

**CHAPTER 21
FOOD AND DRUGS**

Authority

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R.2000 d.427, effective September 22, 2000.
See: 32 N.J.R. 2386(a), 32 N.J.R. 3831(a).

Executive Order No. 66(1978) Expiration Date

Chapter 21, Food and Drugs, expires on September 22, 2005.

Chapter Historical Note

Pursuant to Executive Order No. 66(1978), Chapter 21, Food and Drugs, was readopted as R.1990 d.563, effective October 23, 1990, and Subchapter 1, Food, Drug, Cosmetic, and Device Labeling, and Subchapter 5, Manufacturing, Storage, Distribution, and Handling of Bottled Water, were adopted as new rules, and Subchapter 12, Manufacturing, Storage, Distribution, and Handling of Nonalcoholic Beverages and Bottled Water, was repealed by R.1990 d.563, effective November 19, 1990. See: 22 N.J.R. 2465(a), 22 N.J.R. 3559(a).

Subchapter 3A, Registration of Wholesale Distributors of Prescription Drugs, was adopted as R.1992 d.354, effective September 8, 1992. See: 24 N.J.R. 2410(b), 24 N.J.R. 3100(a).

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SUBCHAPTER 1. FOOD, DRUG, COSMETIC, AND DEVICE LABELING

8:21-1.1 Definitions

The following words and terms shall have the following meanings, when used in this subchapter:

“Consumer” means an individual who secures a cosmetic for his or her self application and has not received any special training or experience in its use.

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

“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” means an individual or firm, partnership, company, corporation, trustee, association, or any public or private entity.

“Professional” means an individual qualified through special training and experience and licensed by the State to perform beauty culture services.

“Professional use only” means for use only by a professional, or words of similar import.

“Retail” means sale or distribution directly to the consumer.

“Retail establishment” means any place used in the production, preparation, processing, manufacture, packing, storage, or handling of cosmetics for sale or distribution directly to the consumer.

“Wholesale establishment” means any place used in the production, preparation, processing, manufacture, packing, storage, or handling of cosmetics for sale or distribution to a person other than the consumer.

8:21-1.2 General labeling requirements

The general labeling requirements of 21 CFR 1.1, 1.3, 1.4, 1.20, 1.21, 1.23, 1.24 are incorporated herein by reference.

8:21-1.3 Food labeling

The food labeling requirements of 21 CFR 101, 102, 104, and 105 are incorporated herein by reference.

8:21-1.4 Drug labeling

The drug labeling requirements of 21 CFR 201 are incorporated herein by reference.

8:21-1.5 Cosmetic labeling

The cosmetic labeling requirements of 21 CFR 701 are incorporated herein by reference.

8:21-1.6 Labeling, sale, and distribution of cosmetics for professional use only

(a) For the purposes of this section, a cosmetic labeled for professional use only which is offered for sale or distribution to a consumer shall be deemed to be misbranded within the meaning of N.J.S.A. 24:5-18.1 at the time such cosmetic is offered for such sale or distribution.

(b) No person shall distribute or sell, or have in his or her possession with intent to distribute or sell, any cosmetic labeled for professional use only except to professional barbers, professional beauticians, licensed beauty salons, licensed schools of beauty culture, other beauty culture professions, or licensed wholesale establishments.

(c) Any person who offers a cosmetic labeled for professional use only for sale or distribution shall make reasonable inquiries regarding a person’s professional status or affiliation as necessary to determine their qualifications to purchase such products so that the retail sale or distribution of such cosmetic may be prevented. This requirement shall not apply to the sale or distribution of cosmetics labeled for professional use only between wholesale establishments.

(d) Cosmetics labeled for professional use only when displayed for sale in a combined retail-wholesale establishment shall be kept separate and apart from retail merchandise. Where such cosmetics are accessible to the general public, posters measuring at least 8½ by 11 inches with lettering measuring at least one-half inch in height shall be conspicuously displayed in all such display areas and contain the following statement, “NOTICE—FOR SALE ONLY TO LICENSED PROFESSIONALS.”

(e) A cosmetic labeled for professional use only shall be exempt from all the provisions of this section if it can be shown through factual and scientific evidence in the possession of the person offering such product for sale or distribution prior to such offering that:

1. Such cosmetic does not require professional skill or knowledge for its safe or effective use;
2. Such cosmetic does contain necessary warnings, cautions, and directions for its safe and effective use in such terms as to render it likely to be read and understood by the consumer under customary conditions of purchase and use; and
3. Such cosmetic is labeled in compliance with all State and Federal requirements for retail sale.

(f) A cosmetic labeled for professional use only which has a retail counterpart identical in name, chemical composition, packaging (size, etc.) and labeling (directions, cautions, etc.) shall be exempt from all provisions of these rules.

8:21-1.7 Cosmetic product warning statements

The requirements that apply to feminine deodorant sprays, cosmetics in self-pressurized containers, and coal tar hair dyes posing a risk of cancer of 21 CFR 740, Cosmetic Product Warning Statements are incorporated herein by reference.

8:21-1.8 Definition of soap

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

1. More than 50 percent 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; and

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

8:21-1.9 Device labeling

The device labeling requirements of 21 CFR 801 are incorporated herein by reference.

SUBCHAPTER 2. FOODS

8:21-2.1 Frozen food locker plants

(a) The refrigeration system for a locker plant or branch locker storage plant shall be equipped with adequate and reliable automatic controls for the maintenance of uniform temperatures as required in the various rooms and shall be of adequate capacity to provide these temperatures under peak load conditions in the normal operation of the plant with extreme conditions of outside temperature.

(b) Each locker plant shall have thermometers so placed as to be readily accessible to public view in the various low temperature rooms.

(c) All food products offered for storage shall be placed in clean containers or wrappings suitable for freezing and proper storage, and clearly marked with the date of storage. Persons or firms operating locker or locker storage plants shall not place in a locker storage plant or allow to be received for processing, chilling, freezing, or storage in a locker or locker storage plant, any food articles in a state of decomposition or putrefaction, or in any other condition which renders them unfit for food, or in any condition which may cause deterioration in other food products.

(d) When articles of food, held in a locker plant, are removed from the packages in which they were contained and placed in other packages, the date of original entry into the locker plant of such articles shall be placed upon the containers into which they have been transferred; and if articles of food which have been placed in a locker or locker storage plant on different dates are packed in the same container, the date of storage of the article longest stored shall be placed upon the container to which such articles have been transferred.

(e) Any article of food, if intended for use other than human consumption shall be plainly and legibly labeled or marked with the words "Not for Human Consumption".

(f) All rooms in which food products are stored shall be provided with smooth, water-tight floors which can be readily cleansed. Floors must be kept in a clean condition at all times.

(g) The sidewalls and ceilings of all rooms shall be of smooth material, free from crevices and must be kept clean at all times.

(h) Waste materials shall not be permitted to accumulate in or around buildings in an insanitary manner. Waste materials shall be placed in clean metal containers.

(i) Adequate toilet facilities shall be provided for employees. All toilets shall be kept clean at all times.

(j) Adequate lavatory facilities shall be provided. All persons engaged in handling foods shall be required to wash hands before handling food after visiting toilet.

(k) No employer shall require, permit or allow any person to work in a cold storage warehouse, who is afflicted with any communicable disease.

(l) The license granted by the Department of Health to operate locker plant shall be displayed in the plant.

Recodified from N.J.A.C. 8:21-2.14 by R.2000 d.427, effective October 16, 2000.
See: 32 N.J.R. 2386(a), 32 N.J.R. 3831(a).

8:21-2.2 Sale of enriched white flour and unenriched white flour

(a) All flour, excepting that sold under a certificate as provided in N.J.S.A. 24:11A-4, intended for sale for human consumption in New Jersey shall be held in containers which are marked in a plain and conspicuous manner with the words, "Enriched Flour" and with the name and address of the manufacturer, packer or distributor.

(b) All flour sold to distributors, bakers or other processors under the proviso contained in N.J.S.A. 24:11A-4, which allows the sale of unenriched flour under certain conditions, shall be held in containers which are marked in a plain and conspicuous manner with the words, "Unenriched Flour", and the name and address of the manufacturer, packer or distributor.

(c) All persons purchasing flour which has not been enriched and which is to be resold or used as outlined in the proviso contained in N.J.S.A. 24:11A-4 shall furnish a certificate to the seller on the form adopted by the Board of Health of the State of New Jersey, and this certificate shall be kept on file by the seller for a period of two years. The purchaser shall keep a copy of each certificate for a period of two years.

Amended by R.1990 d.563, effective November 19, 1990.

See: 22 N.J.R. 2465(a), 22 N.J.R. 3559(a).

Citation added.

Recodified from N.J.A.C. 8:21-3.19 by R.2000 d.427, effective October 16, 2000.

See: 32 N.J.R. 2386(a), 32 N.J.R. 3831(a).

8:21-3.5 Compressed air used in self contained underwater breathing apparatus (SCUBA)

Components of compressed air shall not exceed the following limits:

CARBON MONOXIDE	10 parts/million (PPM) 0.001%
CARBON DIOXIDE	1000 PPM 0.1%
OIL	0.02 mg/liter
WATER	Saturation
ODOR	Free from objectionable odors
OTHER	Contaminants deleterious to health shall not be present

Recodified from N.J.A.C. 8:21-3.20 by R.2000 d.427, effective October 16, 2000.

See: 32 N.J.R. 2386(a), 32 N.J.R. 3831(a).

8:21-3.6 SCUBA recommendations

The following recommendations are primarily directed to purveyors of SCUBA air to protect public health.

(a) Compressed air containers. No compressed air container used for self-contained underwater breathing apparatus should be filled or refilled unless it shows evidence of a recent I.C.C. hydrostatic test.

(b) Preparation of compressed air. Uncontaminated air may be compressed by means of suitable equipment and the compressed air should not exceed the limits set forth in the regulations. The following sampling, testing and test procedures may be used to determine the quantitative composition of the compressed air.

1. Carbon monoxide. Determination of carbon monoxide may be made by using:

- i. Mine Safety Appliance Detector Co., Carbon Monoxide Tester No. Ds-47133;
- ii. U.S. Safety Services Detector, model 300 "Saf-Co-Meter";
- iii. Kitagawa Precision Gas Detection Unico Model No. 400, with the cartridge No. 106A; or its equivalents;
- iv. Any other device or method acceptable to the Department of Health.

2. Carbon dioxide. Determination of carbon dioxide may be made by using:

- i. Kitagawa Precision Gas Detection Unico Model No. 400;
- ii. Davis Emergency Co., Gas Detector Kit;

iii. Any other device or method acceptable to the New Jersey State Department of Health.

3. Oil. Determination of oil may be made by passing 100 liters of air at atmospheric pressures and room temperature through a Number 41 Whatman Filter and measuring the increase in weight over the original weight of the filter. Air contamination with 0.02 milligrams of oil per liter of air will add two milligrams to the weight of the filter. Other forms of particulate matter may be similarly assayed. Assays may be made by this or by any other device or method acceptable to the Department of Health.

4. Water. Compressed air may be saturated with water vapor but should not contain water in separated form. This may be determined by using:

i. Dew point equipment as manufactured by Mine Safety Appliance Co., Foxboro Co., or American Instrument Co.;

ii. Any other device or method acceptable to the New Jersey State Department of Health.

5. Odor. Compressed air may be tested for odor by cracking the valve and smelling the escaping air. Filled cylinders having any objectionable odors should be rejected.

(c) Equipment. Equipment for compressing air should be of suitable design, size, construction and location to facilitate maintenance and operation for its intended purpose in a manner that is orderly and clean. Such equipment should be:

1. So constructed that any surface that comes in contact with the air be nonreactive, nonadditive, or nonabsorptive to the finished product;

2. So constructed that any substances required for its operation, such as lubricants or coolants, may be employed without hazard or without becoming additive to the finished compressed air;

3. So constructed to facilitate maintenance to assure reliability of the finished product within the limits as set forth in section 20 of this subchapter.

Recodified from N.J.A.C. 8:21-3.21 by R.2000 d.427, effective October 16, 2000.

See: 32 N.J.R. 2386(a), 32 N.J.R. 3831(a).

8:21-3.7 Animal repellants

(a) The list of animal repellants which are non-injurious to canines or other animals and which immobilize only temporarily and produce only temporary physical discomfort covered by the exemptions pursuant to the provisions of N.J.S.A. 2C:39-6(h) shall include, but not be limited to, the following trade products:

1. Dog Chaser;
2. Guardian;

3. Halt;
4. Sentinel;
5. Stinger;
6. Stop Dog.

(b) The following list of active and inactive ingredients can be used in animal repellants that are non-injurious to canines or other animals and immobilize only temporarily and produce only temporary physical discomfort covered by the exemptions pursuant to the provisions of N.J.S.A. 2C:39-6(h).

1. Active ingredient:
 - i. Oleoresin Capsicum.
2. Inactive ingredient:
 - i. Mineral Oil;
 - ii. Nitrogen Propellant.

(c) The Department shall add to or delete from the above list those active and inactive ingredients and products to be consistent with the provisions of the Act.

R.1982 d.123, effective April 19, 1982.
 See: 14 N.J.R. 79(a), 14 N.J.R. 389(a).
 Recodified from N.J.A.C. 8:21-3.23 by R.2000 d.427, effective October 16, 2000.
 See: 32 N.J.R. 2386(a), 32 N.J.R. 3831(a).

8:21-3.8 List of ingredients for human self-defense sprays

(a) The following list of active and inactive ingredients can be used in devices which contain and release chemical substances which cause temporary physical discomfort covered by the exemptions pursuant to the provisions of N.J.S.A. 2C:39-6(i):

1. Active ingredients:
 - i. Chloroacetophenone
 - ii. Ortho-chlorobenzalmalonitrile
2. Inactive ingredients:
 - i. 1,1,1-trichloroethane
 - ii. Trichlorotrifluoroethane
 - iii. Kerosene
 - iv. Mineral oil

R.1982 d.451, effective December 20, 1982.
 See: 14 N.J.R. 1029(a); 14 N.J.R. 1456(a).
 Recodified from N.J.A.C. 8:21-3.24 by R.2000 d.427, effective October 16, 2000.
 See: 32 N.J.R. 2386(a), 32 N.J.R. 3831(a).
 Former N.J.A.C. 8:21-3.8, Warning statements for drug labels, repealed.

8:21-3.9 Permit for nitrous oxide

(a) Every person or firm desiring to use or distribute nitrous oxide, except a duly licensed physician, dentist, veterinarian, nurse, hospital, sanitarium, or other medical institution, or a resident physician or intern of a hospital, sanitarium, or medical institution, and those buying or selling nitrous oxide for use in food preparation equipment or registered pursuant to N.J.S.A. 24:6B-1 shall complete a permit application provided by the Department of Health and Senior Services and provide the following information:

1. The name of the person or firm requesting the permit;
2. The address of the person or firm;
3. The telephone number of person or firm;
4. The location at which the nitrous oxide is to be used;
5. The signature of person in charge of the location where the nitrous oxide is to be used;
6. The purpose for such use;
7. The name and address of the distributor from whom the nitrous oxide is to be obtained; and
8. Any other information as may be requested by the Department of Health and Senior Services.

(b) Upon approval of the application, the Department of Health and Senior Services shall issue a permit that shall expire two years from the date the permit is issued. A copy of the permit issued to the user shall be maintained by the distributor of the nitrous oxide for a period of two years.

(c) Those selling nitrous oxide for food preparation purposes shall require that the person purchasing the nitrous oxide show proof that they are at least 19 years of age before the sale is made.

(d) All sellers of nitrous oxide shall keep a record of all sales in conformance with N.J.S.A. 24:6G-3 to include the name and address of the buyer, permit number, date of sale, and amount of nitrous oxide. The permit number is not applicable for purchase of nitrous oxide for food preparation purposes.

(e) Every permit issued by the Department of Health and Senior Services for the use or sale of nitrous oxide shall be valid only for the location listed in that permit and shall not be transferable.

(f) Every person or firm distributing or using nitrous oxide for either manufacturing or research purposes shall allow inspection of such permit by a public officer or employee engaged in the enforcement of this Act.

(g) A permit shall be issued for a period of two years.

R.1983 d.41, effective February 22, 1983.

See: 14 N.J.R. 1190(a), 15 N.J.R. 244(b).
 Recodified from N.J.A.C. 8:21-3.25 and amended by R.2000 d.427,
 effective October 16, 2000.
 See: 32 N.J.R. 2386(a), 32 N.J.R. 3831(a).
 Rewrote the section. Former N.J.A.C. 8:21-3.9, Restrictions on
 sales of dangerous drugs, repealed.

8:21-3.10 (Reserved)

Repealed by R.2000 d.427, effective October 16, 2000.
 See: 32 N.J.R. 2386(a), 32 N.J.R. 3831(a).
 Section was "Other dangerous drug regulations".

8:21-3.11 (Reserved)

Repealed by R.2000 d.427, effective October 16, 2000.
 See: 32 N.J.R. 2386(a), 32 N.J.R. 3831(a).
 Section was "Rulings on dangerous drugs".

8:21-3.12 (Reserved)

Recodified to N.J.A.C. 8:21-3.2 by R.2000 d.427, effective October 16,
 2000.
 See: 32 N.J.R. 2386(a), 32 N.J.R. 3831(a).

8:21-3.13 (Reserved)

Recodified to N.J.A.C. 8:21-3.3 by R.2000 d.427, effective October 16,
 2000.
 See: 32 N.J.R. 2386(a), 32 N.J.R. 3831(a).

8:21-3.14 through 8:21-3.18 (Reserved)**8:21-3.19 (Reserved)**

Recodified to N.J.A.C. 8:21-3.4 by R.2000 d.427, effective October 16,
 2000.
 See: 32 N.J.R. 2386(a), 32 N.J.R. 3831(a).

8:21-3.20 (Reserved)

Recodified to N.J.A.C. 8:21-3.5 by R.2000 d.427, effective October 16,
 2000.
 See: 32 N.J.R. 2386(a), 32 N.J.R. 3831(a).

8:21-3.21 (Reserved)

Recodified to N.J.A.C. 8:21-3.6 by R.2000 d.427, effective October 16,
 2000.
 See: 32 N.J.R. 2386(a), 32 N.J.R. 3831(a).

8:21-3.22 (Reserved)**8:21-3.23 (Reserved)**

Recodified to N.J.A.C. 8:21-3.7 by R.2000 d.427, effective October 16,
 2000.
 See: 32 N.J.R. 2386(a), 32 N.J.R. 3831(a).

8:21-3.24 (Reserved)

Recodified to N.J.A.C. 8:21-3.8 by R.2000 d.427, effective October 16,
 2000.
 See: 32 N.J.R. 2386(a), 32 N.J.R. 3831(a).

8:21-3.25 (Reserved)

Recodified to N.J.A.C. 8:21-3.9 by R.2000 d.427, effective October 16,
 2000.

See: 32 N.J.R. 2386(a), 32 N.J.R. 3831(a).

SUBCHAPTER 3A. REGISTRATION OF WHOLESALE DISTRIBUTORS OF PRESCRIPTION DRUGS

8:21-3A.1 Scope

This subchapter sets forth standards for the registration and operation of any person, partnership, corporation or business firm engaging in the wholesale distribution of human prescription drugs.

8:21-3A.2 Purpose

The purpose of this subchapter is to implement the requirements of the Federal Prescription Drug Marketing Act of 1987, 21 U.S.C. 351, 353, 371 and 374, and 21 C.F.R. 205, and for the benefit of the health and safety of the ultimate consumers of prescription drugs.

8:21-3A.3 Definitions

The words and terms used in this subchapter shall have the following meanings, unless the context clearly indicates otherwise:

"Blood" means whole blood collected from a single donor and processed either for transfusion or further manufacturing.

"Blood component" means that part of blood separated by physical or mechanical means.

"Department" means the New Jersey Department of Health.

"Drug sample" means a unit of a prescription drug that is not intended to be sold and is intended to promote the sale of the drug.

"Manufacturer" means anyone who is engaged in the manufacturing of drugs or devices, as defined in N.J.S.A. 24:6B-12, or engaged in the manufacturing, preparing, propagating, compounding, processing, packaging, repackaging, or labeling of a prescription drug.

"Non-prescription" or "Non-legend" or "O.T.C." drugs mean drugs directly available to the consumer over the counter, without a physician's prescription.

"Prescription drug" means any human drug required by Federal law or regulation to be dispensed only by a prescription, including dosage forms and active ingredients subject to section 503(b) of the Federal Food, Drug and Cosmetic Act.

“Wholesale distribution” means the distribution of drugs or devices to persons other than a consumer or patient, but does not include:

1. Intracompany sales;
2. The purchase or other acquisition by a hospital or other health care entity that is a member of a group purchasing organization, of a drug or device for its own use from the group purchasing organization or from other hospitals or health care entities that are members of such organizations;
3. The sale, purchase, or trade of a drug or device or an offer to sell, purchase, or trade a drug or device by a charitable organization described in section 501(c)(3) of the Internal Revenue Code of 1954 to a nonprofit affiliate of the organization to the extent otherwise permitted by law;
4. The sale, purchase, or trade of a drug or device or an offer to sell, purchase, or trade a drug or device among hospitals or other health care entities that are under common control; for purposes of this definition “common control” means the power to direct or cause the direction of the management and policies of a person or an organization, whether by ownership of stock, voting rights, by contract, or otherwise;

5. The sale, purchase or trade of a drug or device or an offer to sell, purchase, or trade a drug or device for emergency medical reasons; for purposes of this definition, “emergency medical reasons” includes transfers of prescription drugs by a retail pharmacy to another retail pharmacy to alleviate a temporary shortage;

6. The sale, purchase, or trade of a drug, an offer to sell, purchase, or trade a drug, or the dispensing of a drug pursuant to a prescription;

7. The distribution of drug or device samples by manufacturers’ representatives or distributors’ representatives; or

8. The sale, purchase, or trade of blood and blood components intended for transfusion.

“Wholesale distributor” means anyone engaged in wholesale distribution of prescription drugs including, but not limited to, manufacturers; repackagers; own-label distributors; private label distributors; jobbers; brokers; warehouses, including manufacturers’ and distributors’ warehouses, chain drug warehouses, and wholesale drug warehouses; and independent wholesale drug traders, but does not include a retail pharmacy whose sales of prescription drugs to other than the ultimate user, including physicians for office use, nursing homes, institutions, etc. does not exceed five percent of the total gross annual sales of prescription drugs of the pharmacy.

(b) A separate license shall be obtained for each wholesale food and cosmetic establishment operated within the State.

As amended, R.1973 d.89, eff. March 30, 1973.

See: 5 N.J.R. 81(b), 5 N.J.R. 143(a).

Amended by R.1990 d.563, effective November 19, 1990.

See: 22 N.J.R. 2465(a), 22 N.J.R. 3559(a).

Provision for wholesale establishment added.

8:21-9.3 Exemptions

(a) The following establishments shall be exempt from the licensing provisions of P.L. 1971, c.158, 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:

1. Retail food and cosmetic establishments;
2. Establishments subject to licensure under other provisions of Title 24, N.J.S.A.;
3. Establishments inspected and licensed by a local health department;
4. Growers of raw agricultural commodities delivering their produce to food processing establishments.

As amended, R.1974 d.184, eff. July 9, 1974.

See: 6 N.J.R. 232(a), 6 N.J.R. 310(a).

Case Notes

Health officer can inspect and license wholesale food and cosmetic establishments; health officer must be full time public employee; services cannot be outside contracted. *State v. Board of Health of Morris Twp.*, 208 N.J.Super. 415, 506 A.2d 52 (App.Div.1986), appeal dismissed 107 N.J. 50, 526 A.2d 139 (1986).

See *Eisler and Co. v. State*, 124 N.J. Super. 357, 307 A.2d 113 (App. Div. 1973).

8:21-9.4 License requirement

(a) Every person owning or operating a wholesale food or cosmetic establishment within the State shall apply annually for a license to operate such establishment on forms provided by the department.

(b) 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.

As amended, R.1978 d.167, eff. May 22, 1978.

See: 10 N.J.R. 147(a), 10 N.J.R. 249(b).

Amended by R.1990 d.563, effective November 19, 1990.

See: 22 N.J.R. 2465(a), 22 N.J.R. 3559(a).

Provision for wholesale establishment added.

8:21-9.5 License fees

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

1. For each wholesale food or cosmetic establishment with a gross annual business not in excess of \$100,000, \$100.00;

2. For each wholesale food or cosmetic establishment with a gross annual business in excess of \$100,000 but not in excess of \$500,000, \$300.00;

3. For each wholesale food or cosmetic establishment with a gross annual business in excess of \$500,000, \$500.00.

As amended, R.1983 d.456, effective October 17, 1983.

See: 15 N.J.R. 1317(a), 15 N.J.R. 1762(b).

License fees increased.

Amended by R.1990 d.563, effective November 19, 1990.

See: 22 N.J.R. 2465(a), 22 N.J.R. 3559(a).

Fees restructured and lowered.

Case Notes

Fees not applicable to registrant for drug business. *Eisler and Co. v. State*, 124 N.J.Super. 357, 307 A.2d 113 (App.Div.1973).

8:21-9.6 Expiration of license; nontransferability of license

(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.

As amended, R.1978 d.167, eff. May 27, 1978.

See: 10 N.J.R. 147(a), 10 N.J.R. 249(b).

8:21-9.7 Revocation of license

(a) 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 hereinbefore provided, the Department shall upon hearing and proof of allegation, revoke the license of such licensee. The hearing shall be conducted pursuant to the Administrative Procedure Act, N.J.S.A. 52:14B-1 et seq., and the Uniform Administrative Procedure Rules, N.J.A.C. 1:1.

(b) 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 complied with.

(c) 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.

Amended by R.1990 d.563, effective November 19, 1990.

See: 22 N.J.R. 2465(a), 22 N.J.R. 3559(a).
Reference to Administrative Procedure Act added.

SUBCHAPTER 10. DESIGNATED FLUID MILK PRODUCTS

8:21-10.1 Pasteurized Milk Ordinance (PMO) adopted

The Grade "A" Pasteurized Milk Ordinance (PMO) 1978 Recommendations of the United States Public Health Service/Food and Drug Administration, Publication No. 229, is adopted and incorporated herein by reference, as amended and supplemented, as the legal requirements for the production and processing of milk and milk products in the State of New Jersey, provided, however, that certain sections of the PMO as identified in this subchapter are not adopted and that certain additional requirements as set forth in this subchapter are promulgated. Copies of the PMO may be obtained from the Food and Drug Administration (FDA), Milk Safety Branch, HFS-626, 200 "C" Street S.W., Washington, DC 20204 or reviewed at the offices of the New Jersey Department of Health and Senior Services.

Amended by R.1990 d.563, effective November 19, 1990.
See: 22 N.J.R. 2465(a), 22 N.J.R. 3559(a).

Definition of certified milk deleted; definitions added for eggnog, frozen yogurts, goat milk, nonfat yogurt, yogurt added.
Amended by R.1993 d.689, effective December 20, 1993.
See: 25 N.J.R. 4373(a), 25 N.J.R. 6013(a).
Repeal and New Rule, R.2000 d.427, effective October 16, 2000.
See: 32 N.J.R. 2386(a), 32 N.J.R. 3831(a).
Section was "Definitions and product standards".

8:21-10.2 Definitions

(a) The following definitions contained in Section 1. Definitions of the Pasteurized Milk Ordinance are not adopted.

1. Definition L "Milk products" is replaced by the definition in statute at N.J.S.A. 24:10-57.1(b).
2. Definition O "Adulterated milk" is replaced by the definition in statute at N.J.S.A. 24:5-8.
3. Definition P "Misbranded milk" is replaced by the definition in statute at N.J.S.A. 24:5-17.
4. Definition U "Milk producer" is replaced by the definition in statute at N.J.S.A. 24:10-57.1(e).
5. Definition V "Milk hauler" is replaced by the definition in statute at N.J.S.A. 24:10-57.1(i).
6. Definition W "Milk distributor" is replaced by the definition in statute at N.J.S.A. 24:10-57.1(f).
7. Definition Y "Dairy farm" is replaced by the definition in statute at N.J.S.A. 24:10-57.1(d).
8. Definition Z "Milk plant" is replaced by the definition in statute at N.J.S.A. 24:10-57.1(g).

(b) The following words and terms, as used in this subchapter and in the PMO as incorporated by reference herein, shall have the following meanings:

"Butter" means the food product known as butter, and which is made exclusively from milk or cream, or both, with or without common salt, and with or without additional coloring matter, and containing not less than 80 percent of milkfat, all tolerances having been allowed for.

"Butter oil" means the clean, wholesome and unadulterated milkfat obtained from milk, cream, or butter, and which contains not less than 99 percent milkfat.

"Certified industry inspector" means an individual certified by the Department to conduct dairy farm inspections of producers shipping to New Jersey permit holders. Such certification shall be in accordance with the procedures established by the Department pursuant to the provisions of the Pasteurized Milk Ordinance.

"CFR" means the Code of Federal Regulations of the United States Government.

"Cheese" shall mean and include those cheeses, processed cheeses, cheese foods, cheese spreads and related food for which definitions and standards of identify have been promulgated under the provisions of the Federal Food, Drug and Cosmetic Act and shall conform to such definitions and standards of identify as set forth therein.

"Commissioner" shall mean the Commissioner of the Department of Health and Senior Services or his/her duly appointed agent.

"Dairy drink" means a product consisting of fluid skim milk or concentrated or dried skim milk recombined with water, with or without added milkfat, to which has been added a syrup or flavoring material, and which contains not less than 7½ percent milk solids-not-fat.

"Department" means the Department of Health and Senior Services.

"Frozen yogurt mix" means the unfrozen fluid mixture from which frozen yogurt is made by freezing and shall contain not less than 3.25 percent milkfat and 8.25 percent milk solids not fat prior to the addition of bulky characterizing ingredients or sweeteners. In addition, the mix shall meet the requirements of N.J.A.C. 8:21-7.7 regarding culturing, titratable acidity and live yogurt culture organisms.

"Health Authority" means the duly authorized agent of the Department of Health and Senior Services to act in the enforcement of the sanitary laws of the State.