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New Jersey State
Department of Health
John Fitch Plaza, P.O. Box 1540
Trenton, New Jersey 08625

LAWS AND REGULATIONS GOVERNING THE SANITATION, HANDLING, SHIPPING AND PRODUCTION OF COSMETICS WITH APPLICABLE EXCERPTS FROM FOOD, DRUG AND COSMETIC LAWS AND REGULATIONS

Note:

References below are to Title, Chapter, and Section. Regulations are italicized.

New Jersey Statutes Annotated (N.J.S.A.) references begin with Title 24.

New Jersey Administrative Code (N.J.A.C.) references begin with Title 8.

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

a. "State department," "department of health" and "department" means 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 the law.

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.

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

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.

m. If an article is alleged to be misbranded because the labeling is misleading, then in determining whether such labeling is misleading there shall be taken into account (among other things) not only representations made or

suggested by statement, word, design, or any combination thereof, but also 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.

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 of any such articles in the conduct of any food, drug or cosmetic establishment.

8:64-3.1 Definition of soap

"Soap", as quoted in N.J.S.A. 24:1-1 h (2), shall apply only to products that meet all of the following conditions:

1. More than 50 per cent of the nonvolatile matter in the product consists of a salt resulting from an alkali-fatty acid chemical reaction commonly known as saponification and detergent properties of the product are due to the alkali-fatty acid salt.

2. The product is labeled, sold and represented only as soap.

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 department 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 department 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 department 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; penalties. 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. Right of entry; opening packages; inspection.

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 the 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 tendered 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 prosecutor, notwithstanding the fact that the article may have been purchased by some person other than a representative of the department, if such article shall immediately after such sale be delivered by the purchaser to the department.

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

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.

24:4-5. 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.

24:4-8. 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.

24:4-12. Adulterated or misbranded foods, drugs, etc.; marking; detaining. Whenever an agent of the State department or of a local board of health finds, or has probable cause to believe, that any food, drug, device, or cosmetic is adulterated or so misbranded as to be dangerous or fraudulent, within the meaning of this subtitle, he shall affix to such article a tag or other appropriate marking, giving notice that such article is, or is suspected of being, adulterated or misbranded and has been detained or embargoed, and warning all persons not to remove or dispose of such article by sale or otherwise until permission for removal or disposal is given by such agent or the court. It shall be unlawful for any person to remove or dispose of such detained or embargoed article by sale or otherwise without such permission.

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

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 pure food and drug law; guaranty 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.

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 adulterated or misbranded within the meaning of the Federal legislation specified in section 24:5-2 of this title shall be effective to exempt any dealer from prosecution under this subtitle unless the requirements of the Federal legislation and of this subtitle covering the adulteration and misbranding of the guaranteed article are identical.

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.

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.

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 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.

8:21—1.6 Coal-tar hair dye

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.

8:21—3.12 Rulings on dangerous cosmetics

(a) *The toxic effect of paraphenylenediamine is well known. A number of persons have suffered severe injury, and in some cases blindness has resulted from the application of this dye to the eyelashes and eyebrows. There is no doubt that preparations containing this dye are in violation of the Food, Drug and Cosmetic Act. The Department of Health of the State of New Jersey has obtained very definite evidence of injury from this dye. Based upon a serious consideration of the injurious effects of paraphenylenediamine, eyelash and eyebrow dyes containing paraphenylenediamine in any amount will be considered adulterated under N.J.S.A. 24:5—11.1(a) and appropriate action taken. It has also been noted that substances such as oils, argyrol, magnesium carbonate, paper shields, and the like are customarily included in packages of eyelash and eyebrow dye preparations to be used to prevent the introduction of the dye into the eyes. It is the opinion of the Department that the use of these precautionary measures cannot guarantee protection of the eyes against such dangerous product as paraphenylenediamine. This notice should not be interpreted as indicating that other dyes used for eyelash and eyebrow dyeing are to be accepted as meeting the requirements of N.J.S.A. 24:5—11.1(a).*

(b) *The toxic effect of paratoluylenediamine is well known. There is no doubt that preparations containing this dye are in violation of the Food, Drug and Cosmetic Act. Based upon a serious consideration of the injurious effects of paratoluylenediamine, eyelash and eyebrow dyes containing paratoluylenediamine in any amount will be considered adulterated under N.J.S.A. 24:5—11.1(a) and appropriate action taken. It has also been noted that substances such as oils, argyrol, magnesium carbonate, paper shields, and the like are customarily included in packages of eyelash and eyebrow dye preparations to be used to prevent the introduction of the dye into the eyes. It is the opinion of the Department that the use of these precautionary measures cannot guarantee protection of the eyes against such dangerous product as paratoluylenediamine. This notice should not be interpreted as indicating that other dyes used for eyelash and eyebrow dyeing are to be accepted as meeting the requirements of N.J.S.A. 24:5—11.1(a).*

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.

24:5-18.1. Cosmetic misbrandings. For purposes of this subtitle a cosmetic shall also be deemed to be misbranded:

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

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

8:21—1.18 Labeling of cosmetics; misrepresentations

(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.*

8:21-1.19 Name and place of business of manufacturer, packer, or distributor

(a) *The label of a cosmetic in package form shall specify conspicuously the name and place of business of the manufacturer, packer or distributor.*

(b) *The requirement for declaration of the name of the manufacturer, packer or distributor shall be deemed to be satisfied in the case of a corporation only by the actual corporate name, which may be preceded or followed by the name of the particular division of the corporation. Abbreviations for "Company", "Incorporated", and so forth, may be used and "The" may be omitted. In the case of an individual, partnership or association, the name under which the business is conducted shall be used.*

(c) *Where the cosmetic is not manufactured by the person whose name appears on the label the name shall be qualified by a phrase that reveals the connection such person has with such cosmetic; such as, "Manufactured for _____", "Distributed by _____", or any other wording that expresses the facts.*

(d) *The statement of the place of business shall include the street address, city, State, and Zip code; however, the street address may be omitted if it is shown in a current city or telephone directory. The requirement for inclusion of the Zip code shall apply only to consumer commodity labels developed or revised after the effective date of this Section. In the case of nonconsumer packages, the Zip code shall appear either on the label or the labeling (including the invoice).*

(e) *If 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 such cosmetic was manufactured or packed or is to be distributed, unless such statement would be misleading.*

8:21—1.20 Lack of prominence and conspicuousness

(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 N.J.S.A. 24:5—18.1(c) 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 of 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) *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.*

(c) *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.*

(d) *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.*

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

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

24:5-18.2. Exemptions from labeling and packaging requirements. 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.

8:21—1.21 Shipments of food, drugs, cosmetics, labeling requirements

(a) *Except as provided by subsections (b) and (c) of this Section, 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*

N.J.S.A. 24:5-17(c), (e), (g), (h), (i), (j) and (k), 24:5-10(b), 24:5-18(b), (d), (e), (f), and (g), 24:5-11.1(a), and of 24:5-18.1(b) 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 reasonable 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 subsection (a) 1 of this Section 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 subsection (a) 2 of this Section 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 subsection (a) 2 of this Section 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.*

8:21-1.24 Labeling of feminine deodorant sprays

(a) *As used in this regulation, the following terms shall have the following meanings.*

"Feminine deodorant spray" means any spray deodorant product whose labeling represents or suggests that the product is for use in the female genital area or for use all over the body.

"Label" means "label" as defined in N.J.S.A. 24:1-1j.

"Labeling" means "labeling" as defined in N.J.S.A. 24:1-1k.

"Person" shall mean an individual or firm, partnership, company, corporation, trustee, association or any public or private entity.

(b) *Rules concerning the wording on the label follow:*

1. The label of a feminine deodorant spray shall bear the following statement: "Caution—For external use only. Spray at least eight inches from skin. Do not apply to broken, irritated, or itching skin. Persistent, unusual odor or discharge may indicate condition for which a physician should be consulted. Discontinue use immediately if rash, irritation, or discomfort develops."

2. The sentence "spray at least eight inches from skin" need not be included in the cautionary statement for products whose expelled contents do not contain a liquidified gas propellant such as a halocarbon or hydrocarbon propellant.

(c) Use of the word "hygiene" or "hygenic" or a similar word or words renders any such product misbranded under N.J.S.A. 24:5-18.1a. The use of any word or words which represent or suggest that such products have a medical usefulness renders such products misbranded under N.J.S.A. 24:5-18.1a and illegal new drugs marketed in violation of N.J.S.A. 24:6A-1a.

(d) Rules concerning the effective dates of these rules follow:

1. All feminine deodorant sprays labeled after November 30, 1976, and all such products introduced into intrastate commerce after November 30, 1977, shall comply with this regulation.

2. No person shall distribute or sell, or have in his possession with intent to distribute or sell, any feminine deodorant sprays, after November 30, 1978, unless all labeling is in compliance with this rule.

8:21-1.25 Cosmetic product warning statements

(a) As used in these regulations, the following words and terms shall have the following meanings, unless the context clearly indicates otherwise.

"Commissioner" means the New Jersey State Commissioner of Health.

"Cosmetic" means "cosmetic" as defined in N.J.S.A. 24:1-1h.

"Department" means the New Jersey State Department of Health.

"Label" means "label" as defined in N.J.S.A. 24:1-1j.

"Labeling" means "labeling" as defined in N.J.S.A. 24:1-1k.

(b) Rules concerning the establishment of warning statements are:

1. The label of a cosmetic product shall bear a warning statement whenever necessary or appropriate to prevent a health hazard that may be associated with the product.

2. The commissioner either on his own initiative or on behalf of an interested person who has submitted a petition, may publish a proposal to establish or amend subsection (b) of this Section, a regulation prescribing a warning for a cosmetic. Any such petition shall include an adequate factual basis to support the petition, and will be published for comment if it contains reasonable grounds for the proposed regulation.

(c) Rules on the conspicuousness of warning statements are:

1. A warning statement shall appear on the label prominently and conspicuously as compared to other words, statements, designs or devices and in bold type on contrasting background to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use, but in no case may the letters and/or numbers be less than 1/16 inch in height, unless an exemption pursuant to paragraph 2 of this subsection.

2. If the label of any cosmetic package is too small to accommodate the information as required by this Section, the commissioner may establish by regulation an acceptable alternative method.

(d) Rules on the labeling of cosmetic products for which adequate substantiation of safety has not been obtained are:

1. Each ingredient used in a cosmetic product and each finished cosmetic product shall be adequately substantiated for safety prior to marketing. Any such ingredient or product whose safety is not adequately substantiated prior to marketing is misbranded unless it contains the following conspicuous statement on the principal display panel: "Warning: The safety of this product has not been determined."

2. An ingredient or product having a history of use in or as a cosmetic may at any time have its safety brought into question by new information that in itself is not conclusive. The warning required by paragraph 1 of this subsection is not required for such an ingredient or product if:

i. The safety of the ingredient or product had been adequately substantiated prior to development of the new information;

ii. The new information does not demonstrate a hazard to human health; and

iii. Adequate studies are being conducted to determine expeditiously the safety of the ingredient or product.

3. Paragraph 2 of this subsection does not constitute an exemption to the adulteration provisions of Title 24, N.J.S.A., or to any other requirement in Title 24, N.J.S.A., or this regulation.

(e) Rules on cosmetics in self-pressurized containers are:

1. The label of a cosmetic packaged in a self-pressurized container and intended to be expelled from the package under pressure shall bear the following warning: "Warning: Avoid spraying in eyes. Contents under pressure. Do not puncture or incinerate. Do not store at temperature above 120 degrees Fahrenheit. Keep out of reach of children."

2. In the case of products intended for use by children, the phrase "except under adult supervision" may be added at the end of the last sentence in the warning required by paragraph 1 of this subsection.

3. In case of products packaged in glass containers, the word "break" may be substituted for the word "puncture" in the warning required by paragraph 1 of this subsection.

4. The words "avoid spraying in eyes" may be deleted from the warning required by paragraph 1 of this subsection in the case of a product not expelled as a spray.

5. In addition to the warning required by paragraph 1 of this subsection, the label of a cosmetic packaged in a self-pressurized container in which the propellant consists of in whole or in part of a halocarbon or a hydrocarbon shall bear the following warning: "Warning: Use only as directed. Intentional misuse by deliberately concentrating and inhaling the contents can be harmful or fatal."

6. The warning required by paragraph 5 of this subsection is not required for the following products:

i. Products expelled in the form of a foam or cream, which contain less than ten per cent propellant in the container;

ii. Products in a container with a physical barrier that prevents escape of the propellant at the time of use;

iii. Products of a net quantity of contents of less than two ounces that are designed to release a measured amount of product with each valve actuation;

iv. *Products of a net quantity of contents of less than one-half ounce.*

(f) *All products labeled after November 30, 1976, and all products introduced into intrastate commerce after November 30, 1977, shall comply with these regulations. No person shall distribute or sell, or have in his possession with intent to distribute or sell any cosmetic product after November 30, 1978, unless all labeling is in compliance with this regulation.*

8:21-1.27 Cosmetic package principal display panel

(a) *The term "principal display panel" as it applies to cosmetics in package form and as used in this part, means the part of a label that is most likely to be displayed, presented, shown, or examined under customary conditions of display for retail sale. The principal display panel shall be large enough to accommodate all the mandatory label information required to be placed thereon by this part with clarity and conspicuousness and without obscuring designs, vignettes, or crowding. Where packages bear alternate principal display panels, information required to be placed on the principal display panel shall be duplicated on each principal display panel. For the purpose of obtaining uniform type size in declaring the quantity of contents of all packages of substantially the same size, the term "area of the principal display panel" means the area of the side or surface that bears the principal display panel, which area shall be:*

1. *In the case of a rectangular package where one entire side properly can be considered to be the principal display panel side, the product of the height times the width of that side;*

2. *In the case of a cylindrical or nearly cylindrical container, 40 per cent of the product of the height of the container times the circumference; and*

3. *In the case of any other shape of container, 40 per cent of the total surface of the container: Provided, however, that where such container presents an obvious "principal display panel" such as the top of a triangular or circular package, the area shall consist of the entire top surface.*

(b) *In determining the area of the principal display panel, exclude tops, bottoms, flanges at the tops and bottoms of cans, and shoulders and necks of bottles or jars. In the case of cylindrical or nearly cylindrical containers, information required by this part to appear on the principal display panel shall appear within that 40 percent of the circumference which is most likely to be displayed, presented, shown or examined under customary conditions of display for retail sale.*

8:21-1.28 Cosmetic product identity labeling

(a) *The principal display panel of a cosmetic in package form shall bear as one of its principal features a statement of the identity of the commodity.*

(b) *Such statement of identity shall be in terms of:*

1. *The common or usual name of the cosmetic; or*

2. *An appropriately descriptive name or, when the nature of the cosmetic is obvious, a fanciful name understood by the public to identify such cosmetic; or*

3. *An appropriate illustration or vignette representing the intended cosmetic use.*

(c) *The statement of identity shall be presented in bold type on the principal display panel, shall be in a size reasonably related to the most prominent printed matter on such panel, and shall be in lines generally parallel to the base on which the package rests as it is designed to be displayed.*

Chapter 15. SANITATION IN FOOD [AND COSMETIC] ESTABLISHMENTS

24:15-1. "Food establishment" defined. As used in this chapter, "food establishment" includes any place used in the production, preparation, manufacture, packing, storage, transportation or handling of food intended for sale or distribution.

"Drug establishment" defined. A "drug establishment" includes any place used in the production, preparation, manufacture, packing, storage, transportation and handling of drugs intended for sale or distribution.

"Cosmetic establishment" defined. A "cosmetic establishment" includes any place used in the production, preparation, manufacture, packing, storage, transportation and handling of cosmetics intended for sale or distribution "but not including pharmacies licensed by the New Jersey Board of Pharmacy."

24:15-2. Cleanliness, lighting, plumbing and ventilation. Every room in the building of a food, drug or cosmetic establishment shall be properly lighted, drained, plumbed and ventilated and the operations carried on therein shall be conducted in such a manner that the purity, quality and wholesomeness of the food, drug or cosmetic therein produced, manufactured, prepared, packed, stored, sold or distributed shall not be impaired.

24:15-3. Construction of walls, interior woodwork and floors. The side walls of every room in a food, drug or cosmetic establishment wherein food or drugs are produced, manufactured, packaged, stored or handled, shall be made of or coated with a suitable washable surface.

Every room of a food, drug or cosmetic establishment in which food, drugs or cosmetics are exposed shall have a tight floor made of cement or of tile laid in cement, brick, hard wood or other suitable material which can be properly cleaned.

24:15-4. Cleanliness of walls, floors, furniture and machinery.

(a) The floors, side walls, ceilings, furniture, receptacles, implements and machinery of every food, drug or cosmetic establishment and all vehicles used in the transportation of food products, drugs or cosmetics shall be kept in a clean and sanitary condition. No person shall transport food, drugs or cosmetics in such manner that the purity, quality or wholesomeness thereof shall be impaired.

(b) No polishes or substances containing hydrocyanic acid or salts thereof shall be used for the cleaning or polishing of articles or utensils used for the service or preparation of food or foodstuffs in any food establishment or articles used in the processing, packing or storage of drugs or cosmetics in a drug or cosmetic establishment.

(c) An adequate supply of running water under pressure shall be easily accessible to all rooms in which food, drugs or cosmetics are prepared, manufactured, packed, stored or handled and shall be provided in all rooms in which utensils and equipment are washed.

(d) All multi-use utensils, equipment, tools and receptacles in a food, drug or cosmetic establishment, used in connection with the processing, manufacture, packing, storage or handling of food, drugs or cosmetics intended for distribution or sale, shall be thoroughly cleaned and sanitized immediately after each usage.

24:15-5. Protection of food from contamination; removal of refuse. All food, drugs or cosmetics intended for distribution or sale in the process of production, manufacture, preparation, packing, storing or transportation shall be securely protected from flies, vermin, dust, dirt and so far as possible, by the use of all reasonable means, from all other foreign or injurious contamination. The refuse, dirt and waste products subject to decomposition of fermentation shall be removed daily.

24:15-6. Clothing of employees to be kept clean. The clothing worn by all persons while engaged in work in any food, drug or cosmetic establishment shall be in a clean condition at all times.

24:15-7. Toilet facilities for and personal cleanliness of employees. All employees of a food, drug or cosmetic establishment who handle the material from which food, drugs or cosmetics intended for distribution or sale are prepared, or the finished product shall, before beginning work and after visiting the toilet, wash their hands and arms thoroughly with clean water and soap. Every person owning or operating a food, drug or cosmetic establishment shall provide adequate facilities for such washing and shall take all reasonable means to compel such employees to perform such washing.

Adequate, conveniently located toilet facilities shall be provided for employees on the premises of a food, drug or cosmetic establishment.

All toilet rooms shall be separate from the rooms where any processes incident to the production, manufacture, preparation, packing, storage, sale or distribution of food, drugs or cosmetics are carried on and shall be kept in a clean and sanitary condition.

24:15-8. Expectorating. No person shall expectorate in any room in a food, drug or cosmetic establishment used for the production, manufacture, preparation, packing, storage, sale or distribution of food, drugs or cosmetics.

24:15-9. Sleeping in rooms of food, drug or cosmetic establishment. No person shall be allowed to live or sleep in any room where food, drugs or cosmetics intended for sale or distribution are produced, manufactured, packed, stored, distributed or sold.

24:15-10. Persons affected with communicable disease. No employer shall require, permit or allow any person to work, nor shall any person work in any food, drug or cosmetic establishment who is ill or infected with a communicable disease as defined in section 26:4-1 of the Revised Statutes.

24:15-11. Order to abate violation in lieu of prosecution. Whenever a person shall violate any provision of this chapter the state department or local board may, in its discretion, instead of prosecuting such person for the recovery of any prescribed penalty, cause an order to be served on such person commanding him to discontinue or abate the violation or to make such improvement as may be necessary to abate the violation with a reasonable time to be fixed in the order by the state department or local board. The order shall be in writing and the person receiving it shall have the right to be heard either in person or by attorney by the department or board issuing the order.

24:15-12. Furnishing and posting abstract of law. Every person conducting a food, drug or cosmetic establishment shall upon request be furnished by the state department with an abstract of this chapter. The person receiving such abstract shall keep it posted in plain view in such place so that it can be easily read by the employees entering and leaving the establishment.

24:15-13. Every establishment falling within the scope of this chapter shall be licensed by the Commissioner of Health with a fee to be charged therefor, except that a license pursuant to this chapter need not be secured by any such establishment, the activities of which are subject to licensure pursuant to any other provision of this Title or to inspection and licensure by a local department of health, or the facilities and warehouses or growers and associations or organizations of growers of raw agricultural commodities and all raw agricultural commodity farm area sales and shipping points where such raw agricultural commodities are not subjected to processing other than washing, cleaning, cooling, waxing, grading, sizing and packaging.

(Chapter 158, P.L. 1971)

(Amended by Chapter 12, P.L. 1973)

24:15-14. Where no other fee is provided by law or regulation, the commissioner may in accordance with a fee schedule adopted by him as a rule or regulation establish and charge reasonable fees for any service performed in the licensing and inspection of any premises coming within the provisions of this chapter. The fees charged as provided for by this section shall be no more than \$250.00 based on criteria set forth in the rule or regulation.

(Chapter 158, P.L. 1971)

Regulations Governing the Licensing of Food and Cosmetic Manufacturing and Wholesale Establishments.

(Effective 3/30/73)

8:21-9.1. General Definitions.

As used in these regulations the following terms shall have the following meanings:

Regulation 1 (a) and (b) Repealed. N.J. Register 3/8/73

(c) "*Retail establishment*" means any place engaged in the production, preparation, processing, manufacture, packing, storage, or handling of food or cosmetics for sale or distribution directly to the consumer.

(d) "*Person*" shall mean an individual or firm, partnership, company, corporation, trustee, association, or any public or private entity.

8:21-9.2. Scope of Regulations.

Every establishment falling within the definitions of N.J.S.A. 24:15-1 must obtain a license from the department except as hereinafter exempted. A separate license shall be obtained for each food and cosmetic establishment operated within the state.

8:21-9.3. Exemptions.

The following establishments shall be exempt from the licensing provisions of Chapter 158, P.L. 1971, but shall comply with all other provisions of Chapter 15, Title 24, N.J.S.A., and all pertinent rules and regulations enforced by the department.

(a) *Retail food and cosmetic establishments.*

(b) *Establishments subject to licensure under other provisions of Title 24, N.J.S.A.*

(c) Establishments inspected and licensed by a local health department.

(d) Repealed.

(e) Growers of raw agricultural commodities delivering their produce to food processing establishments.

8:21-9.4. License Requirement.

(a) Every person owning or operating a food or cosmetic establishment within the State shall apply annually for a license to operate such establishment on forms provided by the department. The application shall have attached thereto an affidavit of the person or some member or officer of the association, partnership, or corporation applying therefor, stating that the facts set forth therein are true and correct.

8:21-9.5. License Fees.

(a) The department shall collect from each applicant for a license under the provisions of these regulations an annual fee in the following amounts:

(1) For each wholesale food or cosmetic establishment having an annual gross business of less than \$25,000, twenty-five dollars (\$25.00); for each wholesale food or cosmetic establishment with a gross annual business in excess of \$25,000 but not in excess of \$50,000, forty dollars (\$40.00); for each wholesale food or cosmetic establishment with a gross annual business in excess of \$50,000 but not in excess of \$100,000, fifty dollars (\$50.00); for each wholesale food or cosmetic establishment with a gross annual business in excess of \$100,000 but not in excess of \$500,000, seventy-five dollars (\$75.00); for each wholesale food or cosmetic establishment with a gross annual business in excess of \$500,000 but not in excess of \$1,000,000, one hundred fifty dollars (\$150.00); for each wholesale food or cosmetic establishment with a gross annual business in excess of \$1,000,000, two hundred fifty dollars (\$250.00). (This fee schedule became effective May 1, 1976).

8:21-9.6.

(a) Upon approval of the application for a license and of the sanitary condition of the food or cosmetic establishment and upon payment of the required license fee, the department shall issue to each applicant a license which shall expire one year from the last day of the month in which the original application is received and yearly thereafter.

(b) Such license shall not be transferable with respect to persons or locations.

8:21-9.7.

Upon evidence duly ascertained by the department or furnished to the department by any local board of health, that the licensee licensed under the provisions of this act is violating any of the rules, regulations or statutes as herein before provided, the department shall upon hearing and proof of allegation, revoke the license of such licensee.

No such license shall be renewed or restored until the department is satisfied that all the provisions of this act and pertinent rules and regulations are compiled with.

The department, when in its judgment the protection of public health warrants, may, before hearing suspend such license pending the hearing, in which event it shall be unlawful for the licensee whose license is thus suspended to engage in the business for which the license was granted during such period of suspension.

Chapter 17. VIOLATIONS, PENALTIES; RECOVERY.

24:17-1. Penalties.

(a) 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:

(1) For each first offense a penalty of \$50.00;

(2) For each second offense a penalty of \$100.00;

(3) For each third and every subsequent offense a penalty of \$200.00.

(b) Any person who shall remove or dispose of any depressant or stimulant drug as defined pursuant to law in violation of section 24:4-12 of this Title is guilty of a misdemeanor.

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

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

