02 NCAC 09B .0116 is amended with changes as published in 32:08 NCR 722-726 as follows:

**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 six hundred thirty dollars ($630.00).

(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 Standards on Engine Coolants," published by ASTM International. Copies of this document may be obtained from ASTM International, 100 Bar Harbor Drive, West Conshohocken, PA 19428-2959, at a cost of two hundred eleven dollars ($211.00).

(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 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 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 http://www.fda.gov/iceci/compliancemanuals/compliancepolicy guidancemanual/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 of one hundred thirty-seven dollars and ninety-nine cents ($137.99).

(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 from http://www.fsis.usda.gov science/ microbiological_Lab_Guidebook/ at no charge.

(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/FoodScience Research/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 ($85.00).

(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 fifty dollars ($150.00).

(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 | Labeling - 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? |

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| (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 Non-transporters Establish and Maintain to Identify the Nontransporter and Transporter Immediate Previous Sources of Food? |
| (12) | 1.345 | What Information Must Non-transporters 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 Provisioned Color Additives for Use in Foods, Drugs and Cosmetics |
| (39) | 82 | Listing of Certified Provisionally Listed Colors and Specifications |
| (40) | 100 | General |

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|---|---|---|
| (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 Quality Control Procedures |
| (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 |
| ~~(51)~~(52) | 113 | Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers |
| ~~(52)~~(53) | 114 | Acidified Foods |
| ~~(53)~~(54) | 115 | Shell Eggs |
| (55) | 117 | Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food |
| ~~(54)~~(56) | 118 | Production, Storage, and Transportation of Shell Eggs |
| ~~(55)~~(57) | 120 | Hazard Analysis and Critical Control Point (HACCP) Systems |
| ~~(56)~~(58) | 123 | Fish and Fishery Products |
| ~~(57)~~(59) | 129 | Processing and Bottling of Bottled Drinking Water (Except as amended by 02 NCAC 09C .0700 - Bottled Water) |
| ~~(58)~~(60) | 130 | Food Standards: General |
| ~~(59)~~(61) | 131 | Milk and Cream |
| ~~(60)~~(62) | 133 | Cheeses and Related Cheese Products |
| ~~(61)~~(63) | 135 | Frozen Desserts |
| ~~(62)~~(64) | 136 | Bakery Products |
| ~~(63)~~(65) | 137 | Cereal Flours and Related Products |
| ~~(64)~~(66) | 139 | Macaroni and Noodle Products |
| ~~(65)~~(67) | 145 | Canned Fruits |
| ~~(66)~~(68) | 146 | Canned Fruit Juices |
| ~~(67)~~(69) | 150 | Fruit Butters, Jellies, Preserves, and Related Products |
| ~~(68)~~(70) | 152 | Fruit Pies |
| ~~(69)~~(71) | 155 | Canned Vegetables |

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| ~~(70)~~(72) 156 | Vegetable Juices |
| ~~(71)~~(73) 158 | Frozen Vegetables |
| ~~(72)~~(74) 160 | Eggs and Egg Products |
| ~~(73)~~(75) 161 | Fish and Shellfish (Except Section 161.30 and 161.130 through 161.145) |
| ~~(74)~~(76) 163 | Cacao Products |
| ~~(75)~~(77) 164 | Tree Nut and Peanut Products |
| ~~(76)~~(78) 165 | Beverages |
| ~~(77)~~(79) 166 | Margarine |
| ~~(78)~~(80) 168 | Sweeteners and Table Syrups |
| ~~(79)~~(81) 169 | Food Dressings and Flavorings |
| ~~(80)~~(82) 170 | Food Additives |
| ~~(81)~~(83) 172 | Food Additives Permitted for Direct Addition to Food for Human Consumption |
| ~~(82)~~(84) 173 | Secondary Direct Food Additives Permitted in Food for Human Consumption |
| ~~(83)~~(85) 174 | Indirect Food Additives: General |
| ~~(84)~~(86) 175 | Indirect Food Additives: Adhesives and Components of Coatings |
| ~~(85)~~(87) 176 | Indirect Food Additives: Paper and Paperboard Components |
| ~~(86)~~(88) 177 | Indirect Food Additives: Indirect Food Additives: Polymers |
| ~~(87)~~(89) 178 | Indirect Food Additives: Adjuvants, Production Aids, and Sanitizers |
| ~~(88)~~(90) 179 | Irradiation in the Production, Processing and Handling of Food |
| ~~(89)~~(91) 180 | Food Additives Permitted in Food or in Contact with Food on an Interim Basis Pending Additional Study |
| ~~(90)~~(92) 181 | Prior-Sanctioned Food Ingredients |
| ~~(91)~~(93) 182 | Substances Generally Recognized as Safe |
| ~~(92)~~(94) 184 | Direct Food Substances Affirmed as Generally Recognized as Safe |
| ~~(93)~~(95) 186 | Indirect Food Substances Affirmed as Generally Recognized as Safe |
| ~~(94)~~(96) 189 | Substances Prohibited from Use in Human Food |
| ~~(95)~~(97) 190 | Dietary Supplements |
| ~~(96)~~(98) 200 | General |
| ~~(97)~~(99) 201 | Labeling |
| ~~(98)~~(100)202 | Prescription Drug Advertising |
| ~~(99)~~(101)210 | Current Good Manufacturing Practice in Manufacturing, Processing, Packing or Holding of Drugs; General |
| ~~(100)~~(102)211 | Current Good Manufacturing Practice for Finished Pharmaceuticals |
| ~~(101)~~(103)225 | Current Good Manufacturing Practice for Medicated Feeds |
| ~~(102)~~(104)226 | Current Good Manufacturing Practice for Type A Medicated Articles |
| ~~(103)~~(105)250 | Special Requirements for Specific Human Drugs |
| ~~(104)~~(106)290 | Controlled Drugs |

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| ~~(105)~~(107)299 | Drugs; Official Names and Established Names |
| ~~(106)~~(108)300 | General |
| ~~(107)~~(109)310 | New Drugs |
| ~~(108)~~(110)312 | Investigational New Drug Application |
| ~~(109)~~(111)314 | Applications for FDA Approval to Market New Drug |
| ~~(110)~~(112)320 | Bioavailability and Bioequivalence Requirements |
| ~~(111)~~(113)330 | Over-the-Counter (OTC) Human Drugs Which Are Generally Recognized as Safe and Effective and Not Misbranded |
| ~~(112)~~(114)331 | Antacid Products for Over-the-Counter (OTC) Human Use |
| ~~(113)~~(115)332 | Antiflatulent Products for Over-the-Counter Human Use |
| ~~(114)~~(116)361 | Prescription Drugs for Human Use Generally Recognized as Safe and Effective and Not Misbranded: Drugs Used in Research |
| ~~(115)~~(117)369 | Interpretive Statements Re: Warnings on Drugs and Devices for Over-the-Counter Sale |
| ~~(116)~~(118)809 | In Vitro Diagnostic Products for Human Use |
| ~~(117)~~(119)812 | Investigational Device Exemptions |
| ~~(118)~~(120)820 | Quality System Regulation |
| ~~(119)~~(121)860 | Medical Device Classification Procedures |
| ~~(120)~~(122)861 | Procedures for Performance Standards Development |
| ~~(121)~~(123)870 | Cardiovascular Devices |
| ~~(122)~~(124)882 | Neurological Devices |
| ~~(123)~~(125)884 | Obstetrical and Gynecological Devices |
| ~~(124)~~(126)895 | Banned Devices |
| ~~(125)~~(127)500 | General |
| ~~(126)~~(128)501 | Animal Food Labeling |
| ~~(127)~~(129)502 | Common or Usual Names for Nonstandardized Animal Foods |
| ~~(128)~~(130)509 | Unavoidable Contaminants in Animal Food and Food-Packaging Material |
| ~~(129)~~(131)510 | New Animal Drugs |
| ~~(130)~~(132)511 | New Animal Drugs for Investigational Use |
| ~~(131)~~(133)514 | New Animal Drug Applications |
| ~~(132)~~(134)520 | Oral Dosage Form New Animal Drugs |
| ~~(133)~~(135)522 | Implantation or Injectable Dosage Form New Animal Drugs |
| ~~(134)~~(136)524 | Ophthalmic and Topical Dosage Form New Animal Drugs |
| ~~(135)~~(137)526 | Intramammary Dosage Form New Animal Drugs |
| ~~(136)~~(138)529 | Certain Other Dosage Form New Animal Drugs |
| ~~(137)~~(139)556 | Tolerances for Residues of New Animal Drugs in Food |
| ~~(138)~~(140)558 | New Animal Drugs for Use in Animal Feeds |
| ~~(139)~~(141)570 | Food Additives |

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| ~~(140)~~(142)573 | Food Additives Permitted in Feed and Drinking Water of Animals |
| ~~(141)~~(143)582 | Substances Generally Recognized as Safe |
| ~~(142)~~(144)584 | Food Substances Affirmed as Generally Recognized as Safe in Feed and Drinking Water of Animals |
| ~~(143)~~(145)589 | Substances Prohibited from Use in Animal Food or Feed |
| ~~(144)~~(146)700 | General |
| ~~(145)~~(147)701 | Cosmetic Labeling |
| ~~(146)~~(148)720 | Voluntary Filing of Cosmetic Product Ingredient Composition Statements |
| ~~(147)~~(149)740 | Cosmetic Product Warning Statements |

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 from Tolerances for Pesticide Chemicals in or on Raw Agricultural Commodities," 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 for Meats, Meat By-products, and Meat Food Products," 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 for Poultry and Poultry Products," 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, Title 9, Part 317.2(1) of the Code of Federal Regulations. Copies of Title 9 of the Code of Federal Regulations may be obtained from the Superintendent of Documents, Government Printing Office, Washington, DC 20402, at a cost of sixty-four dollars ($64.00).

(t) The Board incorporates by reference, including subsequent amendments and editions, Title 9, Part 381.125(b) 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 the definition of "dietary supplement" found at 21 USC 321(ff).

[~~(w) 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:~~

~~(1) 112 Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption~~

~~(2) 117 Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food~~]

[~~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.~~]

[~~(x)~~](w) The Board incorporates by reference the definition of "processed food" found at 21 USC 321(gg).

[~~(y)~~](x) The Board incorporates by reference the definition of "major food allergen" found at 21 USC 321(qq).

[~~(z)~~](y) The Board incorporates by reference the definition of "knowingly" or "knew" found at 21 USC 321(bb).

*History Note:* *Authority G.S. 106-139; 106-245.16; 106-245.22; 106-245.32; 106-267;*
*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; May 1, 2018;*
*Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. March 22, 2015.*