CHAPTER 21

FOOD AND DRUGS

Authority

N.J.S.A. 24:2-1, 24:5-1, 24:10-57.20, 24:10-73.1 and 24:12-12.

Source and Effective Date

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

Chapter Expiration Date

In accordance with N.J.S.A. 52:14B-5.1d, the expiration date of Chapter 21, Food and Drugs, was extended by gubernatorial directive from March 21, 2006 to March 21, 2007. See: 38 N.J.R. 1733(a).

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and Subchapter 12, Manufacturing, Storage, Distribution, and Handling of Nonalcoholic Beverages and Bottled Water, was repealed by R.1990 d.563, effective November 19, 1990.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).

Pursuant to Executive Order No. 66(1978), Chapter 21, Food and Drugs, was readopted as R.1995 d.588, effective October 23, 1995. See: 27 N.J.R. 3535(a), 27 N.J.R. 4700(b).

Pursuant to Executive Order No. 66(1978), Chapter 21, Food and Drugs, was readopted as R.2000 d.427, effective September 22, 2000. See: Source and Effective Date. See, also, section annotations.

In accordance with N.J.S.A. 52:14B-5.1c, Chapter 21, Food and Drugs, expires on March 21, 2006. See: 37 N.J.R. 3899(a).

CHAPTER TABLE OF CONTENTS

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

8:21-1.1 Definitions
8:21-1.2 General labeling requirements
8:21-1.3 Food labeling
8:21-1.4 Drug labeling
8:21-1.5 Cosmetic labeling
8:21-1.6 Labeling, sale, and distribution of cosmetics for professional use only
8:21-1.7 Cosmetic product warning statements
8:21-1.8 Definition of soap
8:21-1.9 Device labeling
8:21-1.10 Certificate of Free Sale application process, fees, appeal process
8:21-1.11 Certificate of Free Sale inspection procedure, fees

SUBCHAPTER 2. FOODS

8:21-2.1 Frozen food locker plants
8:21-2.2 Sale of enriched white flour and unenriched white flour
8:21-2.3 Inspection reports
8:21-2.4 Sale of ground meat and similar products
8:21-2.5 Prohibition of sale of striped bass
8:21-2.6 Prohibition of sale of channel cat fish
8:21-2.7 through 8:21-2.42 (Reserved)

SUBCHAPTER 3. DRUGS, DEVICES AND COSMETICS

8:21-3.1 Warning statements for drug labels
8:21-3.2 Rulings on dangerous cosmetics
8:21-3.3 Keeping of records by drug manufacturing businesses and wholesale drug businesses
8:21-3.4 Paregoric
8:21-3.5 Compressed air used in self contained underwater breathing apparatus (SCUBA)
8:21-3.6 SCUBA recommendations
8:21-3.7 Animal repellants
8:21-3.8 List of ingredients for human self-defense sprays
8:21-3.9 Permit for nitrous oxide
8:21-3.10 through 8:21-3.25 (Reserved)

SUBCHAPTER 3A. REGISTRATION OF WHOLESALE DISTRIBUTORS OF PRESCRIPTION DRUGS

8:21-3A.1 Scope
8:21-3A.2 Purpose
8:21-3A.3 Definitions
8:21-3A.4 Application requirements; reciprocity
8:21-3A.5 Evaluation criteria
8:21-3A.6 Denial of application
8:21-3A.7 Personnel requirements
8:21-3A.8 Facility
8:21-3A.9 Security
8:21-3A.10 Storage
8:21-3A.11 Examination of materials
8:21-3A.12 Returned, damaged and outdated prescription drugs
8:21-3A.13 Recordkeeping
8:21-3A.14 (Reserved)
8:21-3A.15 Availability of records and inventories
8:21-3A.16 Policies and procedures
8:21-3A.17 List of responsible persons
8:21-3A.18 Inspection and auditing
8:21-3A.19 Salvage; reprocessing
8:21-3A.20 Suspension; revocation
8:21-3A.21 Penalties
8:21-3A.22 Appeals

SUBCHAPTER 4. NEW DRUGS

8:21-4.1 Statement of policy
8:21-4.2 Combination drugs
8:21-4.3 General provisions; definitions
8:21-4.4 Exemptions from section 505(a)
8:21-4.5 General provisions; new drug applications
8:21-4.6 through 8:21-4.50 (Reserved)

SUBCHAPTER 5. MANUFACTURING, STORAGE, DISTRIBUTION, AND HANDLING STANDARDS FOR BOTTLED WATER

8:21-5.1 Separability
8:21-5.2 Definitions
8:21-5.3 Water source protection
8:21-5.4 Springs
8:21-5.5 Bottled water labeling requirements
8:21-5.6 Facilities for the storage, distribution, handling, and bottling of bottled water
8:21-5.7 Production, equipment, and packaging requirements
8:21-5.8 Sanitation and maintenance requirements
8:21-5.9 Storage and handling of chemicals
8:21-5.10 Personnel requirements
8:21-5.11 Sanitizing requirements for multi-use bottles or containers
8:21-5.12 Bulk water facility requirements
8:21-5.13 Recordkeeping requirements
8:21-5.14 Water standards and sampling requirements
8:21-5.15 Bottled water certification requirements
8:21-5.16 Certification fees
8:21-5.17 Exemptions

8:21-5.18 Expiration of certification; nontransferability of certification
8:21-5.19 Revocation of certification

SUBCHAPTER 6. (RESERVED)

SUBCHAPTER 7. FROZEN DESSERTS

8:21-7.1 Definitions
8:21-7.2 Ice cream and frozen custard
8:21-7.3 Sherbet
8:21-7.4 Water ice
8:21-7.5 Mellorine
8:21-7.6 Goat's milk ice cream
8:21-7.7 Frozen yogurt; identity; label statement
8:21-7.8 Quiescently frozen confection; identity; label statement
8:21-7.9 Quiescently frozen dairy confection; identity; label statement
8:21-7.10 Non-fruit (imitation) sherbet; identity; label statement
8:21-7.11 Non-fruit (imitation) water ice; identity; label statement
8:21-7.12 Manufactured desserts mix; identity; label statement
8:21-7.13 Freezer-made shake; freezer-made milk shake; identity; label statement
8:21-7.14 Parevine; identity; label statement
8:21-7.15 Lo-mel; identity; label statement
8:21-7.16 Frozen pudding; identity; label statement
8:21-7.17 Temporary marketing permit
8:21-7.18 Generic frozen dessert; identity; label statement
8:21-7.19 Other standards of identity
8:21-7.20 Plant records
8:21-7.21 Plant buildings and surroundings
8:21-7.22 Plant construction
8:21-7.23 Plant cleanliness
8:21-7.24 Construction and repair of containers and equipment
8:21-7.25 Cleaning and sanitizing of containers and equipment
8:21-7.26 Protection from contamination
8:21-7.27 Pasteurization and cooling
8:21-7.28 Bacterial standards
8:21-7.29 Plant sanitary facilities
8:21-7.30 Plant personnel
8:21-7.31 Supply of milk and fluid milk products
8:21-7.32 Packaging and labeling
8:21-7.33 Self service frozen desserts manufacturing machines
8:21-7.34 Frozen desserts; mobile units
8:21-7.35 Mobile unit depots
8:21-7.36 Procedures for reconstituting dry frozen desserts mix
8:21-7.37 License fees
8:21-7.38 Suspension, revocation or nonrenewal of license
8:21-7.39 through 8:21-7.46 (Reserved)

SUBCHAPTER 8. IMITATION MILK, IMITATION LOW FAT MILK AND IMITATION FLUID MILK PRODUCTS

8:21-8.1 Definitions and standards of identity
8:21-8.2 Misbranding of imitation milk, imitation low fat milk and imitation fluid milk products
8:21-8.3 Misbranding of foods made in semblance of imitation milk, imitation low fat milk or any imitation fluid milk product
8:21-8.4 Adulteration of imitation milk, imitation low fat milk and foods made in semblance of such products

SUBCHAPTER 9. LICENSING OF FOOD AND COSMETIC MANUFACTURING AND WHOLESALE ESTABLISHMENTS

8:21-9.1 Definitions
8:21-9.2 Scope of regulations
8:21-9.3 Exemptions
8:21-9.4 License requirement
8:21-9.5 License fees
8:21-9.6 Expiration of license; nontransferability of license
8:21-9.7 Revocation of license

SUBCHAPTER 10. DESIGNATED FLUID MILK PRODUCTS

8:21-10.1 Pasteurized Milk Ordinance (PMO) adopted
8:21-10.2 Definitions
8:21-10.3 Adulterated or misbranded milk
8:21-10.4 Permits
8:21-10.5 Labeling
8:21-10.6 Inspection of dairy farms and milk plants
8:21-10.7 Examination of milk and fluid milk products
8:21-10.8 Standards for milk and fluid milk products
8:21-10.9 Animal health
8:21-10.10 Milk and milk products which may be sold
8:21-10.11 Transferring; delivery containers; cooling
8:21-10.12 Milk and milk products from points beyond the limits of routine inspection
8:21-10.13 Future dairy farms and milk plants
8:21-10.14 Personnel health
8:21-10.15 Procedure when infection or high risk of infection is discovered
8:21-10.16 Enforcement
8:21-10.17 Penalty
8:21-10.18 Repeal and date of effect
8:21-10.19 Separability clause
8:21-10.20 Dating of milk and fluid milk products
8:21-10.21 Temporary marketing permit
8:21-10.22 License fees; permit application
8:21-10.23 Suspension, revocation or nonrenewal of permit

SUBCHAPTER 11. DENTED CANS; SALVAGE OR DISTRESSED FOODS, ALCOHOL AND NONALCOHOLIC BEVERAGES AND INDUSTRIAL MISHANDLING

8:21-11.1 Scope
8:21-11.2 Definitions
8:21-11.3 Damaged cans unsuitable for sale
8:21-11.4 Damaged food containers suitable for sale
8:21-11.5 Salvage of food, drugs, devices or cosmetics associated with natural or local disasters or distressed food conditions or industrial mishandling
8:21-11.6 Disposal of distressed foods

SUBCHAPTER 12. (RESERVED)

SUBCHAPTER 13. RULES GOVERNING WHOLESALE FOOD ESTABLISHMENTS

8:21-13.1 Scope
8:21-13.2 Separability
8:21-13.3 Definitions
8:21-13.4 Facilities and procedures for the storage, distribution, handling and processing of food and nonalcoholic drinks
8:21-13.5 Sanitary facilities and controls
8:21-13.6 Sanitary operations
8:21-13.7 Equipment and procedures
8:21-13.8 Personnel
8:21-13.9 Production and process controls
8:21-13.10 Code of Federal Regulations references
8:21-13.11 Unsafe foods
8:21-13.12 Emergency occurrences

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:

(e) 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.

(f) 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.

(g) 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.

(h) 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.
Amended by R.2005 d.5, effective January 3, 2005.
See: 36 N.J.R. 1155(a), 37 N.J.R. 52(b).
Rewrote the section.

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.

8:21-3A.4 Application requirements; reciprocity

(a) The Department may permit an out-of-State wholesale distributor to satisfy the registration requirements of this subchapter on the basis of reciprocity provided that:

1. Such out-of-State wholesale distributor possesses a valid license or registration granted by another state pursuant to legal standards comparable to those which must be met by a registrant of this State as prerequisites for satisfying the registration requirements under the laws of this State; and

2. Such other state extends reciprocal treatment under its own laws to wholesale distributors of this State.

(b) Every wholesale distributor of prescription drugs shall apply to the Department in accordance with the provisions of N.J.S.A. 24:6B–2 using forms supplied by the Department. In addition, every applicant shall complete the appropriate sections of the application, which shall include:

1. Name, full business address and telephone number of the applicant;

i. All trade or business names used by the registrant;

ii. Addresses, telephone numbers and name of the contact person for all facilities used by the registrant for the storage, handling and distribution of prescription drugs;

2. The type of ownership or operation (that is, partnership, corporation, or sole proprietorship);

3. The name(s) of the owner and/or operator of the applicant, including:

i. If a person, the name of the person;

ii. If a partnership, the name of each partner, and the name of the partnership;

iii. If a corporation, the name and title of each corporate officer and director, the corporate names, and the name of the State of incorporation, and

iv. If a sole proprietorship, the full name of the proprietor and the name of the business entity;

4. The address of each location in New Jersey at which the business is to be conducted. If an applicant's business is not to be conducted within the State, the application shall give the name and address of an agent resident of this State on whom process against the applicant may be served;

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

6. A description of the business;

7. The name and address of the individual or individuals on whom orders of the Commissioner may be served; and

8. A statement as to whether the registrant engages in the manufacturing, compounding, processing, wholesaling, jobbing, distribution of any controlled dangerous substances as defined pursuant to N.J.S.A. 24:21–2.

8:21-3A.5 Evaluation criteria

(a) In considering any application for registration, the Department shall consider, at a minimum, the following factors in reviewing the qualifications of those persons applying for registration as a wholesale prescription drug distributor:

1. Any convictions of the applicant under any Federal, state, or local laws relating to drug samples, wholesale or retail drug distribution, or distribution of a controlled substance;

2. Any felony conviction under Federal laws, or the equivalent (under whatever statutory term) conviction under state or local laws;

3. The applicant's past experience in the manufacturing or distribution of prescription drugs or controlled substances;

4. The furnishing of false or fraudulent material in any application made in connection with drug or device manufacturing or distribution;

5. Suspension or revocation by Federal, state or local government of any registration currently or previously held by the applicant for the manufacture or distribution of any drugs, including controlled substances;

6. Compliance with license and/or registration requirements under any previously granted license or registration, if any;

7. Compliance with requirements to maintain and/or make available to the Department or Federal or local law enforcement officials those records required by this subchapter; and

8. Any other factors or qualifications the Department considers relevant to and consistent with the public health and safety.

(b) Wholesale drug distributors shall operate in compliance with applicable Federal, State and local laws and regulations and where the wholesale drug distributor also deals in controlled dangerous substances, it shall also register with the Department and Drug Enforcement Administration (DEA) and also comply with all applicable State rules and DEA regulations.

(c) A retail pharmacy wishing to conduct a wholesale business shall operate the wholesale business under a separate name and at a separate location, other than that of the

pharmacy name and address and the wholesale business will be subject to all of the requirements of a wholesale distributor.

8:21-3A.6 Denial of application

The Department shall have the right to deny an application for registration if it determines the granting of such registration would not be in the public interest. Public interest considerations shall be based upon factors and qualifications that are directly related to the protection of the public health and safety as delineated in N.J.A.C. 8:21-3A.5.

8:21-3A.7 Personnel requirements

Personnel employed by a wholesale distributor shall have appropriate education and/or experience to assume responsibility for positions that would affect compliance with registration requirements.

8:21-3A.8 Facility

(a) All facilities at which prescription drugs are stored, warehoused, handled, held, offered, marketed, or displayed shall:

1. Be of suitable size and construction to facilitate cleaning, maintenance, and proper operations;

2. Provide storage areas which include adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions;

3. Provide a quarantine area for storage of outdated, damaged, deteriorated, misbranded or adulterated prescription drugs, or drugs that are in immediate or sealed secondary containers that have been opened;

4. Be maintained in a clean and orderly condition; and

5. Be free from infestation by insects, rodents, birds, or vermin of any kind.

8:21-3A.9 Security

(a) All facilities used for wholesale distribution shall be secure from unauthorized entry and shall provide the following additional security measures:

1. Access from outside the premises shall be kept at a minimum and shall be well controlled;

2. The outside perimeter of the premises shall be well-lighted; and

3. Entry into areas where prescription drugs are held shall be limited to authorized personnel.

(b) All facilities shall be equipped with an alarm system to detect entry after hours.

(c) All facilities shall be equipped with a security system that will provide suitable protection against theft and diversion, and shall provide, when appropriate, protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.

8:21-3A.10 Storage

(a) All prescription drugs shall be stored at appropriate temperature and conditions in accordance with the requirements set forth in the labeling of such drugs or with the requirements of the current edition of an official compendium, such as the United States Pharmacopoeia/National Formulary (USP/NF).

(b) If no storage requirements are established for a prescription drug, the drug may be held at controlled room temperature, as defined in an official compendium, to help ensure that its identity, strength, quality, and purity are not adversely affected.

(c) Appropriate manual, electromechanical or electronic temperature and humidity recording equipment, devices and/or logs shall be utilized to document proper storage of prescription drugs.

8:21-3A.11 Examination of materials

(a) Upon receipt, each outside shipping container shall be visually examined for identity and to prevent the acceptance of contaminated prescription drugs or prescription drugs that are otherwise unfit for distribution, and such examination shall be adequate to reveal container damage that would suggest possible contamination or other damage to the contents;

(b) Each outgoing shipment of prescription drugs shall be carefully examined for the identity of the prescription drug products and to ensure that there is no delivery of prescription drugs that have been damaged in storage or held under improper conditions.

8:21-3A.12 Returned, damaged and outdated prescription drugs

(a) Prescription drugs that are outdated, damaged, deteriorated, misbranded, or adulterated shall be quarantined and physically separated from other prescription drugs until they are destroyed or returned to their supplier.

(b) Prescription drugs whose immediate or sealed outer or sealed secondary containers have been opened or used shall be identified as such, and shall be quarantined and physically separated from other prescription drugs until they are either destroyed or returned to the supplier.

(c) If the conditions under which a prescription drug has been returned cast doubt on the drug's safety, identity, strength, quality or purity, then the drug shall be destroyed or returned to the supplier, unless examination, testing or other investigation proves the drug meets appropriate standards of safety, identity, strength, quality and purity. The wholesale distributor of prescription drugs shall consider, among other things, the conditions under which the drugs were held, stored, or shipped before or during their return and the condition of the drug and its container, carton, or labeling as a result of storage and shipping when considering that there is any doubt of the drug's safety, identity, strength, quality or purity.

8:21–3A.13 Recordkeeping

(a) Wholesale distributors of prescription drugs shall establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of prescription drugs. Such records shall include the following information:

1. The source of the drugs, including the name and principal address of the seller or transferor, and the address of the location from which the drugs were shipped;

2. The identity and quantity of the drugs received and distributed or disposed of; and

3. The dates of receipt and distribution or other disposition of the drugs.

8:21–3A.14 (Reserved)

8:21–3A.15 Availability of records and inventories

(a) Records and inventories, including those related to any prescription drug salvage or reprocessing procedure, shall be made available for inspection and photocopying by Federal, State or local law enforcement agencies and shall be maintained for a period of two years following the disposition of the drugs.

(b) The records that are kept at the inspection site or that can be immediately retrieved by computer or other electronic means shall be readily available for authorized inspection during the retention period, and records kept at a central location apart from the inspection site and not electronically retrievable shall be made available for inspection within two working days of a request by an authorized official of a Federal, state or local enforcement agency.

8:21–3A.16 Policies and procedures

(a) Wholesale prescription drug distributors shall establish, maintain, and adhere to written policies and procedures which shall be followed for the receipt, security, storage, inventory, and distribution of prescription drugs, including policies and procedures for identifying, recording, and reporting losses or thefts, and for correcting all errors and inaccuracies in inventory. Wholesale drug distributors shall include in their policy and procedures the following:

1. A procedure whereby the oldest approved stock of a prescription drug is distributed first. The procedure may permit deviation from this requirement if the deviation is temporary and appropriate;

2. A procedure to be followed for, and which shall be adequate for, handling recalls and withdrawals due to:

i. Any action initiated by the request of the Food and Drug Administration or other Federal, state, local law enforcement or other government agency, including the State registering agency;

ii. Any voluntary action by the manufacturer to remove defective or potentially defective drugs from the market; or

iii. Any action undertaken to promote public health, and safety by replacing existing merchandise with an approved product or new package design.

3. A procedure to ensure that a wholesale distributor prepares for, protects against, and handles any crisis that affects security or the operation of any facility in the event of strike, fire, flood, or other natural disaster, or other situations of a local, State or national emergency; and

4. A procedure to ensure that outdated prescription drugs shall be segregated from other drugs and either returned to the manufacturer or destroyed. Such procedure shall provide for written documentation of the disposition of the outdated prescription drugs and shall be maintained for two years after disposition of the outdated drugs.

8:21–3A.17 List of responsible persons

Wholesale drug distributors shall establish and maintain a list of officers, directors, managers, and other persons in charge of wholesale distribution, storage, and handling of prescription drugs that shall include a description of their duties and a summary of their qualifications.

8:21–3A.18 Inspection and auditing

Wholesale drug distributors shall permit the Department and authorized Federal, State and local law enforcement officials to enter and inspect their premises and delivery vehicles, and to audit their records and written operating procedures, at reasonable times and in a reasonable manner, to the extent authorized by law.

8:21–3A.19 Salvage; reprocessing

Wholesale drug distributors shall be subject to the provisions of any applicable Federal, State or local laws, rules or regulations that relate to prescription drug product salvaging or reprocessing.

8:21–3A.20 Suspension; revocation

The Department shall suspend or revoke any registration granted under this subchapter upon conviction of the registrant of a violation of applicable Federal, State or local drug laws, rules or regulations and may suspend or revoke any registration granted hereunder if the registrant willfully and seriously violated the requirements of this chapter.

8:21–3A.21 Penalties

The Department may provide for fines, imprisonment, or civil penalties as set forth in N.J.S.A. 24:6B–11 or 24:17.1.

8:21–3A.22 Appeals

Prior to the suspension or revocation of a registration issued in accordance with this subchapter, the registrant shall have a right to prior notice and a hearing 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.

SUBCHAPTER 4. NEW DRUGS

8:21–4.1 Statement of policy

(a) The following "new drug" regulations as adopted by the department are to provide guidance in the administration of the provisions of N.J.S.A. 24:6A–1 et seq.

(b) To ensure that a complete and comprehensive review for safety is provided to a new drug application submitted pursuant to the State act, it has been deemed proper and expeditious to adopt by reference such procedures, records, reports, sampling, toxicology, pathology and clinical testing measures afforded to new drugs by the United States Food and Drug Administration as provided in 21 C.F.R. 300, 310, 312 and 314.

(c) It is the intent and policy of the department to implement and administer those provisions of the Federal new drug regulations adopted by this department that pertain to or are concerned with the safety of the product subject of a State new drug application.

8:21–4.2 Combination drugs

21 C.F.R. 300.50, Fixed combinations prescription drugs for humans, is hereby adopted by reference.

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

8:21–4.3 General provisions; definitions

(a) 21 C.F.R. 310.3 (Definitions and interpretations), 21 C.F.R. 310.4 (Biologics, products subject to license control) and 21 C.F.R. 310.9 (Designated journals) are hereby adopted by reference, with the following modifications.

(b) The definitions set forth in subpart A (General provisions), section 21 C.F.R. 310.3 pursuant to the intent and policy of the Department of Health and Senior Services as set forth in a preamble to new drug regulations, mean the following:

1. The term "act" means the Title 24, New Jersey Statutes Annotated.

2. The term "department" means the New Jersey Department of Health and Senior Services.

3. The term "secretary" means the New Jersey Commissioner of Health and Senior Services.

4. Where administrative procedures are set forth in the Federal regulations, the provisions of N.J.S.A. 52:14B–1 et seq. shall apply.

Amended by R.1987 d.227, effective May 18, 1987.
See: 18 N.J.R. 2363(a), 19 N.J.R. 873(a).
Added 21 C.F.R. to (b).
Amended by R.1990 d.563, effective November 19, 1990.
See: 22 N.J.R. 2465(a), 22 N.J.R. 3559(a).
Stylistic changes.
Amended by R.2000 d.427, effective October 16, 2000.
See: 32 N.J.R. 2386(a), 32 N.J.R. 3831(a).

8:21–4.4 Exemptions from section 505(a)

(a) 21 C.F.R. 312.1 (Conditions for exemption of new drugs for investigational use), 21 C.F.R. 312.5 (Confidentiality of data and information in an investigational new drug notice, IND), and 21 C.F.R. 312.9 (New drugs for investigational use in laboratory research animals or in vitro tests) are hereby adopted by reference.

(b) Regarding subpart B (Controlled substances), 21 C.F.R. 312.10, Availability of records, is hereby adopted by reference.

(c) Regarding subpart C (International research), 21 C.F.R. 312.20, Clinical data generated outside the United States and not subject to a "Notice of Claimed Investigational Exemption of a New Drug", is hereby adopted by reference.

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

8:21–4.5 General provisions; new drug applications

(a) 21 C.F.R. 314.1 (Applications), 21 C.F.R. 314.60 (Amended applications), 21 C.F.R. 314.65 (Withdrawal of applications without prejudice), 21 C.F.R. 314.70 (Supplemental applications), 21 C.F.R. 314.90 (Insufficient information in application), 21 C.F.R. 314.105 (New drug application approvals; notification to applicant of approval of application; availability of information), 21 C.F.R. 314.420 (Master files), 21 C.F.R. 314.12 (Untrue statements in application), 21 C.F.R. 314.104 (New drugs with potential for abuse) and 21 C.F.R. 314.140 (Confidentiality of data and information in a new drug application, NDA, file) are hereby adopted by reference.

(b) Subpart B (Administrative actions on applications), 21 C.F.R. 314.102 (Comment on application), 21 C.F.R. 314.125 (Reasons for refusing to file applications), 21 C.F.R. 314.125 (Reasons for refusing to file applications), 21 C.F.R. 314.120 (Refusal to approve the application), 21 C.F.R. 314.150 (Withdrawal of approval of an application), 21 C.F.R. 314.152 (Notice of withdrawal of approval of application), 21 C.F.R. 314.160 (Revocation of order refusing to approve application, or suspending or withdrawing approval of an application), and 21 C.F.R. 314.162 (Notices and orders) are hereby adopted by reference.

8:21–5.2 Definitions

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

"Adequate" means that which is needed to accomplish the intended purpose in keeping with good public health practices.

"Adulteration" means the term "adulteration" as defined in N.J.S.A. 24:5–8.

"Approved" means acceptable to the Department, local health authority, or other appropriate administrative agency based on its determination as to the conformance with applicable standards and good public health practices.

"Approved source" means the source of water from a spring, artesian well, drilled well, municipal water supply, or any other source which has been evaluated and found to be of satisfactory sanitary quality as determined by the governmental regulatory agency having primary jurisdiction for that source.

"Aquifer" means a water bearing stratum used as a source of potable water supply.

"Bottled water" means water that falls within the definition established under 21 CFR 165.110(a)(1).

"Bulk water facility" means a place where water intended for potable uses is drawn from an approved source which is transported to a bottling plant by means of tank trucks.

"Certified laboratory" means a laboratory approved by the New Jersey State Department of Environmental Protection in accordance with N.J.A.C. 7:18, Regulations Governing Laboratory Certification and Standards of Performance.

"CFR" means the Code of Federal Regulations.

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

"Drilled well" means a system whereby water is taken from below the ground through a pipe or piping system or similar installed device utilizing external force or vacuum.

"Expiration date" means the date established by N.J.S.A. 24:12–2 as two years from the date the product was bottled.

"Lot" means a collection of primary containers or units as defined under 21 CFR 165.3.

"Misbranded" means the term "misbranded" as defined in N.J.S.A. 24:5–16 and 17.

"Multi-use containers" means containers intended for use more than one time.

"Nontoxic materials" means materials for product water contact surfaces utilized in the transporting, processing, storing, or packaging of bottled drinking water which are free of substances which may render the water injurious to health or which may adversely affect the flavor, color, odor or bacteriological quality of the water.

"Operations water" means water which is delivered under pressure to a plant for container washing, hand washing, plant and equipment clean up and for other sanitary purposes.

"Plant" means the building or facility or parts thereof, used for or in connection with the manufacturing, storage, processing, packaging, labeling or handling of bottled water.

"Product contact surfaces" means those surfaces that contact product and those surfaces from which drainage onto product or onto surfaces that contact product ordinarily occurs during the normal course of operations.

"Product water" means processed water used by a plant for bottled drinking water.

"Sanitize" means adequate treatment of surfaces by a process that is effective in destroying the vegetative cell of microorganisms of public health significance and in substantially reducing numbers of other microorganisms.

"Source water" means water from a spring, artesian well, drilled well, community water supply or any other approved source which is used for or in connection with bottled water.

"Spring house" means a structure approved by the Department that is constructed over a spring so as to provide complete protection for the source from all types of external sources of contamination.

"Water hauler" means any person who causes bulk water to be transported for bottling for human consumption or other consumer uses from the source to the bottling plant.

Amended by R.2000 d.150, effective April 3, 2000.
See: 31 N.J.R. 2585(a), 32 N.J.R. 1195(a).
Rewrote the introductory paragraph, "Bottled water" and "Lot"; rewrote "Bulk water" as "Bulk water facility"; and deleted "Artesian well water", "Local health authority", "Spring" and "Total Trihalomethanes (TTHM)".

8:21–5.3 Water source protection

(a) The source water supply for bottled water shall be from an approved source which is properly located, protected, and operated and shall be easily accessible, adequate, and of safe, sanitary quality. The water quality and sampling frequency shall be in conformance at all times with the applicable laws and rules and regulations of the Department or other governmental agencies having jurisdiction. Examples of source water supplies which may be used for bottled water upon approval by the Department are as follows:

1. Approved public community water systems;

2. Drilled and driven wells when constructed and protected in accordance with applicable standards set forth in N.J.A.C. 7:10–12, Standards for the Construction of Public Non-community and Non-public Water Systems; and

3. Springs inspected for development as a water source and constructed in accordance with the applicable standards established by the Department of Environmental Protection and set forth in N.J.A.C. 7:10–12.24, Standards for the Construction of Public Non–Community and Non–Public Water Systems (springs) and shall meet the standards for springs set forth under N.J.A.C. 8:21–5.4.

(b) Source water shall be evaluated according to provisions of N.J.A.C. 7:10–9.4, monitoring requirements and criteria for determination for ground water sources under the direct influence of surface water as defined under N.J.A.C. 7:10–11.4(c)1, 2, and 3. Water sources determined to be under the direct influence of surface water shall comply with the provisions of N.J.A.C. 7:10–9.1 and 9.2.

Amended by R.2000 d.150, effective April 3, 2000.
See: 31 N.J.R. 2585(a), 32 N.J.R. 1195(a).
Added (b).

8:21–5.4 Springs

(a) The spring shall be properly protected from the entry of insects, birds, rodents and other vermin.

(b) Adequate ventilation shall be provided.

(c) Sufficient protection shall be provided at the intake end of the draw pipe to prevent the introduction of stone, gravel, sand and other particulate matter.

(d) The overflow shall be free-flowing and shall be constructed in a manner to prevent flooding of the springhouse and surrounding area.

(e) The minimum distance from a spring to a building sewer line, septic tank, and a distribution box shall be 50 feet. The minimum distance from a spring to a disposal field or seepage pit shall be 100 feet.

(f) Plumbing shall be sized, installed and maintained in accordance with applicable State and local standards. Also, plumbing shall be properly designed and protected from contamination and damage.

(g) Walls and ceilings shall be smooth, easily cleanable, free of cracks and crevices and constructed of materials that are not adversely affected by moisture, algae, or mold.

(h) Proper cleaning and sanitization equipment and facilities shall be available and used whenever a spring is damaged, repaired and/or contaminated.

8:21–5.5 Bottled water labeling requirements

(a) Bottled water shall be labeled and conform with the nomenclature established under 21 CFR 165.110(a) (identity).

(b) Each container of bottled water shall have printed on the container an expiration date of two years from the date the water was bottled. Bottled water shall no longer be offered for sale, distributed, or given to the public for consumption after the expiration date.

(c) Label claims of medicinal or health-giving properties shall be prohibited. In addition, references to bacteriological purity or laboratory examination which may have been made by a governmental agency shall also be prohibited.

(d) Products which are not in conformance with the above referenced bottled drinking water labeling requirements shall be deemed misbranded as defined at N.J.S.A. 24:5–16 and 17.

Amended by R.2000 d.150, effective April 3, 2000.
See: 31 N.J.R. 2585(a), 32 N.J.R. 1195(a).
Rewrote the section.

8:21–5.6 Facilities for the storage, distribution, handling, and bottling of bottled water

(a) The grounds surrounding the plant shall be kept in a condition that will not cause the bottled water to be contaminated and/or adulterated.

1. Equipment storage, litter, waste, and excessive weeds or grass within the immediate vicinity of the plant buildings or structures shall not constitute an attractant, breeding place or harborage for rodents, insects or other pests.

2. Roads, yards, and other parking lots shall be maintained so that they do not constitute a source of contamination to the bottled water.

3. Areas surrounding the plant shall be properly drained in order to prevent contamination of the bottled water by seepage, by foot-borne filth, or by providing a breeding place for rodents, insects or other pests.

(b) Plant buildings shall be of suitable size, construction, and design to facilitate maintenance and sanitary operations for processing purposes.

1. The bottle filling operations shall be separated from the balance of plant operations and storage areas by tight walls, ceilings, and self-closing doors or other appropriate barriers. No loading or unloading of trucks or other vehicles shall take place within an establishment unless acceptable segregation or isolation is accomplished.

2. Sufficient space shall be provided for such placement of equipment and storage of materials as is necessary for sanitary operations.