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SUBCHAPTER 9B - RULES AND STANDARDS ADOPTED BY REFERENCE

02 NCAC 09B .0101 INSPECTOR'S MANUAL
02 NCAC 09B .0102 AOAC METHODS
02 NCAC 09B .0103 NATIONAL FORMULARY
02 NCAC 09B .0104 U.S. PHARMACOPEIA
02 NCAC 09B .0105 ASTM STANDARDS
02 NCAC 09B .0106 REFERENCE MANUALS

History Note: *Authority G.S. 150B-14;*
Eff. February 1, 1976;
Repealed Eff. December 14, 1981.

02 NCAC 09B .0107 GENERAL PROVISIONS
02 NCAC 09B .0108 FOOD AND FOOD PRODUCTS
02 NCAC 09B .0109 DRUGS
02 NCAC 09B .0110 DRUGS FOR HUMAN USE
02 NCAC 09B .0111 ANIMAL DRUGS: FEEDS: AND RELATED PRODUCTS
02 NCAC 09B .0112 COSMETICS
02 NCAC 09B .0113 TITLE 40: CODE OF FEDERAL REGULATIONS
02 NCAC 09B .0114 TITLE 9: PART 319: CODE OF FEDERAL REGULATIONS
02 NCAC 09B .0115 TITLE 9: PART 381: CODE OF FEDERAL REGULATIONS

History Note: *Authority G.S. 150B-14;*
Eff. February 1, 1976;
Amended Eff. December 20, 1980;
Repealed Eff. December 1, 1981.

02 NCAC 09B .0116 ADOPTIONS BY REFERENCE

(a) The Board incorporates by reference, including subsequent amendments and editions, "Official Methods of Analysis of AOAC," published by the Association of Official Analytical Chemists. Copies of this document may be obtained from the Association of Official Analytical Chemists International, Department 0742, 1970 Chain Bridge Road, McLean, VA 22109-0742, at a cost of seven hundred thirty dollars ($730.00).

(b) The Board incorporates by reference, including subsequent amendments and editions, "U.S. Pharmacopeia National Formulary USP XXXIII-NFXXVIII" and supplements, published by the U.S. Pharmacopeial Convention, Inc. Copies of this document may be obtained from The United States Pharmacopeial Convention, Inc., Attention: Customer Service, 12601 Twinbrook Parkway, Rockville, MD 20852, at a cost of eight-hundred fifty dollars ($850.00).

(c) The Board incorporates by reference, including subsequent amendments and editions, "ASTM Volume 15.05 Engine Coolants and Related Fluids; Halogenated Organic Solvents and Fire Extinguishing Agents," published by ASTM International. Copies of this document may be obtained from ASTM International, 100 Bar Harbor Drive, West Conshohocken, PA 19428-2959, or by visiting https://www.astm.org/BOOKSTORE/BOS/1505.htm at a cost of one hundred ninety dollars ($190.00).

(d) The Board incorporates by reference, including subsequent amendments and editions, "EPA Manual of Chemical Methods for Pesticides and Devices" and supplements, published by AOAC. Copies of this document may be obtained online at no cost from the Environmental Protection Agency National Service Center for Environmental Publications at http://nepis.epa.gov/EXE/ZyPURL.cgi?Dockey=2000YS3Y.txt.

(e) The Board incorporates by reference, including subsequent amendments and editions, "Pesticide Analytical Manual," Volumes I and II, published by the United States Department of Health and Human Services, Food and Drug Administration. Copies of this document may be obtained online at no cost at http://www.fda.gov/Food/Science Research/LaboratoryMethods/PesticideAnalysisManualPAM/default.htm.

(f) The Board incorporates by reference, including subsequent amendments and editions, "FDA Compliance Policy Guides," published by the United States Department of Health and Human Services, Food and Drug Administration. Copies of this

document may be obtained online at no cost at http://www.fda.gov/iceci/compliancemanuals/compliancepolicyguidancemanual/default.htm or from the State Information Branch (HFC-151), Division of Federal-State Relations, US Food and Drug Administration, 5600 Fishers Lane, Room 12-07, Rockville, MD 20857.

(g) The Board incorporates by reference, including subsequent amendments and editions, "Bergey's Manual of Determinative Bacteriology," Lippincott, Williams & Wilkins Company, Baltimore. Copies of this document may be obtained from the Lippincott, Williams & Wilkins Company, P.O. Box 1620, Hagerstown, MD 21741 at a cost one hundred forty five dollars and ninety nine cents ($145.99).

(h) The Board incorporates by reference, including subsequent amendments and editions, "Microbiology Laboratory Guidebook," published by the United States Department of Agriculture, Food Safety and Inspection Service, Washington, DC. Copies of this document may be obtained online at no cost from http://www.fsis.usda.gov.

(i) The Board incorporates by reference, including subsequent amendments and editions, "FDA Bacteriological Analytical Manual," published by the United States Department of Health and Human Services, Food and Drug Administration. Copies of this document may be obtained online at http://www.fda.gov/Food/FoodScienceResearch/LaboratoryMethods/ucm114664.htm at no charge.

(j) The Board incorporates by reference, including subsequent amendments and editions, "Standard Methods for the Examination of Dairy Products," published by the American Public Health Association. Copies of this document may be obtained from the American Public Health Association Publication Sales, P.O. Box 933019, Atlanta, GA at a cost of eighty-five dollars and fifty cents ($87.50) for members and one hundred twenty-five dollars ($125.00) for non-members.

(k) The Board incorporates by reference, including subsequent amendments and editions, "Compendium of Methods for the Microbiological Examination of Foods," published by the American Public Health Association. Copies of this document may be obtained from the American Public Health Association Publication Sales, P.O. Box 933019, Atlanta, GA at a cost of one hundred forty seven dollars and fifty cents ($147.50).

(l) The Board incorporates by reference, including subsequent amendments and editions, "Bergey's Manual of Systematic Bacteriology," Springer Publishing, New York, NY. Copies of this document may be obtained from Springer Publishing, 233 Spring Street, New York, NY, 10013 at a cost of one hundred fifty-nine dollars ($159.00).

(m) The Board incorporates by reference, including subsequent amendments and editions, "Manual of Clinical Microbiology," published by the American Society for Microbiology. Copies of this document may be obtained from the American Society for Microbiology Press, PO Box 605, Herndon, VA 22070, at a cost of two hundred sixty-nine dollars and ninety-five cents ($269.95).

(n) The Board incorporates by reference, including subsequent amendments and editions, "Standard Methods for the Examination of Water and Waste Water," published by American Public Health Association, American Water Works Association, and Water Pollution Control Federation. Copies of this document may be obtained from the American Public Health Association Publication Sales, P.O. Box 933019, Atlanta, GA at a cost of two hundred ninety-five dollars ($295.00).

(o) The Board incorporates by reference, including subsequent amendments and editions, the following parts or sections of the Code of Federal Regulations, Title 21, Chapter I, as promulgated by the Commissioner of the Food and Drug Administration under the authority of the Federal Food, Drug, and Cosmetic Act:

	Part or Section	Description of Part or Section
(1)	1.1	General
(2)	1.3	Definitions
(3)	1.20	Presence of Mandatory Label Information
(4)	1.21	Failure to Reveal Material Facts
(5)	1.24	Exemptions from Required Label Statements
(6)	1.326	Who is Subject to this Subpart?
(7)	1.327	Who is Excluded from All or Part of the Regulations in this Subpart?
(8)	1.328	What Definitions Apply to this Subpart?
(9)	1.329	Do Other Statutory Provisions and Regulations Apply?
(10)	1.330	Can Existing Records Satisfy the Requirements of this Subpart?
(11)	1.337	What Information Must Nontransporters Establish and Maintain to I dentify the Nontransporter and Transporter Immediate Previous Sources of Food?
(12)	1.345	What Information Must Nontransporter Establish and Maintain to Identify the Nontransporter and Transporter Immediate Subsequent Recipients of Food?
(13)	1.352	What Information Must Transporters Establish and Maintain?
(14)	1.360	What are the Record Retention Requirements?
(15)	1.361	What are the Record Availability Requirements?

(16)	1.362	What Records are Excluded from this Subpart?
(17)	1.363	What are the Consequences of Failing to Establish, or Maintain Records or Make Them Available to FDA as Required by this Subpart?
(18)	1.368	What are the Compliance Dates for this Subpart?
(19)	2.25	Grain Seed Treated with Poisonous Substances; Color Identification to Prevent Adulteration of Human and Animal Food
(20)	2.35	Use of Secondhand Containers for the Shipment or Storage of Food and Animal Feed
(21)	7.1	Scope
(22)	7.3	Definitions
(23)	7.12	Guaranty
(24)	7.13	Suggested Forms of Guaranty
(25)	7.40	Recall Policy
(26)	7.41	Health Hazard Evaluation and Recall Classification
(27)	7.42	Recall Strategy
(28)	7.45	Food and Drug Administration - Requested Recall
(29)	7.46	Firm-initiated Recall
(30)	7.49	Recall Communications
(31)	7.50	Public Notification of Recall
(32)	7.53	Recall Status Reports
(33)	7.55	Termination of a Recall
(34)	7.59	General Industry Guidance
(35)	70	Color Additives
(36)	73	Listing of Color Additives Exempt from Certification
(37)	74	Listing of Color Additives Subject to Certification
(38)	81	General Specifications and General Restrictions for Provisional Color Additives for Use in Foods, Drugs, and Cosmetics
(39)	82	Listing of Certified Provisionally Listed Colors and Specifications
(40)	100	General
(41)	101	Food Labeling
(42)	102	Common or Usual Name for Nonstandardized Foods
(43)	104	Nutritional Quality Guidelines for Foods
(44)	105	Foods for Special Dietary Use
(45)	106	Infant Formula Requirements Pertaining to Current Good Manufacturing Practice, Quality Control Procedures, Quality Factors, Records and Reports, and Notifications
(46)	107	Infant Formula
(47)	108	Emergency Permit Control
(48)	109	Unavoidable Contaminants in Food for Human Consumption and Food-Packaging Material
(49)	110	Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food
(50)	111	Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements
(51)	112	Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption
(52)	113	Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers
(53)	114	Acidified Foods
(54)	115	Shell Eggs
(55)	117	Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food
(56)	118	Production, Storage, and Transportation of Shell Eggs
(57)	120	Hazard Analysis and Critical Control Point (HACCP) Systems
(58)	123	Fish and Fishery Products
(59)	129	Processing and Bottling of Bottled Drinking Water (Except as amended by 02 NCAC

09C.0700 - Bottled Water)

(60)	130	Food Standards: General
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(62)	133	Cheeses and Related Cheese Products
(63)	135	Frozen Desserts
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(65)	137	Cereal Flours and Related Products
(66)	139	Macaroni and Noodle Products
(67)	145	Canned Fruits
(68)	146	Canned Fruit Juices
(69)	150	Fruit Butters, Jellies, Preserves, and Related Products
(70)	152	Fruit Pies
(71)	155	Canned Vegetables
(72)	156	Vegetable Juices
(73)	158	Frozen Vegetables
(74)	160	Eggs and Egg Products
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(96)	189	Substances Prohibited from Use in Human Food
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(100)	202	Prescription Drug Advertising
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(102)	211	Current Good Manufacturing Practice for Finished Pharmaceuticals
(103)	225	Current Good Manufacturing Practice for Medicated Feeds
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(110)	312	Investigational New Drug Application
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(112)	320	Bioavailability and Bioequivalence Requirements
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(114)	331	Antacid Products for Over-the-Counter (OTC) Human Use
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(116)	361	Prescription Drugs for Human Use Generally Recognized as Safe and Effective and NotMisbranded: Drugs Used in Research
(117)	369	Interpretive Statements Re: Warnings on Drugs and Devices for Over-the-Counter Sale
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(130)	507	Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals
(131)	509	Unavoidable Contaminants in Animal Food and Food-Packaging Material
(132)	510	New Animal Drugs
(133)	511	New Animal Drugs for Investigational Use
(134)	514	New Animal Drug Applications
(135)	520	Oral Dosage Form New Animal Drugs
(136)	522	Implantation or Injectable Dosage Form New Animal Drugs
(137)	524	Ophthalmic and Topical Dosage Form New Animal Drugs
(138)	526	Intramammary Dosage Form New Animal Drugs
(139)	529	Certain Other Dosage Form New Animal Drugs
(140)	556	Tolerances for Residues of New Animal Drugs in Food
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(142)	570	Food Additives
(143)	573	Food Additives Permitted in Feed and Drinking Water of Animals
(144)	582	Substances Generally Recognized as Safe
(145)	584	Food Substances Affirmed as Generally Recognized as Safe in Feed and Drinking Water of Animals
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(147)	700	General
(148)	701	Cosmetic Labeling
(149)	720	Voluntary Filing of Cosmetic Product Ingredient Composition Statements
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Copies of the Code of Federal Regulations may be obtained at no cost by accessing the website of the U.S. Government Printing Office at http://www.gpoaccess.gov/cfr/index.html.

(p) The Board incorporates by reference, including subsequent amendments and editions, "Tolerances and Exemptions for Pesticide Chemical Residues in Food," 40 C.F.R. Part 180. Copies of the Code of Federal Regulations may be obtained at no cost by accessing the website of the U.S. Government Printing Office at http://www.gpoaccess.gov/cfr/index.html.

(q) The Board incorporates by reference, including subsequent amendments and editions, "Definitions and Standards of Identity or Composition," 9 C.F.R. Part 319. Copies of the Code of Federal Regulations may be obtained at no cost by accessing the website of the U.S. Government Printing Office at http://www.gpoaccess.gov/cfr/index.html.

(r) The Board incorporates by reference, including subsequent amendments and editions, "Definitions and Standards of Identity or Composition," 9 C.F.R. Sections 381.155 through 381.170. Copies of the Code of Federal Regulations may be

obtained at no cost by accessing the website of the U.S. Government Printing Office at http://www.gpoaccess.gov/cfr/index.html.
(s) The Board incorporates by reference, including subsequent amendments and editions, "Labels: Definitions; Required Features," 9 C.F.R. Section 317.2 of the Code of Federal Regulations. Copies of Title 9 of the Code of Federal Regulations may be obtained at no cost by accessing the website of the U.S. Government Printing Office at http://www.gpoaccess.gov/cfr/index.html.
(t) The Board incorporates by reference, including subsequent amendments and editions, "Special Handling Label Requirements," 9 C.F.R. Section 381.125 of the Code of Federal Regulations. Copies of the Code of Federal Regulations may be obtained at no cost by accessing the website of the U.S. Government Printing Office at http://www.gpoaccess.gov/cfr/index.html.
(u) The Board incorporates by reference, including subsequent amendments and editions, a document entitled, "Fresh Air '2000' - A Look At FDA's Medical Gas Requirements," published by the United States Department of Health and Human Services, Food and Drug Administration. A copy of this material may be obtained at no cost from the Food and Drug Protection Division of the North Carolina Department of Agriculture and Consumer Services.
(v) The Board incorporates by reference, including subsequent amendments and editions, the definition of "dietary supplement" found at 21 USC 321(ff).
(w) The Board incorporates by reference, including subsequent amendments and editions, the definition of "processed food" found at 21 USC 321(gg).
(x) The Board incorporates by reference, including subsequent amendments and editions, the definition of "major food allergen" found at 21 USC 321(qq).
(y) The Board incorporates by reference, including subsequent amendments and editions, the definition of "knowingly" or "knew" found at 21 USC 321(bb).
(z) The Board incorporates by reference, including subsequent amendments and editions, the definition of "animal feed" found at 21 USC 321(w).

History Note: *Authority G.S. 106-139; 106-245.16; 106-245.22; 106-245.32; 106-267; 106-284.41;*
Eff. December 14, 1981;
Amended Eff. May 1, 2013; January 1, 2011; June 1, 2004; April 1, 2003; June 1, 1995; April 1, 1992; June 1, 1988; October 1, 1987;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. March 22, 2015;
Amended Eff. February 1, 2019; May 1, 2018.

02 NCAC 09B .0117 NATIONAL FORMULARY

History Note: *Authority G.S. 150B-14;*
Eff. December 14, 1981;
Repealed Eff. January 1, 1985.

02 NCAC 09B .0118 U.S. PHARMACOPEIA NATIONAL FORMULARY

History Note: *Authority G.S. 106-139; 106-267; 106-267.2;*
Eff. December 14, 1981;
Amended Eff. January 1, 1985;
Transferred to T02.09B .0016 Eff. April 1, 1987.

02 NCAC 09B .0119 ASTM STANDARDS

History Note: *Authority G.S. 106-139; 106-267; 106-267.2;*
Eff. December 14, 1981;
Amended Eff. January 1, 1985;
Transferred to T02.09B .0016 Eff. April 1, 1987.

02 NCAC 09B .0120 REFERENCE MANUALS

History Note: *Authority G.S. 106-139; 106-267; 106-267.2;*

Eff. December 14, 1981;
Amended Eff. January 1, 1985;
Transferred to T02.09B .0016 Eff. April 1, 1987.

02 NCAC 09B .0121 GENERAL

History Note: *Authority G.S. 106-139; 150B-14;*
Eff. December 1, 1981;
Transferred to T02.09B .0016 Eff. April 1, 1987.

02 NCAC 09B .0122 FOOD FOR HUMAN CONSUMPTION

History Note: *Authority G.S. 106-139; 150B-14;*
Eff. December 1, 1981;
Amended Eff. January 1, 1987; July 1, 1985; March 1, 1985; June 1, 1984;
Transferred to T02.09B .0016 Eff. April 1, 1987.

02 NCAC 09B .0123 DRUGS

History Note: *Authority G.S. 106-139; 150B-14;*
Eff. December 1, 1981;
Transferred to T02.09B .0016 Eff. April 1, 1987.

02 NCAC 09B .0124 DRUGS FOR HUMAN USE

History Note: *Authority G.S. 106-139; 150B-14;*
Eff. December 1, 1981;
Transferred to T02.09B .0016 Eff. April 1, 1987.

02 NCAC 09B .0125 MEDICAL DEVICES

History Note: *Authority G. S. 106-139; 150B-14;*
Eff. December 1, 1981;
Transferred to T02.09B .0016 Eff. April 1, 1987.

02 NCAC 09B .0126 ANIMAL DRUGS: FEEDS: AND RELATED PRODUCTS

History Note: *Authority G.S. 106-139; 150B-14;*
Eff. December 1, 1981;
Transferred to T02.09B .0016 Eff. April 1, 1987.

02 NCAC 09B .0127 COSMETICS

History Note: *Authority G.S. 106-139; 150B-14;*
Eff. December 1, 1981;
Transferred to T02.09B .0016 Eff. April 1, 1987.

02 NCAC 09B .0128 TITLE 40: CODE OF FEDERAL REGULATIONS

History Note: *Authority G.S. 106-139; 150B-14;*
Eff. December 1, 1981;
Transferred to T02.09B .0016 Eff. April 1, 1987.

02 NCAC 09B .0129 TITLE 9: PART 319: CODE OF FEDERAL REGULATIONS

History Note: *Authority G.S. 106-139; 150B-14;*
Eff. December 1, 1981;
Transferred to T02.09B .0016 Eff. April 1, 1987.

02 NCAC 09B .0130 TITLE 9: PART 381: CODE OF FEDERAL REGULATIONS

History Note: *Authority G.S. 106-139; 150B-14;*
Eff. December 1, 1981;
Transferred to T02.09B .0016 Eff. April 1, 1987.

02 NCAC 09B .0131 ETHYLENE DIBROMIDE TOLERANCE

History Note: *Authority G.S. 106-139;*
Temporary Rule Eff. February 6, 1984, for a Period of 120 Days to Expire on June 4, 1984;
Eff. June 1, 1984;
Pursuant to G.S. 150B-21.3A, rule Expired April 1, 2015.

02 NCAC 09B .0132 EFFECTIVE DATE FOR ADOPTIONS BY REFERENCE

History Note: *Authority G.S. 106-139; 150B-14;*
Eff. January 1, 1987;
Transferred to T02.09B .0016 Eff. April 1, 1987.

02 NCAC 09B .0133 DOCUMENT AVAILABILITY
Copies of documents adopted by reference in 02 NCAC 09B .0116 are available for inspection in the Office of the Director of the Food and Drug Protection Division and may be obtained at a cost as determined by the publisher by contacting the Superintendent of Documents, Government Printing Office, Washington, D.C. 20402.

History Note: *Authority G.S. 106-139; 150B-14;*
Eff. January 1, 1987;
Amended Eff. June 1, 1988;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. March 22, 2015.

02 NCAC 09B .0134 DEFINING ESTABLISHMENT
The term "establishment" under the North Carolina Food, Drugs and Cosmetics Act, G.S. 106-120 et seq. shall include farms as defined under 21 CFR 112.3, which is hereby incorporated by reference including later amendments or editions and can be accessed free of cost at http://www.gpoaccess.gov/cfr/index.html.

History Note: *Authority G.S. 106-139;*
Eff. May 1, 2018.

02 NCAC 09B .0135 CURRENT GOOD MANUFACTURING PRACTICES FOR RETAIL FOOD ESTABLISHMENTS
Subpart B of 21 C.F.R. Part 117, as incorporated by reference pursuant to Rule .0116(o)(55) of this Subchapter, shall apply to "retail food establishments" as defined by 21 C.F.R. 1.227, and shall include bakeries, retail food outlets, and seafood markets.

History Note: *Authority G.S. 106-139;*
Eff. February 1, 2019.