 section 24:6-1 and 24:6-2 of this title.

24:6-4. Repealed. Laws of 1966, Chapter 74.

24:6-5. Repealed. Laws of 1966, Chapter 74.

24:6-6. Repealed. Laws of 1966, Chapter 74.

24:6-7. Repealed. Laws of 1966, Chapter 74.

Chapter 6A. NEW DRUGS.

24:6A-1. New drugs; introduction into intrastate commerce; application; effective date of application; refusal of application; application of chapter. 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 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.

Regulation. An application which is on its face incomplete in that it does not contain all the matter required by clauses (1), (2), (3), (4), and (6) of section 24:6-A (b) of the Act shall not be accepted for filing; the department of health of the state of New Jersey shall notify the applicant of such non-acceptance and shall specify the clauses in respect of which such application is on its face incomplete. Otherwise the date on which an application is received by the department shall be considered to be the date on which such application is filed, and the department of health of the state of New Jersey shall notify the applicant of such date. If the applicant withdraws his application, such application shall be considered as not having been filed.

c. The application provided for in subsection b shall become effective on the sixtieth day after the filing therof 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.

Regulation. If the department of health determines, before the date prescribed by section 24:6-A c of the Act for an application to become effective, that it has no cause to issue an order under section 24:6-A d of the Act refusing to permit such application to become effective, the department of health shall so notify the applicant in writing and such application shall become effective on the date of the notification.

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.

Chapter 6B. DRUGS, MANUFACTURERS AND WHOLESALERS

24:6B-1. Registration statement; filing with department. No person shall hereafter engage or continue to engage in a drug manufacturing business or a wholesale drug business in this State without first filing a completed registration statement with the department.

24:6B-2.Persons required to sign and verify statement; form and contents. The registration statement shall be signed and verified by the individuals specified in subsection (c) hereof, shall be made on forms prescribed and furnished by the commissioner and shall state such information necessary and proper to the enforcement of this act as the commissioner may require, including:

a. The name under which the business is conducted.

b. The address of each location in New Jersey at which the business is to be conducted. If a wholesale drug business is not to be

conducted from a location within the State, the statement shall give the name and address of an agent resident in this State on whom process against the registrant may be served.

c. If the registrant is a proprietorship, the name and address of the proprietor; if a partnership, the names and addresses of all partners; if a corporation, the date and place of incorporation, the names and addresses of the president and secretary thereof and the name and address of the designated registered agent in this State; or if any other type of business association, the names and addresses of the principals of such association.

d. The names and addresses of those individuals having actual administrative responsibility, which in the case of a proprietorship shall be the managing proprietor; partnership, the managing partners; corporation, the officers and directors; or if any other type of association, those having similar administrative responsibilities.

e. If the business is to be conducted at more than 1 location in this State, the name and address of the individual in charge of each such location.

f. A description of the business engaged in and the drug products manufactured for sale or wholesale.

g. The name and address of the individual or individuals on whom orders of the commissioner may be served.

24:6B-3. Time for filing. A registration statement shall be filed prior to February 1 in each calendar year following the calendar year of original registration.

24:6B-4. Fee. A fee shall accompany each registration statement. It shall be $100.00 if the business has less than 2 locations in this State, and $250.00 if the business has 2 or more locations in this State; except that where the gross total annual business in drugs of a registrant shall not exceed 3% of the gross total annual volume of the business of the registrant, as certified by a certified public accountant, the fee shall be $25.00 for each location in this State. L.1961, c. 52, p.—, para. 4, and amendment, L.1962, c. 110, p.—. The amendment became effective on July 16, 1962.

24:6B-5. Change of address; notice; fee. If any location of a registered business is to be changed, the registrant shall give the department written notice prior to the change of the address of such new location and the name and address of the individual to be in charge thereof. A fee of $10.00 shall accompany such notification.

24:6B-6. Cleanliness of premises. Every room in the premises or place where drugs are manufactured, packaged or stored shall be kept clean and sanitary and shall be properly lighted, drained and ventilated. The walls and floors of such rooms shall be constructed of materials which can be properly cleaned and maintained. The operations carried on therein shall be conducted in a clean and sanitary manner so that the purity of the drugs therein manufactured, packaged or stored shall not be impaired.

24:6B-7. Cleanliness of equipment and machinery. Equipment and machinery used in the manufacture of drugs and any vehicles used for the transportation and delivery of such drugs shall be kept in a clean and sanitary condition.

24:6B-8. Washroom and toilet facilities. Adequate washroom and toilet facilities shall be provided and maintained in the premise or place where drugs are manufactured, packaged or stored and such facilities shall be kept in a clean and sanitary condition.

24:6B-9. Adulteration or misbranding of drugs; examination of records. Whenever an officer or employee of the department finds, or has probable cause to believe, that any drug is adulterated or misbranded, he shall have the right to examine and copy any records listing the ingredients used in the manufacture of such drug and the source of such ingredients and any records concerning the storage or shipment of such drug to determine whether the provisions of this act or of subtitle I of Title 24 of the Revised Statutes relating to adulteration or misbranding are being complied with.

24:6B-10. Order to correct violation. If a registrant shall violate, directly or indirectly through his officers and employees, any of the provisions of this act, or any other provisions of subtitle 1 of Title 24 of the Revised Statutes, the commissioner may order the correction of the violation within such reasonable period of time as the commissioner may prescribe. Such an order shall be in writing, shall state the violation to be corrected, the period of time within which such violation shall be corrected and the individual or individuals who have actual administrative responsibility who shall be responsible for having such correction made. The order shall be delivered in person or by certified mail to an individual designated to receive service of the commissioner's orders.

If the commissioner's order is not complied with within the period specified therein, or within any extension thereof, the commissioner may order the registrant to stop engaging in such business or the part affected by the order until the order is complied with. If the registrant shall continue such business or part thereof after the commissioner has ordered the registrant to stop, any individual designated responsible in the commissioner's order for correcting the violation shall be a disorderly person.

Any registrant ordered by the commissioner to stop engaging in business or any part thereof may appeal from such order to the Superior Court. Pending a hearing and determination upon the appeal, the court may stay execution of all or part of the commissioner's order.

24:6B-11. Penalties. a. Any person who does not comply with an order of the commissioner within the time specified shall be liable for the first offense for a penalty, to be established by the commissioner, of not less than $100.00 nor more than $1,000.00, and for the second and each succeeding offense for a penalty of not less than $500.00 nor more than $5,000.00. The penalties herein provided shall be enforced by the department as plaintiff in a

summary proceeding in accordance with the penalty enforcement law (N. J. S. 2A:57-1 et seq.).

b. Any person, who engages or continues to engage in the manufacturing or wholesaling of drugs without having registered with the department as required by this act is guilty of a misdemeanor.

24:6B-12. Definitions. For the purposes of this registration act, unless otherwise required by the context:

a. "Commissioner" means Commissioner of the State Department of Health or his designated representative.

b. "Department" means the State Department of Health.

c. "Drugs" means "drugs" and "devices" as defined in section 1, chapter 1, part 24, New Jersey Revised Statutes.

d. "Person" means a natural person, partnership, corporation or any other business association.

e. "Registrant" means the person in whose name a drug manufacturing business or wholesale drug business is registered.

f. "Drug manufacturing business" means the business of creating, making or producing drugs by compounding, growing or other process. This definition shall apply to persons engaged in the drug manufacturing business who do not maintain a manufacturing location in this State but do operate distribution depots or warehouses of such business in this State. This definition shall not apply to licensed pharmacies or to licensed professional individuals such as, but not limited to, pharmacists, physicians, dentists, or veterinarians when engaged in the lawful pursuit of their professions.

g. "Wholesale drug business" means the business of supplying drugs to persons other than the ultimate consumer. This definition shall not apply to licensed pharmacies or to licensed professional individuals such as, but not limited to pharmacists, physicians, dentists or veterinarians when engaged in the lawful pursuit of their professions, and shall not apply to a registered drug manufacturing business.

24:6B-13. Appropriation. There is hereby appropriated to the department so much of the revenue, not in excess of $25,000.00, derived from the registration fees as shall be required to administer this act during the fiscal year ending June 30, 1962.

Chapter 17. VIOLATIONS, PENALTIES; RECOVERY.

24:17-1. Penalties. Any person who shall violate any provision of this subtitle, or any rule or regulation of the state department made pursuant thereto, or who shall refuse to comply with any lawful order or direction of the department, shall be liable to the following penalties, unless otherwise specifically provided:

a. For each first offense a penalty of fifty dollars;

b. For each second offense a penalty of one hundred dollars;

c. For each third and every subsequent offense a penalty of hundred dollars.

24:17-2. Different places or days as separate violations. The pro tion, preparation, manufacture, distribution, sale, offering or posing for sale or having in possession with intent to distribu sell of any food, drug, cosmetic or device in different places o same day, or in the same place on different days, in violation o provision of this subtitle, or of any rule or regulation of state department made pursuant thereto, or of any lawful ord direction of the department given thereunder, shall each be dee to be a separate violation.

24:17-3. Payment of penalty equivalent to conviction. Payment penalty for any alleged violation of this subtitle, either befo after the institution of proceedings for the collection thereof, be deemed equivalent to a conviction of the violation for w such penalty was claimed.

24:17-4. Action to restrain violation. The state department e before or after the institution of a proceeding for the colle of a penalty imposed by this subtitle for a violation of any prov thereof, may institute an action in the superior court in name of the state at the relation of the department to restrain violation and for such other or further relief as the court deem proper.

The institution of such action, or any of the proceedings the shall not relieve any party to such proceedings from any pe prescribed by this subtitle for such violation.

24:17-5. Recovery of penalties; plaintiff. Except as otherwise sp ically provided, any and all penalties prescribed by any provisi this subtitle shall be sued for and recovered in a civil action by in the name of the state department of health, or by and i name of the local board of health, as the case may be, as plaint

Jurisdiction of proceedings to collect such penalties is veste the County Court, the county district court and the municipal in any county or municipality where the defendant may be a hended or where he may reside. Process shall be either a sum or warrant and shall be prosecuted in a summary manner purs to the Penalty Enforcement Law (N.J.S. 2A-58-1 et seq.).

24:17-6. Repealed. Laws of 1953, Chapter 24.

24:17-7. Repealed. Laws of 1953, Chapter 24.

24:17-8. Disposition of penalties collected. Any penalty recover an action brought under the provisions of this subtitle shall be to the plaintiff therein. When the plaintiff is the state de ment of health, the penalty shall be paid by the department the treasury of the state. When the plaintiff is a local boa health, the penalty shall be paid by the local board into the trea of the municipality within which the local board has jurisdictio