

CHAPTER 21

FOOD AND DRUGS

Authority

N.J.S.A. 24:2-1, 24:5-1 et seq., 24:6B-1 et seq.,
24:10-57.20, 24:10-73.1 and 24:12-12.

Source and Effective Date

R.2006 d.391, effective October 16, 2006.
See: 37 N.J.R. 3899(a), 38 N.J.R. 4857(b).

Chapter Expiration Date

In accordance with N.J.S.A. 52:14B-5.1b, Chapter 21, Food and
Drugs, expires on October 16, 2013. See: 43 N.J.R. 1203(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 Sub-
chapter 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Bottled Water, was repealed by R.1990 d.563, effective November 19,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: 32 N.J.R. 2386(a), 32 N.J.R. 3831(a).

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 21, Food and Drugs, was readopted as R.2006 d.391, effec-
tive October 16, 2006. As a part of R.2006 d.391, Subchapter 3A, Reg-
istration of Wholesale Distributors of Prescription Drugs, was renamed
Registration of Wholesale Distributors of Drugs, effective November 20,
2006. See: Source and Effective Date. See, also, section annotations.

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 profes-
sional 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 WHOLESAL
DISTRIBUTORS OF 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 Due diligence
- 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 con-
tainers
- 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: