REQUEST FOR TECHNICAL CHANGE

AGENCY: NC Board of Agriculture

RULE CITATION: 02 NCAC 09B .0116

DEADLINE FOR RECEIPT: Monday, April 9, 2018

***PLEASE NOTE:* This request may extend to several pages. Please be sure you have reached the end of the document.**

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may call our office to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends that the following technical changes be made:

Page 7, lines 33-35 – delete these lines

Page 7, lines 36-37 – move this to the appropriate subparagraph in Paragraph (o) and renumber the lines that follow.

Page 8, lines 1-2 – move this to the appropriate subparagraph in Paragraph (o) and renumber the lines that follow.

Page 8, lines 3-4 – delete these lines

Page 8, lines 5-7 – renumber these paragraphs

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Jason Thomas
Commission Counsel
Date submitted to agency: Friday, March 23, 2018

02 NCAC 09B .0116 is amended 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?

(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

(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)	113	Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers
(52)	114	Acidified Foods
(53)	115	Shell Eggs
(54)	118	Production, Storage, and Transportation of Shell Eggs
(55)	120	Hazard Analysis and Critical Control Point (HACCP) Systems
(56)	123	Fish and Fishery Products
(57)	129	Processing and Bottling of Bottled Drinking Water (Except as amended by 02 NCAC 09C .0700 - Bottled Water)
(58)	130	Food Standards: General
(59)	131	Milk and Cream
(60)	133	Cheeses and Related Cheese Products
(61)	135	Frozen Desserts
(62)	136	Bakery Products
(63)	137	Cereal Flours and Related Products
(64)	139	Macaroni and Noodle Products
(65)	145	Canned Fruits
(66)	146	Canned Fruit Juices
(67)	150	Fruit Butters, Jellies, Preserves, and Related Products
(68)	152	Fruit Pies
(69)	155	Canned Vegetables
(70)	156	Vegetable Juices
(71)	158	Frozen Vegetables
(72)	160	Eggs and Egg Products
(73)	161	Fish and Shellfish (Except Section 161.30 and 161.130 through 161.145)

1	(74)	163	Cacao Products
2	(75)	164	Tree Nut and Peanut Products
3	(76)	165	Beverages
4	(77)	166	Margarine
5	(78)	168	Sweeteners and Table Syrups
6	(79)	169	Food Dressings and Flavorings
7	(80)	170	Food Additives
8	(81)	172	Food Additives Permitted for Direct Addition to Food for Human Consumption
9	(82)	173	Secondary Direct Food Additives Permitted in Food for Human Consumption
10	(83)	174	Indirect Food Additives: General
11	(84)	175	Indirect Food Additives: Adhesives and Components of Coatings
12	(85)	176	Indirect Food Additives: Paper and Paperboard Components
13	(86)	177	Indirect Food Additives: Indirect Food Additives: Polymers
14	(87)	178	Indirect Food Additives: Adjuvants, Production Aids, and Sanitizers
15	(88)	179	Irradiation in the Production, Processing and Handling of Food
16	(89)	180	Food Additives Permitted in Food or in Contact with Food on an Interim Basis Pending
17			Additional Study
18	(90)	181	Prior-Sanctioned Food Ingredients
19	(91)	182	Substances Generally Recognized as Safe
20	(92)	184	Direct Food Substances Affirmed as Generally Recognized as Safe
21	(93)	186	Indirect Food Substances Affirmed as Generally Recognized as Safe
22	(94)	189	Substances Prohibited from Use in Human Food
23	(95)	190	Dietary Supplements
24	(96)	200	General
25	(97)	201	Labeling
26	(98)	202	Prescription Drug Advertising
27	(99)	210	Current Good Manufacturing Practice in Manufacturing, Processing, Packing or Holding
28			of Drugs; General
29	(100)	211	Current Good Manufacturing Practice for Finished Pharmaceuticals
30	(101)	225	Current Good Manufacturing Practice for Medicated Feeds
31	(102)	226	Current Good Manufacturing Practice for Type A Medicated Articles
32	(103)	250	Special Requirements for Specific Human Drugs
33	(104)	290	Controlled Drugs
34	(105)	299	Drugs; Official Names and Established Names
35	(106)	300	General
36	(107)	310	New Drugs
37	(108)	312	Investigational New Drug Application

(109)	314	Applications for FDA Approval to Market New Drug
(110)	320	Bioavailability and Bioequivalence Requirements
(111)	330	Over-the-Counter (OTC) Human Drugs Which Are Generally Recognized as Safe and Effective and Not Misbranded
(112)	331	Antacid Products for Over-the-Counter (OTC) Human Use
(113)	332	Antiflatulent Products for Over-the-Counter Human Use
(114)	361	Prescription Drugs for Human Use Generally Recognized as Safe and Effective and Not Misbranded: Drugs Used in Research
(115)	369	Interpretive Statements Re: Warnings on Drugs and Devices for Over-the-Counter Sale
(116)	809	In Vitro Diagnostic Products for Human Use
(117)	812	Investigational Device Exemptions
(118)	820	Quality System Regulation
(119)	860	Medical Device Classification Procedures
(120)	861	Procedures for Performance Standards Development
(121)	870	Cardiovascular Devices
(122)	882	Neurological Devices
(123)	884	Obstetrical and Gynecological Devices
(124)	895	Banned Devices
(125)	500	General
(126)	501	Animal Food Labeling
(127)	502	Common or Usual Names for Nonstandardized Animal Foods
(128)	509	Unavoidable Contaminants in Animal Food and Food-Packaging Material
(129)	510	New Animal Drugs
(130)	511	New Animal Drugs for Investigational Use
(131)	514	New Animal Drug Applications
(132)	520	Oral Dosage Form New Animal Drugs
(133)	522	Implantation or Injectable Dosage Form New Animal Drugs
(134)	524	Ophthalmic and Topical Dosage Form New Animal Drugs
(135)	526	Intramammary Dosage Form New Animal Drugs
(136)	529	Certain Other Dosage Form New Animal Drugs
(137)	556	Tolerances for Residues of New Animal Drugs in Food
(138)	558	New Animal Drugs for Use in Animal Feeds
(139)	570	Food Additives
(140)	573	Food Additives Permitted in Feed and Drinking Water of Animals
(141)	582	Substances Generally Recognized as Safe
(142)	584	Food Substances Affirmed as Generally Recognized as Safe in Feed and Drinking Water of Animals

(143) 589 Substances Prohibited from Use in Animal Food or Feed
(144) 700 General
(145) 701 Cosmetic Labeling
(146) 720 Voluntary Filing of Cosmetic Product Ingredient Composition Statements
(147) 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) The Board incorporates by reference the definition of "processed food" found at 21 USC 321(gg).

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

(z) 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.

02 NCAC 09B .0134 is adopted as published in 32:08 NCR 726 as follows:

02 NCAC 09B .0134 DEFINING ESTABLISHMENT

The term "establishment" under the North Carolina Food, Drugs and Cosmetics Act, N.C. Gen. Stat. § 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 is adopted as published in 32:08 NCR 726 as follows:

02 NCAC 09B .0135 ADULTERATION AND MISBRANDING

(a) Failure to comply with 21 C.F.R. Part 112 as adopted under 02 NCAC 09B .0116(w)(1) may render food adulterated or misbranded, or both, under N.C. Gen. Stat. § 106-129 and N.C. Gen. Stat. § 106-130 for purposes of N.C. Gen. Stat. § 106-122(1)-(3).

(b) Failure to comply with 21 C.F.R. Part 117 as adopted under 02 NCAC 09B .0116(w)(2) may render food adulterated or misbranded, or both, under N.C. Gen. Stat. § 106-129 and N.C. Gen. Stat. § 106-130 for purposes of N.C. Gen Stat. § 106-122(1)-(3).

History Note: *Authority G.S. 106-122; 106-129; 106-130; 106-139;*
Eff. May 1, 2018.