

FOR FURTHER INFORMATION CONTACT: Mary W. Lipien, Bureau of Foods (HFF-334), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-472-5690.

SUPPLEMENTARY INFORMATION: In a regulation published in the Federal Register of January 27, 1981 (46 FR 8461), FDA revised the specification for D&C Orange No. 4 by amending § 74.1254 (21 CFR 74.1254) to include a tolerance of not more than 0.1 percent for 4,4'-(diazamino)-dibenzene-sulfonic acid. No objections or requests for a hearing were received in response to the final rule.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 706 (b) (c), and (d), 74 Stat. 399-403 as amended (21 U.S.C. 376 (b), (c), and (d))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10 (formerly 5.1; see 46 FR 26052; May 11, 1981)), notice is given that no objections or requests for a hearing were filed in response to the final rule of January 27, 1981. Accordingly, the amendment promulgated thereby became effective on February 27, 1981.

Dated: March 15, 1982.

William F. Randolph,
Acting Associate Commissioner for
Regulatory Affairs.

[FR Doc. 82-7473 Filed 3-18-82; 8:45 am]

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21 CFR Parts 101, 102, 103, 114, 122, 131, 133, 135, 136, 137, 139, 145, 146, 150, 155, 160, 161, 163, 164, 166, 168, and 169

[Docket No. 81N-0266]

Incorporation by Reference Regulatory Text

AGENCY: Food and Drug Administration.
ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the incorporating regulatory text in Title 21 of the Code of Federal Regulations to make clear that an incorporation by reference is intended. This action is being taken to meet the drafting requirements for incorporation by reference set forth in Title 1 of the Code of Federal Regulations (1 CFR Part 51).

DATES: Effective March 19, 1982; written comments by April 19, 1982.

ADDRESS: Written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-82, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Vir D. Anand, Bureau of Foods (HFF-334), Food and Drug Administration, 200

C St. SW., Washington, DC 20204, 202-472-5690.

SUPPLEMENTARY INFORMATION: Title 1 of the Code of Federal Regulations (1 CFR 51.6, 51.7, and 51.8) requires, in addition to other information, specific language in a regulation that makes clear that an incorporation by reference is intended.

FDA has reviewed all of its regulations that include materials incorporated by reference. The agency has concluded that it is necessary to amend a number of these regulations to bring them into compliance with the drafting requirements prescribed in 1 CFR 51.6, 51.7, and 51.8. This notice amends certain of the regulations concerned with food. The agency will publish additional notices revising the incorporation by reference in its regulations that cover food and other products in future issues of the Federal Register.

The agency is amending 21 CFR Parts 101, 102, 103, 114, 122, 131, 133, 135, 136, 137, 139, 145, 146, 150, 155, 160, 161, 163, 164, 166, 168, and 169 to include language that: Clearly indicates that an incorporation by reference is intended; contains a complete citation of the material incorporated; and contains a statement about the availability of the incorporated material. These amendments ensure compliance with the drafting requirements specified in Title 1.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 701(a), 52 Stat. 1055 (21 U.S.C. 371(a))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10 (formerly 5.1; see 46 FR 26052; May 11, 1981)), Title 21 of the Code of Federal Regulations is amended as follows:

PART 101—FOOD LABELING

1. Part 101 is amended:

a. In § 101.9 by removing footnotes 1 and 2 and revising paragraph (c)(3) and (4), to read as follows:

§ 101.9 Nutrition labeling of food.

(c) * * *

(3) "Caloric content" or "Calories": A statement of the caloric content per serving (portion), expressed to the nearest 2-calorie increment up to and including 20 calories, 5-calorie increment above 20 calories and up to and including 50 calories, and 10-calorie increment above 50 calories. Caloric content shall be determined by the Atwater method as described in A. L. Merrill and B. K. Watt, "Energy Value of Foods—Basis and Derivation." USDA Handbook 74 (1955), which is incorporated by reference. Copies are

available from the Division of Nutrition, Bureau of Foods (HFF-260), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408. Caloric content may be calculated on the basis of 4, 4, and 9 calories per gram for protein, carbohydrate, and fat respectively unless the use of these values gives a caloric value more than 20 percent greater than the caloric value obtained when using the more accurate values determined by use of the Atwater method as found in USDA Handbook 74 (1955).

(4) "Protein content" or "Protein": A statement of the number of grams of protein in a serving (portion), expressed to the nearest gram except that if a serving (portion) contains less than one gram, the statement "Contains less than one gram" or "less than one gram" may be used as an alternative. Protein content may be calculated on the basis of the factor of 6.25 times the nitrogen content of the food as determined by the appropriate method of analysis of the Association of Official Analytical Chemists, 12th Ed. (1975), which is incorporated by reference, except when the official procedure for a specific food requires another factor. Copies are available from the Division of Nutrition, Bureau of Foods (HFF-260), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

b. In § 101.25 by removing the footnote and revising paragraph (e)(3), to read as follows:

§ 101.25 Labeling of foods in relation to fat and fatty acid and cholesterol content.

(e) * * *

(3) Composites shall be analyzed for fat and saturated fatty acids by the methods of the Association of Official Analytical Chemists (AOAC), 13th Ed. (1980), which is incorporated by reference. Copies are available from the Association of Official Analytical Chemists, P.O. Box 540, Benjamin Franklin Station, Washington, DC 20044. The methods for fat, fatty acids, and cholesterol will be those of the Association of Official Analytical Chemists (AOAC), or other reliable and appropriate methods. Alternative methods of analysis may be submitted to the Food and Drug Administration to determine their acceptability. The determination of *cis*, *cis*-methylene-

interrupted polyunsaturated fatty acids will be the Canadian Food and Drug Directorate Method FA-59 for *cis*, *cis*-methylene-interrupted fatty acid, which is incorporated by reference. Copies are available from the Division of Nutrition, Bureau of Foods (HFF-260), Food and Drug Administration, 200 C St. SW., Washington, DC 20204. Both incorporations by reference are available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

PART 102—COMMON OR USUAL NAME FOR NONSTANDARDIZED FOODS

2. Part 102 is amended:

a. In § 102.23 by removing the footnotes and revising paragraph (c) (1), (2), (3), (4), (5), (6), (7), (8), and (9), to read as follows:

§ 102.23 Peanut spreads.

(c) * * *

(1) Protein quantity: "Official Methods of Analysis of the Association of Official Analytical Chemists," 12th Ed. (1975) ('AOAC'), using the method described in section 27.007, which is incorporated by reference. Copies are available from the Division of Nutrition, Bureau of Foods (HFF-260), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(2) Biological quality of protein: AOAC, 12th Ed. (1975), using the method described in sections 43.183-43.187, which is incorporated by reference. The availability of this incorporation by reference is given in paragraph (c)(1) of this section.

(3) Niacin: AOAC, 12th Ed. (1975), using the method described in sections 43.044-43.046, which is incorporated by reference. The availability of this incorporation by reference is given in paragraph (c)(1) of this section.

(4) Vitamin B₆: AOAC, 12th Ed. (1975), using the method described in sections 43.159-43.164, which is incorporated by reference. The availability of this incorporation by reference is given in paragraph (c)(1) of this section.

(5) Folic acid: Using the method described in U.S. Department of Agriculture Handbook No. 29, modified by use of ascorbate buffer as described by Ford and Scott, *Journal of Dairy Research*, 35:85-90 (1968), which is incorporated by reference. Copies are available from the Division of Nutrition, Bureau of Foods (HFF-260), Food and

Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(6) Iron: AOAC, 12th Ed. (1975), using the method described in sections 43.188-43.190, which is incorporated by reference. The availability of this incorporation by reference is given in paragraph (c)(1) of this section.

(7) Zinc: AOAC, 12th Ed. (1975), using the method described in sections 25.143-25.147, which is incorporated by reference. The availability of this incorporation by reference is given in paragraph (c)(1) of this section.

(8) Copper: AOAC, 12th Ed. (1975), using the method described in sections 25.035-25.040, which is incorporated by reference. The availability of this incorporation by reference is given in paragraph (c)(1) of this section.

(9) Magnesium: AOAC, 12th Ed. (1975), using the method described in sections 2.096-2.099, which is incorporated by reference. The availability of this incorporation by reference is given in paragraph (c)(1) of this section.

b. In § 102.33 by removing the footnote and revising the last sentence and adding a sentence in paragraph (b), to read as follows:

§ 102.33 Diluted fruit or vegetable juice beverages other than diluted orange juice beverages.

(b) * * * The soluble solids content of single-strength high-acid juice (lemon, lime, or cranberry juice) shall be the weight of soluble solids obtained from refractometer readings corrected for acidity as set forth in section 22.025, Official Methods of Analysis of the Association of Official Analytical Chemists, 13th Ed. (1980), which is incorporated by reference. Copies are available from the Association of Official Analytical Chemists, P.O. Box 540, Benjamin Franklin Station, Washington, DC 20044, or available for inspection at the Office of the Federal Register, 1100 L Street, NW., Washington, DC 20408.

PART 103—QUALITY STANDARDS FOR FOODS WITH NO IDENTITY STANDARDS

3. Part 103 is amended in § 103.35 by removing the footnotes, revising the introductory text of paragraphs (b) and (c), and revising paragraphs (d)(1)(ii) and (e)(2), to read as follows:

§ 103.35 Bottled water.

(b) *Microbiological quality.* Bottled water shall, when a sample consisting of analytical units of equal volume is examined by the methods described in applicable sections of "Standard Methods for the Examination of Water and Wastewater," 14th Ed. (1975), American Public Health Association, which is incorporated by reference (copies are available from the Division of Food Technology, Bureau of Foods (HFF-210), 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408), meet the following standards of microbiological quality:

(c) *Physical quality.* Bottled water shall, when a composite of analytical units of equal volume from a sample is examined by the method described in applicable sections of "Standard Methods for the Examination of Water and Wastewater," 14th Ed. (1975), which is incorporated by reference (the availability of this incorporation by reference is given in paragraph (b) of this section), meet the following standards of physical quality:

(d) * * *

(1) * * *

(ii) Analyses conducted to determine compliance with paragraph (d)(1)(i) of this section shall be made in accordance with the methods described in the applicable sections of "Standard Methods for the Examination of Water and Wastewater," 14th Ed. (1975) or "Methods for Chemical Analysis of Water and Wastes," (1974), both of which are incorporated by reference. Analyses for organic substances shall be determined by appropriate methods described in "Methods for Organochlorine Pesticides in Industrial Effluents" and "Methods for Chlorinated Phenoxy Acid Herbicides in Industrial Effluents," November 28, 1973, which are incorporated by reference, and "Part I: The Analysis of Trihalomethanes in Finished Waters by the Purge and Trap Method," Method 501.1 and "Part II: The Analysis of Trihalomethanes in Drinking Water by Liquid/Liquid Extraction," Method 501.2 in 40 CFR Part 141, Appendix C (45 FR 68672; November 29, 1979). The availability of these incorporations by reference are given in paragraph (b) of this section.

(e) * * *

(2) Analyses conducted to determine compliance with paragraph (e)(1) of this section shall be made in accordance with the methods described in the applicable sections of "Standard

Methods for the Examination of Water and Wastewater," 14th Ed. (1975), and "Interim Radiochemical Methodology for Drinking Water," Environmental Monitoring and Support Laboratory, EPA-600/4-75-008 (Revised), March 1976, U.S. Environmental Protection Agency, both of which are incorporated by reference. The availability of these incorporations by reference is given in paragraph (b) of this section.

PART 114—ACIDIFIED FOODS

4. Part 114 is amended in § 114.90 by removing the footnotes, revising paragraph (a)(4)(ii), revising the fifth sentence and adding a new sentence after the revised sentence in paragraph (a)(4)(iv), revising the fourth sentence and adding a new sentence after the revised sentence in paragraph (a)(4)(v), and revising paragraph (c), to read as follows:

§ 114.90 Methodology.

(a) * * *

(4) * * *

(ii) Standardize the instrument and electrodes with commercially prepared standard 4.0 pH buffer or with freshly prepared 0.05 molar potassium acid phthalate buffer solution prepared as outlined in "Official Methods of Analysis of the Association of Official Analytical Chemists," 12th Ed. (1975), section 50.007(c), page 943, which is incorporated by reference. Copies are available from the Division of Food Technology, Bureau of Foods (HFF-210), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408. Note the temperature of the buffer solution and set the temperature compensator control at the observed temperature [room temperature is near 25° C].

(iv) * * * To check the operation of the pH meter, check the pH reading using another standard buffer such as one having a pH of 7.0, or check it with freshly prepared 0.025 molar phosphate solution prepared as outlined in "Official Methods of Analysis of the Association of Official Analytical Chemists," 12th Ed. (1975), section 50.007(e), page 943, which is incorporated by reference. The availability of this incorporation by reference is given in paragraph (a)(4)(ii) of this section. * * *

(v) * * * Electrodes should be rinsed with water, then blotted and immersed in a pH 9.18 borax buffer prepared as

outlined in "Official Methods of Analysis of the Association of Official Analytical Chemists," 12th Ed. (1975), section 50.007(f), page 943, which is incorporated by reference. The availability of this incorporation by reference is given in paragraph (a)(4)(ii) of this section. * * *

(c) *Titrateable acidity.* Acceptable methods for determining titrateable acidity are described in "Official Methods of Analysis of the Association of Official Analytical Chemists," 12th Ed. (1975), sections 22.060–22.061, page 401, which is incorporated by reference. The availability of this incorporation by reference is given in paragraph (a)(4)(ii) of this section. The procedure for preparing and standardizing the sodium hydroxide solution is described in the same publication, sections 50.032–50.035, page 946, which is also incorporated by reference and available as set forth in paragraph (a)(4)(ii) of this section.

PART 122—SMOKED AND SMOKE-FLAVORED FISH

5. Part 122 is amended in § 122.3 by revising paragraph (d), to read as follows:

§ 122.3 Definitions.

(d) "Water phase salt" means the percent salt (sodium chloride) in the finished product as determined by the method described in sections 18.009 and 18.010 of the "Official Methods of Analysis of the Association of Agricultural Chemists," 10th Ed., page 273 (1965), which is incorporated by reference, multiplied by 100 and divided by the percent salt (sodium chloride) plus the percent moisture in the finished product as determined by the method described in section 18.006 of that edition. Copies of the material incorporated by reference are available from the Division of Food Technology, Bureau of Foods (HFF-210), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

PART 131—MILK AND CREAM

6. Part 131 is amended as follows:
a. In § 131.110 by removing the footnote, removing the "2" in paragraph (d)(1), (2), and (3), and revising the introductory text of paragraph (d), to read as follows:

§ 131.110 Milk.

* * * * *

(d) *Methods of analysis.* Referenced methods are from "Official Methods of Analysis of the Association of Official Analytical Chemists," 11th Ed. (1970), which is incorporated by reference. Copies are available from the Division of Food Technology, Bureau of Foods (HFF-210), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 110 L St. NW., Washington, DC 20408.

b. In § 131.111 by removing the footnote and revising the introductory text of paragraph (f), to read as follows:

§ 131.111 Acidified milk.

* * * * *

(f) *Methods of analysis.* The following referenced methods of analysis are from "Official Methods of Analysis of the Association of Official Analytical Chemists," 13th Ed. (1980), which is incorporated by reference. Copies are available from the Association of Official Analytical Chemists, P.O. Box 540, Benjamin Franklin Station, Washington, DC 20044, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

c. In § 131.112 by removing the footnote and revising the introductory text of paragraph (e), to read as follows:

§ 131.112 Cultured milk.

* * * * *

(e) *Methods of analysis.* The following referenced methods of analysis are from "Official Methods of Analysis of the Association of Official Analytical Chemists," 13th Ed. (1980), which is incorporated by reference. Copies may be obtained from the Association of Official Analytical Chemists, P.O. Box 540, Benjamin Franklin Station, Washington, DC 20044, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

d. In § 131.115 by removing the footnote, removing the "2" in paragraph (d)(1), (2), and (3), and revising the introductory text of paragraph (d), to read as follows:

§ 131.115 Concentrated milk.

* * * * *

(d) *Methods of analysis.* Referenced methods are from "Official Methods of Analysis of the Association of Official Analytical Chemists," 11th Ed. (1970), which is incorporated by reference. Copies are available from the Division

of Food Technology, Bureau of Foods (HFF-210), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

e. In § 131.120 by revising paragraph (c), to read as follows:

§ 131.120 Sweetened condensed milk.

(c) *Methods of analysis.* The milkfat content is determined by the method prescribed in "Official Methods of Analysis of the Association of Official Analytical Chemists," 12th Ed. (1975), section 16.167, under "Fat—Official Final Action," which is incorporated by reference. Copies are available from the Division of Food Technology, Bureau of Foods (HFF-210), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

f. In § 131.122 by removing the footnote and revising paragraph (c), to read as follows:

§ 131.122 Sweetened condensed skimmed milk.

(c) *Methods of analysis.* The milkfat content is determined by the method prescribed in "Official Methods of Analysis of the Association of Official Analytical Chemists," 12th Ed. (1975), section 16.167, under "Fat—Official Final Action," which is incorporated by reference. Copies are available from the Division of Food Technology, Bureau of Foods (HFF-210), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

g. In § 131.123 by removing the footnote, removing the "2" in paragraph (d)(1), (2), (3), and revising the introductory text of paragraph (d), to read as follows:

§ 131.123 Lowfat dry milk.

(d) *Methods of analysis.* The following referenced methods of analysis are from "Official Methods of Analysis of the Association of Official Analytical Chemists," 12th Ed. (1975), which is incorporated by reference. Copies are available from the Division of Food Technology, Bureau of Foods (HFF-210), Food and Drug

Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

h. In § 131.125 by removing the footnote, removing the "2" in paragraph (c)(1), and (2), and revising the introductory text of paragraph (c), to read as follows:

§ 131.125 Nonfat dry milk.

(c) *Methods of analysis.* The following referenced methods of analysis are from "Official Methods of Analysis of the Association of Official Analytical Chemists," 12th Ed. (1975), which is incorporated by reference. Copies are available from the Division of Food Technology, Bureau of Foods (HFF-210), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

i. In § 131.127 by removing the footnote, removing the "2" in paragraph (d)(1), (2), and (3), and revising the introductory text of paragraph (d), to read as follows:

§ 131.127 Nonfat dry milk fortified with vitamins A and D.

(d) *Methods of analysis.* The following referenced methods of analysis are from "Official Methods of Analysis of the Association of Official Analytical Chemists," 12th Ed. (1975), which is incorporated by reference. Copies are available from the Division of Food Technology, Bureau of Foods (HFF-210), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

j. In § 131.130 by removing the footnote, removing the "2" in paragraph (d)(1), (2), and (3), and revising the introductory text of paragraph (d), to read as follows:

§ 131.130 Evaporated milk.

(d) *Methods of analysis.* The following referenced methods of analysis are from "Official Methods of Analysis of the Association of Official Analytical Chemists," 12th Ed. (1975), which is incorporated by reference. Copies are available from the Division of Food Technology, Bureau of Foods (HFF-210), Food and Drug

Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

k. In § 131.132 by removing the footnote, removing the "2" in paragraph (d)(1), (2), and (3), and revising the introductory text of paragraph (d), to read as follows:

§ 131.132 Evaporated skimmed milk.

(d) *Methods of analysis.* The following referenced methods of analysis are from "Official Methods of Analysis of the Association of Official Analytical Chemists," 12th Ed. (1975), which is incorporated by reference. Copies are available from the Division of Food Technology, Bureau of Foods (HFF-210), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

l. In § 131.135 by removing the footnote, removing the "2" from paragraph (d)(1), (2), and (3), and revising the introductory text of paragraph (d), to read as follows:

§ 131.135 Lowfat milk.

(d) *Methods of analysis.* Referenced methods are from "Official Methods of Analysis of the Association of Official Analytical Chemists," 11th Ed. (1970), which is incorporated by reference. Copies are available from the Division of Food Technology, Bureau of Foods (HFF-210), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

m. In § 131.136 by revising the introductory text of paragraph (f), to read as follows:

§ 131.136 Acidified lowfat milk.

(f) *Methods of analysis.* The following referenced methods of analysis are from "Official Methods of Analysis of the Association of Official Analytical Chemists," 13th Ed. (1980), which is incorporated by reference. Copies are available from the Association of Official Analytical Chemists, P.O. Box 540, Benjamin Franklin Station, Washington, DC 20044, or available for inspection at the Office of the Federal

Register, 1100 L St. NW., Washington, DC 20408.

n. In § 131.138 by revising the introductory text of paragraph (e), to read as follows:

§ 131.138 Cultured lowfat milk.

(e) *Methods of analysis.* The following referenced methods of analysis are from "Official Methods of Analysis of the Association of Official Analytical Chemists," 13th Ed. (1980), which is incorporated by reference. Copies may be obtained from the Association of Official Analytical Chemists, P.O. Box 540, Benjamin Franklin Station, Washington, DC 20044, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

o. In § 131.143 by removing the footnote, removing the "2" from paragraph (d)(1), (2), and (3), and revising the introductory text of paragraph (d), to read as follows:

§ 131.143 Skim milk.

(d) *Methods of analysis.* Referenced methods are from "Official Methods of Analysis of the Association of Official Analytical Chemists," 11th Ed. (1970), which is incorporated by reference. Copies are available from the Division of Food Technology, Bureau of Foods (HFF-210), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

p. In § 131.144 by revising the introductory text of paragraph (f), to read as follows:

§ 131.144 Acidified skim milk.

(f) *Methods of analysis.* The following referenced methods of analysis are from "Official Methods of Analysis of the Association of Official Analytical Chemists," 13th Ed. (1980), which is incorporated by reference. Copies are available from the Association of Official Analytical Chemists, P.O. Box 540, Benjamin Franklin Station, Washington, DC 20044, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

q. In § 131.146 by removing the footnote and revising the introductory text of paragraph (e), to read as follows:

§ 131.146 Cultured skim milk.

(e) *Methods of analysis.* The following referenced methods of analysis are from "Official Methods of Analysis of the Association of Official Analytical Chemists," 13th Ed. (1980), which is incorporated by reference. Copies are available from the Association of Official Analytical Chemists, P.O. Box 540, Benjamin Franklin Station, Washington, DC 20044, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

r. In § 131.147 by removing the footnote, removing the "2" in paragraph (d)(1), (2), and (3), and revising the introductory text of paragraph (d), to read as follows:

§ 131.147 Dry whole milk.

(d) *Methods of analysis.* The following referenced methods of analysis are from "Official Methods of Analysis of the Association of Official Analytical Chemists," 12th Ed. (1975), which is incorporated by reference. Copies are available from the Division of Food Technology, Bureau of Foods (HFF-210), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

s. In § 131.149 by removing the "2" from paragraph (c)(1) and (2) and revising the introductory text of paragraph (c), to read as follows:

§ 131.149 Dry cream.

(c) *Methods of analysis.* The following referenced methods of analysis are from "Official Methods of Analysis of the Association of Official Analytical Chemists," 12th Ed. (1975), which is incorporated by reference. Copies are available from the Division of Food Technology, Bureau of Foods (HFF-210), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

t. In § 131.150 by removing the footnote and revising paragraph (c), to read as follows:

§ 131.150 Heavy cream.

(c) *Methods of analysis.* The milkfat content is determined by the method prescribed in "Official Methods of

Analysis of the Association of Official Analytical Chemists," 11th Ed. (1970), section 16.114, under "Fat, Roese-Gottlieb Method—Official Final Action," which is incorporated by reference. Copies are available from the Division of Food Technology, Bureau of Foods (HFF-210), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

u. In § 131.155 by revising paragraph (c), to read as follows:

§ 131.155 Light cream.

(c) *Method of analysis.* The milkfat content is determined by the method prescribed in "Official Methods of Analysis of the Association of Official Analytical Chemists," 11th Ed. (1970), section 16.114, under "Fat, Roese-Gottlieb Method—Official Final Action," which is incorporated by reference. Copies are available from the Division of Food Technology, Bureau of Foods (HFF-210), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

v. In § 131.157 by removing the footnote and revising paragraph (c), to read as follows:

§ 131.157 Light whipping cream.

(c) *Methods of analysis.* The milkfat content is determined by the method prescribed in "Official Methods of Analysis of the Association of Official Analytical Chemists," 11th Ed. (1970), section 16.114, under "Fat, Roese-Gottlieb Method—Official Final Action," which is incorporated by reference. Copies are available from the Division of Food Technology, Bureau of Foods (HFF-210), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

w. In § 131.160 by removing the footnote and revising the introductory text of paragraph (c), to read as follows:

§ 131.160 Sour cream.

(c) *Methods of analysis.* Referenced methods in paragraph (c) (1) and (2) of this section are from "Official Methods

of Analysis of the Association of Official Analytical Chemists," 11th Ed. (1970), which is incorporated by reference. Copies are available from the Division of Food Technology, Bureau of Foods (HFF-210), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

x. In § 131.162 by revising the introductory text of paragraph (c), to read as follows:

§ 131.162 Acidified sour cream.

(c) *Methods of analysis.* Referenced methods in paragraph (c) (1) and (2) of this section are from "Official Methods of Analysis of the Association of Official Analytical Chemists," 11th Ed. (1970), which is incorporated by reference. Copies are available from the Division of Food Technology, Bureau of Foods (HFF-210), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

y. In § 131.170 by removing the footnote and revising the introductory text of paragraph (f), to read as follows:

§ 131.170 Eggnog.

(f) *Methods of analysis.* The following referenced methods of analysis are from "Official Methods of Analysis of the Association of Official Analytical Chemists," 13th Ed. (1980), which is incorporated by reference. Copies are available from the Association of Official Analytical Chemists, P.O. Box 540, Benjamin Franklin Station, Washington, DC 20044, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

z. In § 131.180 by removing the footnote and revising paragraph (c), to read as follows:

§ 131.180 Half-and-half.

(c) *Methods of analysis.* The milkfat content is determined by the method prescribed in "Official Methods of Analysis of the Association of Official Analytical Chemists," 11th Ed. (1970), section 16.114, under "Fat, Roesse-Gottlieb Method—Official Final Action," which is incorporated by reference. Copies are available from the Division of Food Technology, Bureau of

Foods (HFF-210), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

aa. In § 131.185 by revising the introductory text of paragraph (c), to read as follows:

§ 131.185 Sour half-and-half.

(c) *Methods of analysis.* Referenced methods in paragraph (c) (1) and (2) of this section are from "Official Methods of Analysis of the Association of Official Analytical Chemists," 11th Ed. (1970), which is incorporated by reference. Copies are available from the Division of Food Technology, Bureau of Foods (HFF-210), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

bb. In § 131.187 by removing the footnote and revising the introductory text of paragraph (c), to read as follows:

§ 131.187 Acidified sour half-and-half.

(c) *Methods of analysis.* Referenced methods in paragraph (c) (1) and (2) of this section are from "Official Methods of Analysis of the Association of Official Analytical Chemists," 11th Ed. (1970), which is incorporated by reference. Copies are available from the Division of Food Technology, Bureau of Foods (HFF-210), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

cc. In § 131.200 by removing the footnote and revising the introductory text of paragraph (d), to read as follows:

§ 131.200 Yogurt.

(d) *Methods of analysis.* The following referenced methods of analysis are from "Official Methods of Analysis of the Association of Official Analytical Chemists," 13th Ed. (1980), which is incorporated by reference. Copies are available from the Association of Official Analytical Chemists, P.O. Box 540, Benjamin Franklin Station, Washington, DC 20044, or available for inspection at the Office

of the Federal Register, 1100 L St. NW., Washington, DC 20408.

dd. In § 131.203 by removing the footnote and revising the introductory text of paragraph (d), to read as follows:

§ 131.203 Lowfat yogurt.

(d) *Methods of analysis.* The following referenced methods of analysis are from "Official Methods of Analysis of the Association of Official Analytical Chemists," 13th Ed. (1980), which is incorporated by reference. Copies are available from the Association of Official Analytical Chemists, P.O. Box 540, Benjamin Franklin Station, Washington, DC 20044, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

ee. In § 131.206 by removing the footnote and revising the introductory text of paragraph (d), to read as follows:

§ 131.206 Nonfat yogurt.

(d) *Methods of analysis.* The following referenced methods of analysis are from "Official Methods of Analysis of the Association of Official Analytical Chemists," 13th Ed. (1980), which is incorporated by reference. Copies are available from the Association of Official Analytical Chemists, P.O. Box 540, Benjamin Franklin Station, Washington, DC 20044, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

PART 133—CHEESES AND RELATED CHEESE PRODUCTS

7. Part 133 is amended:

a. In § 133.113 by revising paragraph (c), to read as follows:

§ 133.113 Cheddar cheese.

(c) Determine moisture by the method prescribed on page 262 (15.124) [Ed. note, 10th Ed. (1965), p. 247 section 15.157], under "Moisture—Official," and milk fat by the method prescribed on page 263 (15.131) [Ed. note, 10th Ed. (1965), p. 248, section 15.164], under "Fat—Official," of "Official Methods of Analysis of the Association of Official Agricultural Chemists," 7th Ed. (1950), which is incorporated by reference. Copies are available from the Division of Food Technology, Bureau of Foods (HFF-210), Food and Drug Administration, 200 C St. SW.,

Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408. Subtract the percent of moisture found from 100; divide the remainder into the percent milkfat found. The quotient, multiplied by 100, shall be considered to be the percent of milkfat contained in the solids.

b. In § 133.129 by removing the footnote and revising paragraph (a), to read as follows:

§ 133.129 Dry curd cottage cheese.

(a) Cottage cheese dry curd is the soft uncured cheese prepared by the procedure set forth in paragraph (b) of this section. The finished food contains less than 0.5 percent milkfat. It contains not more than 80 percent of moisture, as determined by the method prescribed under "Moisture—Official," on page 272 of "Official Methods of Analysis of the Association of Official Analytical Chemists," 11th Ed. (1970), which is incorporated by reference. Copies are available from the Division of Food Technology, Bureau of Foods (HFF-210), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

c. In § 133.133 by revising paragraph (a), to read as follows:

§ 133.133 Cream cheese.

(a) Cream cheese is the soft uncured cheese prepared by the procedure set forth in paragraph (b) of this section. The finished cream cheese contains not less than 33 percent of milkfat and not more than 55 percent of moisture, as determined, respectively, by the methods prescribed under "Fat—Official" on page 302 and under "Moisture—Official" on page 301 of "Official and Tentative Methods of Analysis of the Association of Official Analytical Chemists," 5th Ed. (1940), which is incorporated by reference. (These methods appear in the 10th Ed. (1965), p. 248, section 15.164; p. 247, section 15.157, respectively.) Copies of the material incorporated by reference are available from the Division of Food Technology, Bureau of Foods (HFF-210), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

d. In § 133.162 by revising paragraph (a), to read as follows:

§ 133.162 Neufchatel cheese.

(a) Neufchatel cheese is the soft uncured cheese prepared by the procedure set forth in paragraph (b) of this section. The finished neufchatel cheese contains not less than 20 percent but less than 33 percent of milkfat and not more than 65 percent of moisture, as determined, respectively, by the methods prescribed under "Fat—Official" on page 302 and under "Moisture—Official" on page 301 of "Official and Tentative Methods of Analysis of the Association of Official Analytical Chemists," 5th Ed. (1940), which is incorporated by reference. (These methods appear in the 10th Ed. (1965), p. 248, section 15.164; p. 247, section 15.157, respectively.) Copies of the material incorporated by reference are available from the Division of Food Technology, Bureau of Foods (HFF-210), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

PART 135—FROZEN DESSERTS

8. Part 135 is amended:

a. In § 135.110 by removing the footnote and revising paragraph (d), to read as follows:

§ 135.110 Ice cream and frozen custard.

(d) *Methods of analysis.* The fat content shall be determined by the method prescribed in "Official Methods of Analysis of the Association of Official Analytical Chemists," 12th Ed. (1975), section 16.228, under "Fat: Roesse-Gottlieb Method—Official Final Action," which is incorporated by reference. Copies are available from the Division of Food Technology, Bureau of Foods (HFF-210), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

b. In § 135.130 by removing the footnote and revising the introductory text of paragraph (c), to read as follows:

§ 135.130 Mellorine.

(c) *Methods of analysis.* Fat and protein content, and the PER shall be determined by following the methods contained in "Official Methods of Analysis of the Association of Official Analytical Chemists," 12th Ed. (1975), which is incorporated by reference. Copies are available from the Division

of Food Technology, Bureau of Foods (HFF-210), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

PART 136—BAKERY PRODUCTS

9. Part 136 is amended:

a. In § 136.110 by removing the footnote and revising paragraph (d), to read as follows:

§ 136.110 Bread, rolls, and buns.

(d) Total solids are determined by the method prescribed in "Official Methods of Analysis of the Association of Official Analytical Chemists," (AOAC), 12th Ed. (1975), section 14.083(a), which is incorporated by reference, except that if the baked unit weighs 1 pound or more, one entire unit is used for the determination; if the baked unit weighs less than 1 pound, enough units to weight 1 pound or more are used. Copies of the material incorporated by reference are available from the Division of Food Technology, Bureau of Foods (HFF-210), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

b. In § 136.160 by removing the footnote and revising paragraph (a)(5), to read as follows:

§ 136.160 Raisin bread, rolls, and buns.

(a) * * *

(5) The total solids are determined by the method prescribed in § 136.110(d), except that section 14.083(b) on page 235 of "Official Methods of Analysis of the Association of Official Analytical Chemists," 12th Ed. (1975), which is incorporated by reference, will apply. Copies are available from the Division of Food Technology, Bureau of Foods (HFF-210), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

PART 137—CEREAL FLOURS AND RELATED PRODUCTS

10. Part 137 is amended:

a. In § 137.105 by removing the footnote, revising the fourth sentence and adding a sentence after the revised

sentence in the introductory text of paragraph (a), and revising paragraph (c) (1) and (4), to read as follows:

§ 137.105 Flour.

(a) * * * When tested for granulation as prescribed in paragraph (c)(4) of this section, not less than 98 percent of the flour passes through a cloth having openings not larger than those of woven wire cloth designated "212 m (No. 70)" in Table I of "Annual Book of ASTM Standards, Part 30" published in 1972 by the American Society for Testing and Materials, which is incorporated by reference. Copies are available from University Microfilms International, 300 N. Zeeb Rd., Ann Arbor, MI 48106, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408. * * *

(c) * * *

(1) Ash is determined by the method prescribed in the book "Official and Tentative Methods of Analysis of the Association of Official Agricultural Chemists," 5th Ed. (1940), page 212, under "Method I—Official," which is incorporated by reference. [Ed. note, 10th Ed. (1965), p. 191, section 13.006.] Copies are available from the Division of Food Technology, Bureau of Foods (HFF-210), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408. Ash is calculated to a moisture-free basis by subtracting the percent of moisture in the flour from 100, dividing the remainder into the percent of ash, and multiplying the quotient by 100.

(4) Granulation is determined as follows: Use No. 70 sieve complying with specifications for wire cloth and sieve frames in "Standard Specifications for Sieves," published March 1, 1940, in L.C. 584 of the U.S. Department of Commerce, National Bureau of Standards, which is incorporated by reference. Copies are available from the Division of Food Technology, Bureau of Foods (HFF-210), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408. Attach bottom pan to sieve in Ro-Tap sifter (or an equivalent sifter). Place half of a rubber ball or other sieving aid in the sieve. Pour 100 grams of the sample in the sieve and turn on the sifter with knocker. Sift exactly 5 minutes. Weigh the residue on the No. 70 sieve and convert to percentage.

b. In § 137.180 by revising the introductory text of paragraph (c), to read as follows:

§ 137.180 Self-rising flour.

(c) The method referred to in paragraph (a) of this section is the method prescribed in "Official and Tentative Methods of Analysis of the Association of Official Agricultural Chemists," 5th Ed. (1940), beginning on page 186 [Ed. note, 10th Ed. (1965), p. 119, sections 7.002, 7.003], under Gasometric Method with Chittick's Apparatus—Official," which is incorporated by reference (copies are available from the Division of Food Technology, Bureau of Foods (HFF-210), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408), except that the following procedure is substituted for the procedure specified therein under "6—Determination":

c. In § 137.190 by revising the last sentence in the section and adding a sentence, to read as follows:

§ 137.190 Cracked wheat.

* * * Cracked wheat contains not more than 15 percent of the moisture as determined by the method prescribed in "Official and Tentative Methods of Analysis of the Association of Official Agricultural Chemists," 5th Ed. (1940), page 353 [Ed. note, 10th Ed. (1965), p. 327, sections 22.002, 22.003], under "Preparation of Sample—Official" and "Moisture I. Drying with Heat—Official," which is incorporated by reference. Copies are available from the Division of Food Technology, Bureau of Foods (HFF-210), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

d. In § 137.195 by revising the last sentence in the section and adding a sentence, to read as follows:

§ 137.195 Crushed wheat.

* * * Crushed wheat contains not more than 15 percent of moisture as determined by the method prescribed in "Official and Tentative Methods of Analysis of the Association of Official Agricultural Chemists," 5th Ed. (1940), page 353 [Ed. note, 10th Ed. (1965), p. 327, sections 22.002, 22.003], under "Preparation of Sample—Official" and "Moisture I. Drying with Heat—Official," which is incorporated by reference. Copies are available from the

Division of Food Technology, Bureau of Foods (HFF-210), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

e. In § 137.200 by revising paragraph (c)(1) and revising the first sentence and adding a sentence after the revised sentence in paragraph (c)(2), to read as follows:

§ 137.200 Whole wheat flour.

(c) * * *

(1) Moisture is determined by the method prescribed in "Official and Tentative Methods of Analysis of the Association of Official Agricultural Chemists," 5th Ed. (1940), page 211, under "Vacuum Oven Method—Official" [Ed. note, 10th Ed. (1965), p. 191, sections 13.002, 13.005], which is incorporated by reference. Copies are available from the Division of Food Technology, Bureau of Foods (HFF-210), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(2) The method referred to in paragraph (a) of this section is as follows: Use No. 8 and No. 20 sieves, having standard 8-inch full height frames, complying with the specifications for wire cloth and sieve frames in "Standard Specifications for Sieves," published March 1, 1940, in L.C. 548 of the U.S. Department of Commerce, National Bureau of Standards, which is incorporated by reference. Copies are available from the Division of Food Technology, Bureau of Foods (HFF-210), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408. * * *

f. In § 137.211 by revising the first sentence and adding a sentence after the revised sentence in paragraph (b)(2), to read as follows:

§ 137.211 White corn flour.

(b) * * *

(2) The method referred to in paragraph (a) of this section is as follows: Weigh 5 grams of sample into a tared truncated metal cone (top diameter 5 centimeters, bottom diameter 2 centimeters, height 4 centimeters), fitted at bottom with 70-mesh wire cloth complying with the specifications for No. 70 wire cloth in "Standard

Specifications for Sieves," published March 1, 1940, in L.C. 584 of the U.S. Department of Commerce, National Bureau of Standards, which is incorporated by reference. Copies are available from the Division of Food Technology, Bureau of Foods (HFF-210), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408. * * *

g. In § 137.230 by revising the first sentence and adding a sentence after the revised sentence in paragraph (b)(2), to read as follows:

§ 137.230 Corn grits.

(b) * * *

(2) The method referred to in paragraph (a) of this section is as follows: Use No. 10 and No. 25 sieves, having standard 8-inch diameter full-height frames, complying with the specifications for wire cloth and sieve frames in "Standard Specifications for Sieves," published March 1, 1940, in L.C. 584 of the U.S. Department of Commerce, National Bureau of Standards, which is incorporated by reference. Copies are available from the Division of Food Technology, Bureau of Foods (HFF-210), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408. * * *

h. In § 137.250 by revising paragraph (b)(1) and by revising the first sentence and adding a sentence after the revised sentence in paragraph (b)(2), to read as follows:

§ 137.250 White corn meal.

(b) * * *

(1) For the purposes of this section moisture is determined by the method prescribed in "Official and Tentative Methods of Analysis of the Association of Official Agricultural Chemists," 6th Ed., p. 259, sections 20.70 and 20.71, which is incorporated by reference [Ed. note, 10th Ed. (1965), p. 202, sections 13.058, 13.059]; fat is determined by the method prescribed on pages 259 and 260, sections 20.70 and 20.73 [Ed. note, 10th Ed. (1965), p. 202, sections 13.058, 13.063]; and crude fiber determined by the method prescribed on pages 259 and 260, sections 20.70 and 20.74 [Ed. note, 10th Ed. (1965), p. 202, sections 13.058, 13.061]. Copies of the material incorporated by reference are available from the Division of Food Technology, Bureau of Foods (HFF-210), Food and Drug Administration, 200 C St. SW.,

Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(2) The method referred to in paragraph (a) of this section is as follows: Use No. 12 and No. 25 sieves, having standard 8-inch diameter, full-height frames, complying with the specifications for wire cloth and sieve frames in "Standard Specifications for Sieves," published March 1, 1940, in L.C. 584 of the U.S. Department of Commerce, National Bureau of Standards, which is incorporated by reference. Copies are available from the Division of Food Technology, Bureau of Foods (HFF-210), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408. * * *

i. In § 137.270 by revising the introductory test of paragraph (b), to read as follows:

§ 137.270 Self-rising white corn meal.

(b) The method referred to in paragraph (a) of this section is the method prescribed in "Official and Tentative Methods of Analysis of the Association of Official Agricultural Chemists," 6th Ed., beginning on page 208 [Ed. note, 10th Ed. (1965), p. 119, sections 7.002, 7.003], under "Gasometric Method (2) with Chittick's Apparatus—Official," which is incorporated by reference (copies are available from the Division of Food Technology, Bureau of Foods (HFF-210), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408), except that the following procedure is substituted for the procedure specified therein under "17.6—Determination":

j. In § 137.300 by revising the first sentence and adding a sentence after the revised sentence in paragraph (b)(2), to read as follows:

§ 137.300 Farina.

(b) * * *

(2) The method referred to in paragraph (a) of this section is as follows: Use No. 20 and No. 100 sieves, having standard 8-inch full-height frames, complying with the specifications for wire cloth and sieve frames in "Standard Specifications for Sieves," published March 1, 1940, in L.C. 584 of the U.S. Department of Commerce, National Bureau of

Standards, which is incorporated by reference. Copies are available from the Division of Food Technology, Bureau of Foods (HFF-210), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408. * * *

k. In § 137.350 by revising the thirteenth sentence and adding a sentence after the revised sentence in paragraph (e), to read as follows:

§ 137.350 Enriched rice.

(e) * * * Dilute an aliquot of filtrate with 0.1 N hydrochloric acid, so that each milliliter contains about 0.2 microgram of thiamine, and determine thiamine by the method entitled "Rapid Fluorometric Method—Official," beginning with section 38.32 of the book "Official Methods of Analysis of the Association of Official Agricultural Chemists," 8th Ed. (1955) [Ed. note, 10th Ed. (1965), p. 761, section 39.028], which is incorporated by reference. Copies are available from the Division of Food Technology, Bureau of Foods (HFF-210), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408. * * *

PART 139—MACARONI AND NOODLE PRODUCTS

11. Part 139 is amended:

a. In § 139.110 by revising paragraph (a)(5), to read as follows:

§ 139.110 Macaroni products.

(a) * * *

(5) Gum gluten, in such quantity that the protein content of the finished food is not more than 13 percent by weight. The finished macaroni product contains not less than 87 percent of total solids as determined by the method prescribed in "Official and Tentative Methods of Analysis of the Association of Official Agricultural Chemists," 5th Ed. (1940), page 235 [Ed. note, 10th Ed. (1965), p. 209, section 13.115], under "Vacuum Oven Method—Official," which is incorporated by reference. Copies are available from the Division of Food Technology, Bureau of Foods (HFF-210), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

b. In § 139.117 by revising the introductory text of paragraph (a)(2), to read as follows:

§ 139.117 Enriched macaroni products with fortified protein.

(a) * * *

(2) Each such finished food, when tested by the methods described in the cited sections of the book "Official Methods of Analysis of the Association of Official Analytical Chemists," 11th Ed. (1970), which is incorporated by reference (copies are available from the Division of Food Technology, Bureau of Foods (HFF-210), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408), meets the following specifications:

c. In § 139.150 by revising paragraph (a)(4), to read as follows:

§ 139.150 Noodle products.

(a) * * *

(4) Concentrated glyceryl monostearate (containing not less than 90 percent monoester) in a quantity not exceeding 3 percent by weight of the finished food. The finished noodle product contains not less than 87 percent of total solids as determined by the method prescribed in "Official and Tentative Methods of Analysis of the Association of Official Agricultural Chemists," 5th Ed. (1940), page 235 [Ed. note, 10th Ed. (1965), p. 209, section 13.115], under "Vacuum Oven Method—Official," which is incorporated by reference. Copies are available from the Division of Food Technology, Bureau of Foods (HFF-210), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408. The total solids of noodle products contains not less than 5.5 percent by weight of the solids of egg, or egg yolk.

PART 145—CANNED FRUITS

12. Part 145 is amended:

a. In § 145.3 by removing the footnote, revising paragraph (m), and revising the third sentence and adding a sentence after the revised sentence in paragraph (n), to read as follows:

§ 145.3 Definitions.

(m) The procedure for determining the densities of the packing media means the following: The density of the packing medium, when measured 15 days or

more after packing, or the density of the blended homogenized slurry of the comminuted entire contents of the container, when measured less than 15 days after canning, is determined according to "Official Methods of Analysis of the Association of Official Analytical Chemists," 11th Ed. (1970), p. 526, which is incorporated by reference, section 31.011 (Solids) "By Means of the Refractometer—Official Final Action" (and 47.012 and 47.015) with result expressed as percent by weight of sucrose (degrees Brix) with correction for temperature to the equivalent at 20° C, but without correction for invert sugar or other substances. Copies of the material incorporated by reference are available from the Division of Food Technology, Bureau of Foods (HFF-210), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(n) The bottom of the sieve is woven-wire cloth which complies with the specifications for the No. 8 sieve set forth in the "Definitions of Terms and Explanatory Notes," p. xviii, of the "Official Methods of Analysis of the Association of Official Analytical Chemists," 11th Ed. (1970), which is incorporated by reference. The availability of this incorporation by reference is given in paragraph (m) of this section. * * *

b. In § 145.110 by removing the footnote and revising the last sentence and adding a sentence after the revised sentence in paragraph (a)(1), to read as follows:

§ 145.110 Canned applesauce.

(a) * * * (1) * * * The soluble solids content, measured by refractometer and expressed as percent sucrose (degrees Brix) with correction for temperature to the equivalent at 20° C (68° F), is not less than 9 percent (exclusive of the solids of any added optional nutritive carbohydrate sweeteners) as determined by the method prescribed in "Official Methods of Analysis of the Association of Official Analytical Chemists," 11th Ed. (1970), page 371, section 22.109, "Soluble Solids (by Refractometer) in Fresh and Canned Fruits, Jams, Marmalades, and Preserves—Official First Action," which is incorporated by reference, but without correction for invert sugar or other substances. Copies of the material incorporated by reference are available from the Division of Food Technology, Bureau of Foods (HFF-210), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for

inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

c. In § 145.125 by revising the third sentence and adding a sentence after the revised sentence in paragraph (b)(2)(ii), to read as follows:

§ 145.125 Canned cherries.

(b) * * *

(2) * * *

(ii) * * * The bottom of the sieve is No. 8 woven-wire cloth which complies with the specifications for such cloth set forth on page 3 of "Standard Specifications for Sieves," published October 25, 1938, by U.S. Department of Commerce, National Bureau of Standards, which is incorporated by reference. Copies are available from the Division of Food Technology, Bureau of Foods (HFF-210), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408. * * *

d. In § 145.135 by revising the first sentence and adding a sentence after the revised sentence in paragraph (b)(1)(i) and revising the fourth sentence and adding a sentence after the revised sentence in paragraph (c)(1), to read as follows:

§ 145.135 Canned fruit cocktail.

(b) * * *

(1) * * *

(i) Not more than 20 percent by weight of the units in the container of peach or pear, or of pineapple if the units thereof are diced, are more than ¼ inch in greatest edge dimension, or pass through the meshes of a sieve designated as ½ inch in Table I of "Standard Specifications for Sieves," published March 1, 1940, in L.C. 584 of the National Bureau of Standards, U.S. Department of Commerce, which is incorporated by reference. Copies are available from the Division of Food Technology, Bureau of Foods (HFF-210), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408. * * *

(c) * * *

(1) * * * The bottom of the sieve is woven-wire cloth which complies with the specifications for such cloth set forth under "2380 Micron (No. 8)" in Table I of "Standard Specifications for Sieves,"

published March 1, 1940, in L.C. 584 of the National Bureau of Standards, U.S. Department of Commerce, which is incorporated by reference. The availability of this incorporation by reference is given in paragraph (b)(1)(i) of this section. * * *

e. In § 145.145 by removing the footnotes, revising the introductory text of paragraph (a)(3)(iii), and revising the third sentence and adding a sentence after the revised sentence in paragraph (c)(2), to read as follows:

§ 145.145 Canned grapefruit.

(a) * * *

(3) * * *

(iii) The respective densities of packing media in paragraph (a)(3)(i)(d) to (j) of this section as measured on the refractometer, expressed as percent by weight sucrose (degrees Brix) with correction for temperature to the equivalent at 20° C (68° F), 15 days or more after the grapefruit are canned or the blended homogenized slurry of the comminuted entire contents of the container if canned for less than 15 days, according to the "Official Methods of Analysis of the Association of Official Analytical Chemists," 11th Ed. (1970), page 526, section 31.011 (Solids) "By Means of Refractometer—Official Final Action" (and 47.012 and 47.015), which is incorporated by reference (copies are available from the Division of Food Technology, Bureau of Foods (HFF-210), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408), without correction for invert sugar or other substances, are as follows:

(c) * * *

(2) * * * The bottom of the sieve is woven-wire cloth which complies with the specifications for the No. 8 sieve set forth in the "Definitions of Terms and Explanatory Notes," page xviii, of the "Official Methods of Analysis of the Association of Official Analytical Chemists," 11th Ed. (1970), which is incorporated by reference. The availability of this incorporation by reference is given in paragraph (a)(3)(iii) of this section. * * *

PART 146—CANNED FRUIT JUICES

13. Part 146 is amended:

a. In § 146.113 by revising the third sentence and adding a sentence after the revised sentence in paragraph (a) and revising the seventh sentence and

adding a sentence after the revised sentence in paragraph (b)(3), to read as follows:

§ 146.113 Canned fruit nectars.

(a) * * * The consistency of the finished product is such that the time of flow is not less than 30 seconds when tested by the method set forth in "Consistency Measurement of Fruit Nectars and Fruit Juice Products," published in the "Journal of the Association of Official Agricultural Chemists," p. 411, Vol. 42 (1959), which is incorporated by reference. Copies are available from the Division of Food Technology, Bureau of Foods (HFF-210), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408. * * *

(b) * * *

(3) * * * The weight of any fruit ingredient shall be determined as follows: Determine the percent of soluble solids in such fruit ingredient by the method prescribed in section 29.011 of "Official Methods of Analysis of the Association of Official Agricultural Chemists," 10th Ed. (1965), page 487, under "Solids," which is incorporated by reference. Copies are available from the Division of Food Technology, Bureau of Foods (HFF-210), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408. * * *

b. In § 146.114 by removing the footnote and revising the fifth sentence and adding a sentence after the revised sentence in paragraph (a)(1), to read as follows:

§ 146.114 Lemon juice.

(a) * * * (1) * * * When prepared from concentrated lemon juice, the finished food contains not less than 6 percent, by weight, of soluble solids taken as the refractometric sucrose value (of the filtrate), corrected to 20° C, but uncorrected for acidity, in accordance with the "International Scale of Refractive Indices of Sucrose Solutions" in table 52.012 of "Official Methods of Analysis of the Association of Official Analytical Chemists," 12th Ed. (1975), which is incorporated by reference, and has a titratable acidity content of not less than 4.5 percent, by weight, calculated as anhydrous citric acid. Copies of the material incorporated by reference are available from the Division of Food Technology, Bureau of Foods (HFF-210), Food and Drug Administration, 200 C St. SW.,

Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408. * * *

c. In § 146.120 by removing the footnote and revising the second sentence and adding a sentence after the revised sentence in paragraph (a), to read as follows:

§ 146.120 Frozen concentrate for lemonade.

(a) * * * The product contains not less than 48.0 percent by weight of soluble solids taken as the sucrose value determined by refractometer and corrected for acidity as given in "Correction of Refractometer Sucrose Readings for Citric Acid Content in Frozen Concentrate for Lemonade," by Yeatman, Senzel, and Springer, "Journal of the Association of Analytical Chemists," Vol. 59, page 368 (1976), which is incorporated by reference. Copies are available from the Division of Food Technology, Bureau of Foods (HFF-210), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408. * * *

d. In § 146.132 by removing the footnote and revising the seventh sentence and adding a sentence after the revised sentence in paragraph (a)(1), to read as follows:

§ 146.132 Grapefruit juice.

(a) * * * (1) * * * When prepared from concentrated grapefruit juice, exclusive of added sweeteners, the finished food contains not less than 9 percent, by weight, of soluble solids taken as the refractometric sucrose value (of the filtrate), corrected to 20° C, and corrected for acidity by the method prescribed in "Official Methods of Analysis of the Association of Official Analytical Chemists," 13th Ed. (1980), section 22.025, "Frozen Concentrate for Lemonade (12)," under the heading "Soluble Solids by Refractometer—Official First Action," which is incorporated by reference. Copies are available from the Association of Official Analytical Chemists, P.O. Box 540, Benjamin Franklin Station, Washington, DC 20044, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408. * * *

e. In § 146.185 by revising paragraph (b)(2)(i), to read as follows:

§ 148.185 Canned pineapple juice.

(b) * * *

(2) * * *

(i) Determine the degrees Brix of the canned pineapple juice by the method prescribed in "Official Methods of Analysis of the Association of Official Agricultural Chemists," "Solids By Means of Spindle—Official" [Ed. note, 10th Ed. (1965), p. 486, section 29.009], which is incorporated by reference. Copies are available from the Division of Food Technology, Bureau of Foods (HFF-210), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

PART 150—FRUIT BUTTERS, JELLIES, PRESERVES, AND RELATED PRODUCTS

14. Part 150 is amended:

a. In § 150.110 by revising paragraph (d) (3) and (5), to read as follows:

§ 150.110 Fruit butter.

(d) * * *

(3) The soluble solids content of the finished fruit butter is not less than 43 percent, as determined by the method prescribed in "Official Methods of Analysis of the Association of Official Analytical Chemists," 12th Ed. (1975), page 397, section 22.024, under "Soluble Solids (by Refractometer) in Fresh and Canned Fruits, Fruit Jellies, Marmalades, and Preserves—Official First Action," which is incorporated by reference, except that no correction is made for water-insoluble solids. Copies are available from the Division of Food Technology, Bureau of Foods (HFF-210), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(5) The weight of fruit juice or diluted fruit juice or concentrated fruit juice (optional ingredient, paragraph (c)(6)) from a fruit specified in paragraph (b)(1) of this section is the weight of such juice, as determined by the method prescribed in paragraph (d)(2) of this section, except that the percent of soluble solids is determined by the method prescribed in "Official Methods of Analysis of the Association of Official Analytical Chemists," 12th Ed. (1975), page 566, section 31.011, under "Solids by Means of Refractometer—Official Final Action," which is

incorporated by reference; the weight of diluted concentrated juice from any other fruit is the original weight of the juice before it was diluted or concentrated. The availability of this incorporation by reference is given in paragraph (d)(3) of this section.

b. In § 150.140 by removing the footnote and revising paragraph (d)(3), to read as follows:

§ 150.140 Fruit jelly.

(d) * * *

(3) The soluble-solids content of the finished jelly is not less than 65 percent, as determined by the method prescribed in "Official Methods of Analysis of the Association of Official Analytical Chemists," 11th Ed. (1970), page 526, section 31.001, "Solids by Means of Refractometer—Official Final Action," which is incorporated by reference. Copies are available from the Division of Food Technology, Bureau of Foods (HFF-210), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

c. In § 150.160 by removing the footnote and revising paragraph (d)(5), to read as follows:

§ 150.160 Fruit preserves and jams.

(d) * * *

(5) The soluble-solids content of the finished jam or preserve is not less than 65 percent, as determined by the method prescribed in "Official Methods of Analysis of the Association of Official Analytical Chemists," 11th Ed. (1970), page 371, section 22.019, "Soluble Solids (By Refractometer) in Fresh and Canned Fruits, Jams, Marmalades, and Preserves—Official First Action," which is incorporated by reference, except that no correction is made for water-insoluble solids. Copies of the material incorporated by reference are available from the Division of Food Technology, Bureau of Foods (HFF-210), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

PART 155—CANNED VEGETABLES

15. Part 155 is amended:

a. In § 155.3 by removing the footnote and revising paragraph (a), to read as follows:

§ 155.3 Definitions.

(a) The procedure for determining drained weight is set forth in the "Official Methods of Analysis of the Association of Official Analytical Chemists," 13th Ed. (1980), sections 32.001–32.003, which is incorporated by reference. Copies are available from the Association of Official Analytical Chemists, P.O. Box 540, Benjamin Franklin Station, Washington, DC 20044, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

b. In § 155.120 by removing the footnote and revising the fourth sentence and adding a sentence after the revised sentence in paragraph (b)(2)(i), to read as follows:

§ 155.120 Canned green beans and canned wax beans.

(b) * * *

(2) * * *

(i) * * * The bottom of the sieve is woven-wire cloth that complies with the specifications for such cloth set forth in the "Definitions of Terms and Explanatory Notes," page xviii, of the "Official Methods of Analysis of the Association of Official Analytical Chemists," 12th Ed. (1975), which is incorporated by reference. Copies are available from the Division of Food Technology, Bureau of Foods (HFF-210), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

c. In § 155.130 by removing the footnote, revising the fourth sentence and adding a sentence after the revised sentence in paragraph (b)(2)(i), and revising paragraph (c)(1)(ii), to read as follows:

§ 155.130 Canned corn.

(b) * * *

(2) * * *

(i) * * * The bottom of the sieve is woven-wire cloth which complies with the specifications for such sieve set forth in the "Definitions of Terms and Explanatory Notes," page xviii, of the "Official Methods of Analysis of the Association of Official Analytical Chemists," 11th Ed. (1970), which is incorporated by reference. Copies are available from the Division of Food Technology, Bureau of Foods (HFF-210), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or

available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408. * * *

(c) * * *

(1) * * *

(ii) In whole kernal corn, the drained weight of the corn ingredient, as determined by sections 32.001 and 32.002, "Canned Products—Drained Weight—Procedure," in "Official Methods of Analysis of the Association of Official Analytical Chemists," 11th Ed. (1970), page 559, which is incorporated by reference, shall not be less than 61 percent of the water capacity of the container. The availability of the incorporation by reference is given in paragraph (b)(2)(i) of this section.

d. In § 155.170 by removing the footnote and revising paragraph (b)(1)(vi), to read as follows:

§ 155.170 Canned peas.

(b) * * *

(1) * * *

(vi) *Alcohol-insoluble solids.* The alcohol-insoluble solids of smooth-skin or substantially smooth-skin peas, such as Alaska-type peas or hybrids having similar characteristics, may not be more than 23.5 percent and, of sweet green wrinkled varieties or hybrid having similar characteristics, not more than 21 percent based on the procedure set forth in the "Official Methods of Analysis of the Association of Official Analytical Chemists," 13th Ed. (1980), section 30.012, which is incorporated by reference. Copies are available from the Association of Official Analytical Chemists, P.O. Box 540, Benjamin Franklin Station, Washington, DC 20044, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

e. In § 155.191 by removing the footnote and revising the third sentence and adding two sentences after the revised sentence in paragraph (a)(7), to read as follows:

§ 155.191 Tomato paste.

(a) * * *

(7) * * * It contains not less than 24.0 percent of natural tomato soluble solids as determined by the following method set forth in "Collaborative Study of the Determination of Soluble Solids in Tomato Products by Refractive Index Expressed as Percent Sucrose" by Frank C. Lamb, National Canners Association, 1950 Sixth St., Berkeley, CA 94710, "Journal of the Association of Official

Analytical Chemists," Vol. 52, No. 5 (1969), pages 1050-1054. Adopted as Official—First Action at the 1969 AOAC meeting: Determine the refractive index of the clear serum obtained from the product, corrected for temperature, converting the resultant index to "% Sucrose" in accordance with the "International Scale of Refractive Indices of Sucrose at 20° C," pages 828-830, Reference Tables 43.008 and 43.009 of the Book "Official Methods of Analysis of the Association of Official Agricultural Chemists," 10th Ed. (1965). The works cited are incorporated by reference. Copies are available from the Division of Food Technology, Bureau of Foods (HFF-210), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408. * * *

f. In § 155.192 by removing the footnote and revising the seventh sentence and adding two sentences after the revised sentence in paragraph (a)(4), to read as follows:

§ 155.192 Tomato puree.

(a) * * *

(4) * * * It contains not less than 8.0 percent, but less than 24.0 percent, of natural tomato soluble solids, as determined by the following method set forth in "Collaborative Study of the Determination of Soluble Solids in Tomato Products by Refractive Index Expressed as Percent Sucrose" by Frank C. Lamb, National Canners Association, 1950 Sixth St., Berkeley, CA 94710, "Journal of the Association of Official Analytical Chemists," Vol. 52, No. 5 (1969), pages 1050-1054. Adopted as Official—First Action at the 1969 AOAC meeting: Determine the refractive index of the clear serum obtained from the product, corrected for temperature, converting the resultant index to "% Sucrose" in accordance with the "International Scale of Refractive Indices of Sucrose at 20° C," pages 931-933, 935, Reference Tables 47.012, 47.013, and 47.015 of the book "Official Methods of Analysis of the Association of Official Analytical Chemists," 11th Ed. (1970). The works cited are incorporated by reference. Copies are available from the Division of Food Technology, Bureau of Foods (HFF-210), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408. * * *

g. In § 155.201 by revising the third sentence and adding a sentence after

the revised sentence in paragraph (c)(4), to read as follows:

§ 155.201 Canned mushrooms.

(c) * * *

(4) * * * The bottom of the sieve is woven-wire cloth which complies with the specifications for such cloth set forth under "2380 Micron (No. 8)" in Table I of "Standard Specifications for Sieves," published March 1, 1940, in L.C. 584 of the U.S. Department of Commerce, National Bureau of Standards, which is incorporated by reference. Copies are available from the Division of Food Technology, Bureau of Foods (HFF-210), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408. * * *

PART 160—EGGS AND EGG PRODUCTS

16. Part 160 is amended in § 160.180 by revising the first sentence and adding a sentence after the revised sentence, to read as follows:

§ 160.180 Egg yolks.

Egg yolks, liquid egg yolks, yolks, liquid yolks are yolks of eggs of the domestic hen, so separated from the whites thereof as to contain not less than 43 percent total egg solids, as determined by the method prescribed in "Official Methods of Analysis of the Association of Official Agricultural Chemists," 10th Ed. (1965), page 257, sections 16.002 and 16.003, under "Total Solids," which is incorporated by reference. Copies are available from the Division of Food Technology, Bureau of Foods (HFF-210), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408. * * *

PART 161—FISH AND SHELLFISH

17. Part 161 is amended:

a. In § 161.145 by revising the fourth sentence and adding a sentence after the revised sentence in paragraph (c)(3), to read as follows:

§ 161.145 Canned oysters.

(c) * * *

(3) * * * The bottom of the sieve is woven-wire cloth which complies with the specifications for such cloth set forth under "2380 Micron (No. 8)" in Table I of "Standard Specifications for Sieves,"

published March 1, 1940, in L.C. 584 of the U.S. Department of Commerce, National Bureau of Standards, which is incorporated by reference. Copies are available from the Division of Food Technology, Bureau of Foods (HFF-210), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408. * * *

b. In § 161.173 by removing the footnote and revising the sixth sentence and adding a sentence after the revised sentence in paragraph (c)(1), to read as follows:

§ 161.173 Canned wet pack shrimp in transparent or nontransparent containers.

(c) * * *

(1) * * * The bottom of the sieve is woven-wire cloth that complies with the specification for such cloth set forth as a 2.36-millimeter (No. 8) sieve in the "Definitions of Terms and Explanatory Notes," page xvi of the "Official Methods of Analysis of the Association of Official Analytical Chemists," 12th Ed. (1975), which is incorporated by reference. Copies are available from the Division of Food Technology, Bureau of Foods (HFF-210), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408. * * *

c. In § 161.175 by removing the footnote and revising paragraph (g)(1)(v), to read as follows:

§ 161.175 Frozen raw breaded shrimp.

(g) * * *

(1) * * *

(v) U.S. Standard Sieve No. 20, 12 inch diameter. The sieves shall comply with the specifications for wire cloth and sieve frames in "Standard Specifications for Sieves," published March 1, 1940, in L.C. 584 of the U.S. Department of Commerce, National Bureau of Standards, which is incorporated by reference. Copies are available from the Division of Food Technology, Bureau of Foods (HFF-210), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408. * * *

d. In § 161.190 by revising paragraph (a)(2), revising the second sentence and adding a sentence after the revised sentence in paragraph (a)(7), revising paragraph (a)(7)(iii), and revising the second sentence and adding a new

sentence after the revised sentence in paragraph (c)(3)(iv), to read as follows:

§ 161.190 Canned tuna.

(a) * * *

(2) The fish included in the class known as tuna fish are:

Thunnus thynnus—Bluefin tuna¹
Thunnus maccoyii—Southern bluefin tuna¹
Thunnus orientalis—Oriental tuna²
Thunnus germon—Albacore
Thunnus atlanticus—Blackfin tuna⁵
Parathunnus mebachii—Big-eyed tuna³
Neothunnus macropterus—Yellowfin tuna³
Neothunnus rarus—Northern bluefin tuna¹
Katsuwonus pelamis—Skipjack¹
Euthynnus alletteratus—Little tunny²
Euthynnus lineatus—Little tunny²
Euthynnus yaito—Kawakawa⁴

The description of each species will be found in the text to which reference is made. All of these materials are incorporated by reference. Copies are available from the Division of Food Technology, Bureau of Foods (HFF-210), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408. * * *

(7) * * * Pass the combined portions through a sieve fitted with woven-wire cloth of ¼-inch mesh which complies with the specifications for such wire cloth set forth in "Standard Specifications for Sieves," published March 1, 1940, in L.C. 584 of the U.S. Department of Commerce, National Bureau of Standards, which is incorporated by reference. Copies are available from the Division of Food Technology, Bureau of Foods (HFF-210), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408. * * *

¹ "A Comparison of the Bluefin Tunas, Genus Thunnus, from New England, Australia, and California," by H. C. Godsil and Edwin K. Holmberg, State of California, Department of Natural Resources, Division of Fish and Game, Bureau of Marine Fisheries, Fish Bulletin No. 77 (1950).

² "Contributions to the Comparative Study of the So-called Scombrotoxic Fishes," by Kamakichi Kishinouye, Journal of the College of Agriculture, Imperial University of Tokyo, Vol. VIII, No. 3 (1923).

³ "A Systematic Study of the Pacific Tunas," by H. C. Godsil and Robert D. Byers, State of California, Department of Natural Resources, Division of Fish and Game, Bureau of Marine Fisheries, Fish Bulletin No. 80 (1944).

⁴ "Descriptive Study of Certain Tuna-Like Fishes," by H. C. Godsil, State of California, Department of Fish and Game, Fish Bulletin No. 97.

⁵ "Comparative Anatomy and Systematics of the Tunas, Genus Thunnus," by Robert H. Gibbs, Jr. and Bruce B. Collette, Division of Fisheries, U.S. National Museum and Bureau of Commercial Fisheries, Fish and Wildlife Service, U.S. Department of the Interior, Fishery Bulletin Vol. 66, No. 1 (1967), pp. 65-130.

(iii) The standards with which comparisons are made are essentially neutral matte-finish standards, equivalent in luminous reflectance of light of 555μ wavelength to 33.7 percent of the luminous reflectance of magnesium oxide (for Munsell value 6.3) and 22.6 percent of the luminous reflectance of magnesium oxide (for Munsell value 5.3), as given by the relationship between Munsell value and luminous reflectance derived by a subcommittee of the Optical Society of America and published in the "Journal of the Optical Society of America," Vol. 33, page 406 (1943), which is incorporated by reference. Copies are available from the Division of Food Technology, Bureau of Foods (HFF-210), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408. * * *

(c) * * *

(3) * * *

(iv) * * * The mesh in the top sieve complies with the specifications for 1½-inch woven-wire cloth as set forth in "Standard Specifications for Sieves," published March 1, 1940, in L.C. 584 of the U.S. Department of Commerce, National Bureau of Standards, which is incorporated by reference. The availability of this incorporation by reference is given in paragraph (a)(7) of this section. * * *

PART 163—CACAO PRODUCTS

18. Part 163 is amended:

a. In § 163.110 by revising the last sentence and adding a sentence in paragraph (a), to read as follows:

§ 163.110 Cacao nibs.

(a) * * * The cacao shell content of cacao nibs is not more than 1.75 percent by weight (calculated to an alkali-free basis if they or the cacao beans from which they were prepared have been processed with alkali), as determined by the method prescribed under "Shell in Cacao Nibs—Tentative" beginning on page 208 [Ed. note, 10th Ed. (1965), p. 180, sections 12.009-12.013] of "Official and Tentative Methods of Analysis of the Association of Official Agricultural Chemists," 5th Ed. (1940), which is incorporated by reference. Copies are available from the Division of Food Technology, Bureau of Foods (HFF-210), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408. * * *

b. In § 163.111 by revising the last sentence and adding a sentence in paragraph (a)(5), to read as follows:

§ 163.111 Chocolate liquor.

(a) * * *

(5) * * * Unless the chocolate liquor is seasoned with butter, milk fat, or ground nut meats, the percentage of cacao fat is determined by the method prescribed under "Fat Method I—Official" beginning on page 202 [Ed. note, 10th Ed. (1965), p. 184, section 12.022] of "Official and Tentative Methods of Analysis of the Association of Official Agricultural Chemists," 5th Ed. (1940), which is incorporated by reference. Copies are available from the Division of Food Technology, Bureau of Foods (HFF-210), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

c. In § 163.112 by revising the last sentence and adding a sentence in paragraph (a)(4), to read as follows:

§ 163.112 Breakfast cocoa.

(a) * * *

(4) * * * The finished breakfast cocoa contains not less than 22 percent of cacao fat, as determined by the method prescribed under "Fat Method I—Official" beginning on page 202 [Ed. note, 10th Ed. (1965), p. 184, section 12.022] of "Official and Tentative Methods of Analysis of the Association of Official Agricultural Chemists," 5th Ed. (1940), which is incorporated by reference. Copies are available from the Division of Food Technology, Bureau of Foods (HFF-210), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

PART 164—TREE NUT AND PEANUT PRODUCTS

19. Part 164 is amended in § 164.150 by revising the last sentence and adding a sentence in paragraph (a), to read as follows:

§ 164.150 Peanut butter.

(a) * * * The fat content of the finished food shall not exceed 55 percent when determined as prescribed in section 25.004, "Crude Fat—Official, First Action," paragraph (a) "Direct method," in "Official Methods of Analysis of the Association of Official Agricultural Chemists," 10th Ed. (1965),

page 412, which is incorporated by reference. Copies are available from the Division of Food Technology, Bureau of Foods (HFF-210), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

PART 166—MARGARINE

20. Part 166 is amended in § 166.110 by removing the footnote and revising the first sentence and adding a sentence after the revised sentence in paragraph (a), to read as follows:

§ 166.110 Margarine.

(a) Margarine (or oleomargarine) is the food in plastic form or liquid emulsion, containing not less than 80 percent fat determined by the method prescribed under section 16.163, "Indirect Method," of the "Official Methods of Analysis of the Association of Official Analytical Chemists," 11th Ed. (1970), which is incorporated by reference. Copies are available from the Division of Food Technology, Bureau of Foods (HFF-210), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

PART 168—SWEETENERS AND TABLE SIRUPS

21. Part 168 is amended:

a. In § 168.111 by removing the footnote and revising the introductory text of paragraph (d), to read as follows:

§ 168.111 Dextrose monohydrate.

(d) For purposes of this section, the methods of analysis to be used to determine if the food meets the specifications of paragraph (b) (1) and (2) of this section are the following sections in "Official Methods of Analysis of the Association of Official Analytical Chemists," 11th Ed. (1970), which is incorporated by reference. Copies are available from the Division of Food Technology, Bureau of Foods (HFF-210), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

b. In § 168.120 by removing the footnote and revising the introductory text of paragraph (d), to read as follows:

§ 168.120 Glucose sirup.

(d) For purposes of this section, the methods of analysis to be used to determine if a food meets the specifications of paragraph (b) (1) and (2) of this section are the following sections in "Official Methods of Analysis of the Association of Official Analytical Chemists," 11th Ed. (1970), which is incorporated by reference. Copies are available from the Division of Food Technology, Bureau of Foods (HFF-210), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

c. In § 168.122 by removing the footnote and revising the introductory text of paragraph (d)(1), to read as follows:

§ 168.122 Lactose.

(d)(1) The methods of analysis to be used to determine whether the food meets the requirements of paragraph (b) (1), (2), and (3) of this section are the following sections in "Official Methods of Analysis of the Association of Official Analytical Chemists," 12th Ed. (1975), which is incorporated by reference. Copies are available from the Division of Food Technology, Bureau of Foods (HFF-210), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

PART 169—FOOD DRESSINGS AND FLAVORINGS

22. Part 169 is amended in § 169.3 by revising the third sentence and adding a sentence after the revised sentence in paragraph (b), to read as follows:

§ 169.3 Definitions.

(b) * * * The moisture content of vanilla beans is determined by the method prescribed in "Official Methods of Analysis of the Association of Official Agricultural Chemists," 9th Ed. (1960), sections 22.004 and 22.005 [Ed. note, 10th Ed. (1965), p. 327, sections 22.004, 22.005], which is incorporated by reference, except that the toluene used is blended with 20 percent by volume of benzene and the total distillation time is 4 hours. Copies of the material incorporated by reference are available

from the Division of Food Technology, Bureau of Foods (HFF-210), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408. * * *

The agency has determined that because these amendments do not make any substantive changes in the regulations but merely are editorial, bringing the incorporation by reference text into compliance with the drafting requirements of 1 CFR 51.6, 51.7, and 51.8, notice, public procedure, and delayed effective date are unnecessary. However, interested persons may, on or before April 19, 1982 submit to the Dockets Management Branch (address above), written comments regarding these amendments. Two copies of any comments are to be submitted, except individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document.

If the agency determines by the comments received that the amended text should be modified, a notice containing those modifications will be published in the Federal Register. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 26, 1982.

William F. Randolph,
Acting Associate Commissioner for
Regulatory Affairs.

[FR Doc. 82-7232 Filed 3-18-82; 8:45 am]

BILLING CODE 4160-01-M

21 CFR Parts 170, 172, 173, 175, 176, 177, 178, 179, 180, 181, 184, 186, and 189

[Docket No. 81N-0266]

Incorporation by Reference Regulatory Text

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the incorporating regulatory text in Title 21 of the Code of Federal Regulations, Parts 170-189, to make clear that an incorporation by reference is intended. This action is being taken to meet drafting requirements for incorporation by reference as set forth in Title I of the Code of Federal Regulations (1 CFR Part 51).

DATES: Effective March 19, 1982; written comments by April 19, 1982.

ADDRESS: Written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Vir D. Anand, Bureau of Foods (HFF-334), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-472-5690.

SUPPLEMENTARY INFORMATION: Title 1 of the Code of Federal Regulations (1 CFR 51.6, 51.7, and 51.8) requires, in addition to other information, specific language that makes clear that an incorporation by reference is intended.

FDA has reviewed all of its regulations that include materials incorporated by reference. The agency has concluded that it is necessary to amend a number of these regulations to bring them into compliance with the drafting requirements prescribed in 21 CFR 51.6, 51.7, and 51.8.

This notice amends Parts 170, 172, 173, 175, 176, 177, 178, 179, 180, 181, 184, 186, and 189 to include language that clearly indicates that an incorporation by reference is intended; contains a complete citation of the material incorporated; and contains a statement about the availability of the incorporated material. These amendments ensure compliance with the essential requirements specified in Title 1.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 701(a), 52 Stat. 1055 (21 U.S.C. 371(a))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10 (formerly 5.1; see 46 FR 26052; May 11, 1981)), Title 21 of the Code of Federal Regulations is amended as follows:

PART 170—FOOD ADDITIVES

1. Part 170 is amended in § 170.3 in the introductory tests of paragraphs (n) and (o) by revising the second sentence and adding a new sentence to read as follows:

§ 170.3 Definitions.

(n) * * * Individual food products will be included within these categories according to the detailed classifications lists contained in Exhibit 33B of the report of the National Academy of Sciences/National Research Council report, "A Comprehensive Survey of Industry on the Use of Food Chemicals Generally Recognized as Safe" (September 1972), which is incorporated by reference. Copies are available from the National Technical Information Service (NTIS), 5285 Port Royal Rd., Springfield, VA 22151, or available for

inspection at the Office of the Federal Register, 1100 L St. NW., Washington, D.C. 20408.

(o) * * * They are adopted from the National Academy of Sciences/National Research Council national survey of food industries, reported to the Food and Drug Administration under the contract title "A Comprehensive Survey of Industry on the Use of Food Chemicals Generally Recognized as Safe" (September 1972), which is incorporated by reference. Copies are available from the National Technical Information Service (NTIS), 5285 Port Royal Rd., Springfield, VA 22151, or available for inspection at the Office of the Federal Register, 1100 L St., NW., Washington, D.C. 20408.

PART 172—FOOD ADDITIVES PERMITTED FOR DIRECT ADDITION TO FOOD FOR HUMAN CONSUMPTION

2. Part 172 is amended as follows:
a. In § 172.215 by revising paragraph (b)(1) to read as follows:

§ 172.215 Coumarone-indene resin.

(b) * * *
(1) Soft point, ring and ball: 126° C minimum as determined by ASTM method E28-51T, "Tentative Method of Test for Softening Point by Ring and Ball Apparatus" (Revised 1951), which is incorporated by reference. Copies are available from University Microfilm International, 300 N. Zeeb Rd., Ann Arbor, MI 48106, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, D.C. 20408.

b. In § 172.250 by amending paragraph (b)(3) by revising footnote 1 under "APPARATUS" and by revising under "PROCEDURE" the paragraphs headed "Determination of boiling-point range" and "Determination of nonvolatile residue," to read as follows:

§ 172.250 Petroleum naphtha.

(b) * * *
(3) * * *
* As determined by procedure using potassium chromate for reference standard and described in National Bureau of Standards Circular 484, Spectrophotometry, U.S. Department of Commerce, (1949). The accuracy is to be determined by comparison with the standard values at 290, 345, and 400 millimicrons. The procedure is incorporated by reference. Copies of the material incorporated by reference are available from the Division of Food and Color Additives,

Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

Determination of boiling-point range. Use ASTM method D86-67, "Standard Method of Test for Distillation of Petroleum Products" (Revised 1962), which is incorporated by reference. Copies are available from University Microfilms International, 300 N. Zeeb Rd., Ann Arbor, MI 48106, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

Determination of nonvolatile residue. For hydrocarbons boiling below 250° F, determine the nonvolatile residue by ASTM method D1353-64, "Standard Method of Test for Nonvolatile Matter in Volatile Solvents for Use in Paint, Varnish, Lacquer, and Related Products" (Revised 1964); for those boiling above 250° F, use ASTM method D381, "Standard Method of Test for Existent Gum in Fuels by Jet Evaporation" (Revised 1965), which methods are incorporated by reference. Copies of the material incorporated by reference are available from the University Microfilms International, 300 N. Zeeb Rd., Ann Arbor, MI 48106, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

c. In § 172.320 by revising the introductory text of paragraph (b) (1) and (2), the last portion of paragraph (c)(1) beginning with "recommended by"; and the first sentence of paragraph (d) and by adding a new sentence immediately thereafter to read as follows:

§ 172.320 Amino acids.

(b) * * *
(1) As found in "Food Chemicals Codex," National Academy of Sciences-National Research Council (NAS-NRC), 2d Ed. (1972), which is incorporated by reference (copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408) for the following:

(2) As found in "Specifications and Criteria for Biochemical Compounds," NAS/NRC Publication, 3rd Ed. (1972), which is incorporated by reference (copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408) for the following:

(c) * * *
(1) * * * recommended by the National Academy of Sciences in "Recommended Dietary Allowances," NAS Publication No. 1694, 7th Ed. (1968), which is incorporated by reference. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(d) Compliance with the limitations concerning PER under paragraph (c) of this section shall be determined by the method described in secs. 39.166-39.170, "Official Methods of Analysis of the Association of Official Analytical Chemists," 11th Ed. (1970), which is incorporated by reference. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408. * * *

d. In § 172.372(d) by revising the first sentence and by adding a new sentence immediately thereafter to read as follows:

§ 172.372 N-Acetyl-L-methionine.

(d) Compliance with the limitations concerning PER under paragraph (c) of this section shall be determined by the method described in secs. 43.183-43.187, "Official Methods of Analysis of the Association of Official Analytical Chemists," 12th Ed. (1975), which is incorporated by reference. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408. * * *

e. In § 172.385(c) (1), (2), and (3) by adding a new sentence at the end of each to read as follows:

§ 172.385 Whole fish protein concentrate.

(c) * * *
(1) * * * The 10th Edition is incorporated by reference, and copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for

inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(2) * * * See paragraph (c)(1) of this section for availability of the material incorporated by reference.

(3) * * * See paragraph (c)(1) of this section for availability of the material incorporated by reference.

§ 172.510 [Amended]

f. In § 172.510 *Natural flavoring substances and natural substances used in conjunction with flavors*, paragraph (b) is amended by revising footnote 1 at the end of the paragraph, to read as follows:

¹ As determined by using the method (or, in other than alcoholic beverages, a suitable adaptation thereof) in sec. 9.091 of the "Official Methods of Analysis of the Association of Official Agricultural Chemists," 10th Ed. (1965), which is incorporated by reference. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

g. In § 172.615, paragraph (a) is amended in the table by revising the entry for "Paraffin," to read as follows:

§ 172.615 Chewing gum base.

(a) * * *

Masticatory Substances

Natural (Coagulated or Concentrated Latexes) of Vegetable Origin

Synthetic	Specifications
Paraffin * * *	Synthesized by Fischer-Tropsch process from carbon monoxide and hydrogen which are catalytically converted to a mixture of paraffin hydrocarbon. Lower molecular weight fractions are removed by distillation. The residue is hydrogenated and further treated by percolation through activated charcoal. The product has a congealing point of 200°-210° F as determined by ASTM method D938-49—Congealing Point of Pharmaceutical Petroleum, ASTM method D721-56T—Tentative Method of Test for Oil Content of Petroleum Waxes and ASTM method E131-61T—Definition of Terms and Symbols Relating to Absorption Spectroscopy (Revised 1961), which are incorporated by reference. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

h. In § 172.804(b)(2) by revising that portion of the first sentence beginning with "in accordance" and adding after it a new sentence to read as follows:

§ 172.804 Aspartame.

(b) * * *
(2) * * * in accordance with the test for optical rotation described in the "Food Chemicals Codex," 2d Ed. (1972), page 939, which is incorporated by reference. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

i. In § 172.810, the introductory text is revised to read as follows:

§ 172.810 Diethyl sodium sulfosuccinate.

The food additive diethyl sodium sulfosuccinate, which meets the specifications of the Food Chemicals Codex, 2d Ed. (1972), under "Diethyl sodium sulfosuccinate," which is incorporated by reference (copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408) may be safely used in food in accordance with the following prescribed conditions:

j. In § 172.812 by revising paragraph (a) to read as follows:

§ 172.812 Glycine.

(a) The additive complies with the specifications for "Glycine" prescribed in "Food Chemicals Codex," 2d Ed. (1972), which is incorporated by reference. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

k. In § 172.846 paragraph (b) is revised to read as follows:

§ 172.846 Sodium stearoyl lactylate.

(b) The additive meets the specifications under "Sodium stearoyl-2-lactylate" of the "Food Chemicals Codex," 2d Ed. (1972) which is incorporated by reference. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

l. In § 172.860, paragraphs (c) (1), (2), and (3) are revised to read as follows:

§ 172.860 Fatty acids.

(c) * * *
(1) Unsaponifiable matter shall be determined by the method described in the 13th Ed. (1980) of the "Official Methods of Analysis of the Association of Official Analytical Chemists," which is incorporated by reference. Copies are available from the Association of Official Analytical Chemists, P.O. Box 540, Benjamin Franklin Station, Washington, DC 20044, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(2) Chick-edema factor shall be determined by the bioassay method described in "Official Methods of Analysis of the Association of Official Analytical Chemists," 10th Ed. (1965), secs. 26.087 through 26.091, which is incorporated by reference. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(3) The gas chromatographic-electron capture method for testing fatty acids for chick-edema shall be the method described in the "Journal of the Association of Official Analytical Chemists," Volume 50 (No. 1), pages 216-218 (1967), or the modified method using a sulfuric acid clean-up procedure, as described in the "Journal of the Association of the Official Analytical Chemists," Volume 51 (No. 2), pages 489-490 (1968), which are incorporated by reference. See paragraph (c)(2) of this section for availability of these references.

m. In § 172.862 by revising paragraph (b) (1) and (2) to read as follows:

§ 172.862 Oleic acid derived from tall oil fatty acids.

(b) The additive meets the following specifications:

(1) Specifications for oleic acid prescribed in the "Food Chemicals Codex," 2d Ed. (1972), which is incorporated by reference, except that titer (solidification point) shall not exceed 13.5° C and unsaponifiable matter shall not exceed 0.5 percent. Copies of the material incorporated by reference are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(2) The resin acid content does not exceed 0.01 as determined by ASTM Method D1240-54, "Standard Method of Test for Rosin Acids in Fatty Acids" (Revised 1961), which is incorporated by reference. Copies are available from University Microfilms International, 300 N Zeeb Rd., Ann Arbor, MI 48106, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

n. In § 172.864 by revising paragraph (b)(2) and by amending paragraph (b)(3) by revising footnote 1 under "APPARATUS," to read as follows:

§ 172.864 Synthetic fatty alcohols.

(b) * * *
(2) Use ASTM method D86-62, "Standard Method of Test for Distillation of Petroleum Products" (Revised 1962), which is incorporated by reference, to determine boiling point range. Copies of the material incorporated by reference are available from University Microfilms International, 300 N. Zeeb Rd., Ann Arbor, MI 48106, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

¹ As determined by using potassium chromate for reference standard and described in National Bureau of Standards Circular 484, Spectrophotometry, U.S. Department of Commerce, (1949). The accuracy is to be determined by comparison with the standard values at 290, 345, and 400 millimicrons. Circular 484 is incorporated by reference. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

o. In § 172.878 by revising paragraph (a)(3) to read as follows:

§ 172.878 White mineral oil.

(a) * * *

(3) It meets the specifications prescribed in the "Journal of the Association of Official Analytical Chemists," Volume 45, page 66 (1962), which is incorporated by reference, after correction of the ultraviolet absorbance for any absorbance due to added antioxidants. Copies of the material incorporated by reference are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

p. In § 172.882, paragraph (a) is revised to read as follows:

§ 172.882 Synthetic isoparaffinic petroleum hydrocarbons.

(a) They are produced by synthesis from petroleum gases and consist of a mixture of liquid hydrocarbons meeting the following specifications:

Boiling point 200°–500° F as determined by ASTM method D86–62, "Standard Method of Test for Distillation of Petroleum Products" (Revised 1962), which is incorporated by reference. Copies are available from University Microfilms International, 300 N. Zeeb Rd., Ann Arbor, MI 48106, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

Ultraviolet absorbance:

260–319 millimicrons—1.5 maximum.
320–329 millimicrons—0.08 maximum.
330–350 millimicrons—0.05 maximum.

Nonvolatile residual: 0.002 gram per 100 milliliters maximum.

Synthetic isoparaffinic petroleum hydrocarbons containing antioxidants shall meet the specified ultraviolet absorbance limits after correction for any absorbance due to the antioxidants. The ultraviolet absorbance shall be determined by the procedure described for application of mineral oil, disregarding the last sentence of the procedure, under "Specifications" on page 66 of the *Journal of the Association of Official Analytical Chemists*, Volume 45 (February 1962), which is incorporated by reference. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408. For

hydrocarbons boiling below 250° F, the nonvolatile residue shall be determined by ASTM method D1353–64, "Standard Method of Test for Nonvolatile Matter in Volatile Solvents for Use in Paint Varnish, Lacquer, and Related Products" (Revised 1964); for those boiling above 250° F, ASTM method D381–64, "Standard Method of Test for Existent Gum in Fuels by Jet Evaporation" (Revised 1965) shall be used. These methods are incorporated by reference. Copies are available from University Microfilms International, 300 N. Zeeb Rd., Ann Arbor, MI 48106, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

q. In § 172.886(b) by revising footnote 1 under "Apparatus" to read as follows:

§ 172.886 Petroleum wax.

(b) * * *

¹ As determined by using potassium chromate for reference standard and described in National Bureau of Standards Circular 484, Spectrophotometry, U.S. Department of Commerce, (1949). The accuracy is to be determined by comparison with the standard values at 290, 345, and 400 millimicrons. Circular 484 is incorporated by reference. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

PART 173—SECONDARY DIRECT FOOD ADDITIVES PERMITTED IN FOOD FOR HUMAN CONSUMPTION

3. Part 173 is amended as follows:
a. In § 173.25, paragraph (a)(2) is revised to read as follows:

§ 173.25 Ion-exchange resins.

(a) * * *

(2) Sulfonated anthracite coal meeting the requirements of ASTM method D388–38, Class I, Group 2, "Standard Specifications for Classification of Coal by Rank," which is incorporated by reference. Copies are available from University Microfilms International, 300 N. Zeeb Rd., Ann Arbor, MI 48106, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

b. In § 173.160, paragraph (b)(2) and (d) are revised to read as follows:

§ 173.160 *Candida guilliermondii*.

* * *

(b) * * *

(2) The taxonomic characteristics of the reference culture strain ATCC No. 20474 agree in the essentials with the standard description for *Candida guilliermondii* variety *guilliermondii* listed in "The Yeasts—A Taxonomic Study," 2d Ed. (1970), by Jacomina Lodder, which is incorporated by reference. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(d) The additive is so used that the citric acid produced conforms to the specifications of the "Food Chemicals Codex," 2d Ed. (1972), under "Citric acid," which is incorporated by reference. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

c. In § 173.165 paragraph (b)(2) is revised and paragraph (d) is amended by revising the introduction text to read as follows:

§ 173.165 *Candida lipolytica*.

(b) * * *

(2) The taxonomic characteristics of the culture agree in essential with the standard description for *Candida lipolytica* variety *lipolytica* listed in "The Yeasts—A Taxonomic Study," 2d Ed. (1970), by Jacomina Lodder, which is incorporated by reference. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(d) The additive is so used that the citric acid produced conforms to the specifications of the "Food Chemicals Codex," 2d Ed. (1972), which is incorporated by reference. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408. The additive meets the following ultraviolet absorbance limits when subjected to the

analytical procedure described in this paragraph:

d. In § 173.280 by revising paragraph (c), to read as follows:

§ 173.280 Solvent extraction process for citric acid.

(c) The citric acid so produced meets the specifications of the "Food Chemicals Codex," 2d Ed. (1972) and supplements thereto, under "citric acid," which is incorporated by reference, (copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408) and the polynuclear aromatic hydrocarbon specifications of § 173.165.

e. In § 173.310(c) by revising the entry for "Sodium carboxymethylcellulose" to read as follows:

§ 173.310 Boiler water additives.

(c) * * *

Substances	Limitations
Sodium carboxymethylcellulose.	Contains not less than 95 percent sodium carboxymethylcellulose on a dry-weight basis, with maximum substitution of 0.9 carboxymethylcellulose groups per anhydroglucose unit, and with a minimum viscosity of 15 centipoises for 2 percent by weight aqueous solution at 25° C; by method prescribed in the "Food Chemicals Codex," 2d Ed. (1972), in the monograph for sodium carboxymethylcellulose, which is incorporated by reference. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

f. In § 173.395 paragraph (d) is revised to read as follows:

§ 173.395 Trifluoromethane sulfonic acid.

(d) No residual catalyst may remain in the product at a detection limit of 0.2 part per million fluoride as determined by the method described in "Official Methods of Analysis of the Association of Official Analytical Chemists," sec. 25.046, 12th Ed. (1975), which is incorporated by reference. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-

330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

PART 175—INDIRECT FOOD ADDITIVES: ADHESIVE COATINGS AND COMPONENTS

4. Part 175 is amended as follows:
a. In § 175.250 by revising paragraph (b) (1), (2), and (3) to read as follows:

§ 175.250 Paraffin (synthetic).

(b) * * *
(1) *Congealing point.* The substance has a congealing point of not less than 200° F nor more than 210° F as determined by ASTM method D938-49, "Congealing Point of Pharmaceutical Petrolatums" (Adopted 1949), which is incorporated by reference. Copies are available from University Microfilms International, 300 N. Zeeb Rd., Ann Arbor, MI 48106, or available for inspection at the Office of the Federal Register, 1100 L St., NW., Washington, DC 20408.

(2) *Oil content.* The substance has an oil content not exceeding 0.5 percent as determined by ASTM method D721-56T, "Tentative Method of Test for Oil Content of Petroleum Waxes" (Revised 1956), which is incorporated by reference. See paragraph (b)(1) of this section for availability of the incorporation by reference.

(3) *Absorptivity.* The substance has an absorptivity at 290 millimicrons in decahydronaphthalene at 190° F not exceeding 0.01 as determined by ASTM method E131-61T, "Definition of Terms and Symbols Relating to Absorption Spectroscopy" (Revised 1961), which is incorporated by reference. See paragraph (b)(1) of this section for availability of the incorporation by reference.

b. In § 175.270, the introductory text of paragraph (b) is revised, and paragraph (b)(5) is amended by revising the introductory text, to read as follows:

§ 175.270 Poly (vinyl fluoride) resins.

(b) The poly (vinyl fluoride) basic resins have an intrinsic viscosity of not less than 0.75 deciliter per gram as determined by ASTM method D1243-66, "Standard Method of Test for Dilute Solution Viscosity of Vinyl Chloride Polymers" (Revised 1966), which is incorporated by reference. Copies are available from University Microfilms International, 300 N. Zeeb Rd., Ann Arbor, MI 48106, or available for

inspection at the Office of the Federal Register, 1100 L St., NW., Washington, DC 20408.

(5) *Calculation:* The calculation method used is that described in appendix A1.2.2 (ASTM Method D1243-66, "Standard Method of Test for Dilute Solutions Viscosity of Vinyl Chloride Polymers" (Revised 1966), which is incorporated by reference; see paragraph (b) of this section for availability of the incorporation by reference) with the reduced viscosity determined for three concentration levels not greater than 0.5 gram per deciliter and extrapolated to zero concentration for intrinsic viscosity. The following formula is used for determining reduced viscosity:

c. In § 175.300 by revising in paragraph (b)(3)(xix) that portion of item "Maleic anhydride" beginning with "by a method"; in (b)(3)(xxix) by revising that portion of the first sentence in item "Poly[2-(diethylamino)ethyl methacrylate]" beginning with "as determined" and ending with "for use"; and in (b)(3)(xxxiii) by revising that portion of item "Cyclohexanone-formaldehyde" beginning with "as determined" and ending with "for use only"; to read as follows:

§ 175.300 Resinous and polymeric coatings.

(b) * * *

(3) * * *

(xix) * * *

* * * by a method titled "Method for Determination of Intrinsic Viscosity of Maleic Anhydride Adduct of Polypropylene," which is incorporated by reference. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(xxix) * * *

* * * as determined by ASTM method D1243-60, "Standard Method of Test for Dilute Solution Viscosity of Vinyl Chloride Polymers" (Reapproved 1961), which is incorporated by reference (copies are available from University Microfilms International, 300 N. Zeeb Rd., Ann Arbor, MI 48106, or available for inspection at the Office of the Federal Register, 1100 L St.,

NW., Washington, DC 20408), for use

(xxxiii) * * *

* * * as determined by ASTM method D2503-67, "Standard Method of Test for Molecular Weight of Hydrocarbons by Thermoelectric Measurement of Vapor Pressure" (Revised 1967), which is incorporated by reference. Copies are available from University Microfilms International, 300 N. Zeeb Rd., Ann Arbor, MI 48106, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408. For use only * * *

PART 176—INDIRECT FOOD ADDITIVES: PAPER AND PAPERBOARD COMPONENTS

5. Part 176 is amended as follows:

a. In § 176.170(a)(5) under the "List of substances" column by revising items "Petroleum asphalt" and "Poly[(methylimino)]" and by revising the first sentence of item "Poly[oxyethylene(dimethylimino)]" and adding a new sentence immediately thereafter; in (b)(2) under the "List of substances column" the items "Cyclized rubber" and "Ethylene-acrylic acid" are revised, "Petroleum alicyclic hydrocarbon resins" and "Styrene-dimethylstyrene * * *" are amended by revising that portion beginning with "as determined" and adding a new sentence; and in (d)(3), that portion of the paragraph beginning with "described in" and ending with "except that" is revised to read as follows:

§ 176.170 Components of paper and paperboard in contact with aqueous and fatty foods.

(a) * * *

(5) * * *

List of substances

Limitations

Petroleum asphalt, steam and vacuum refined to meet the following specifications: Softening point 190° F-200° F, as determined by ASTM method D36-64T, "Tentative Method of Test for Softening Point of Asphalts and Tar Pitches (Ring and Ball Apparatus)" (Revised 1964); penetration at 77° F not to exceed 0.3 mm, as determined by ASTM method D5-61, "Standard Method of Test for Penetration of Bituminous Materials" (Revised 1961), which are incorporated by reference. Copies are available from University Microfilms International, 300 N. Zeeb Rd., Ann Arbor, MI 48106, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408; and maximum weight loss not to exceed 3% when distilled to 700° F, nor to exceed an additional 1.1% when further distilled between 700° F and thermal decomposition.

List of substances

Limitations

Poly[(methylimino)(2-hydroxyethyl)ethylene] produced by reaction of 1:1 molar ratio of methylamine and epichlorohydrin so that a 31-percent aqueous solution at 25° C has a Stokes viscosity range of 2.5-4.0 as determined by ASTM method D1545-63, "Standard Method of Test for Viscosity of Transparent Liquids by Bubble Time Method" (Revised 1963), which is incorporated by reference. Copies are available from University Microfilms International, 300 N. Zeeb Rd., Ann Arbor, MI 48106, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

Poly[oxyethylene(dimethylimino)ethylene(dimethylimino)ethylene dichloride] produced by reacting equimolar quantities of *N,N,N,N*-tetramethylethylenediamine and dichloroethyl ether to yield a solution of the solid polymer in distilled water at 25° C with a reduced viscosity of not less than 0.15 deciliter per gram as determined by ASTM method D1243-66, "Standard Method of Test for Dilute Solution Viscosity of Vinyl Chloride Polymers" (Revised 1966), which is incorporated by reference. Copies are available from University Microfilms International, 300 N. Zeeb Rd., Ann Arbor, MI 48106, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408. * * *

(b) * * *

(2) * * *

List of substances

Limitations

Cyclized rubber produced when natural pale crepe rubber dissolved in phenol is catalytically cyclized so that the finished cyclized rubber has a melting point of 293° F to 311° F as determined by ASTM method E28-58T ("Tentative Method of Test for Softening Point by Ring and Ball Apparatus" (Revised 1958), which is incorporated by reference; copies are available from University Microfilms International, 300 N. Zeeb Rd., Ann Arbor, MI 48106, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408), and contains no more than 4000 ppm of residual-free phenol as determined by a gas liquid chromatographic procedure titled "Determination of Free Phenol in Cyclized Rubber Resin," which is incorporated by reference. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

Ethylene-acrylic acid copolymers produced by the copolymerization of ethylene and acrylic acid and/or their partial ammonium salts. The finished copolymer shall contain no more than 25 weight percent of polymer units derived from acrylic acid and no more than 0.35 weight percent of residual monomeric acrylic acid, and have a melt index not to exceed 350 as determined by ASTM method D1238-73, "Standard Method of Measuring Flow Rates of Thermoplastics by Extrusion Plastometer" (Adopted 1973), which is incorporated by reference. Copies are available from University Microfilms International, 300 N. Zeeb Rd., Ann Arbor, MI 48106, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

List of substances

Limitations

Petroleum alicyclic hydrocarbon resins * * * as determined by ASTM method E28-58T, "Tentative Method of Test for Softening Point by Ring and Ball Apparatus" (Revised 1958); aniline point 120° C minimum, as determined by ASTM method D611-64, "Standard Method of Test for Aniline Point and Mixed Aniline Point of Petroleum Products and Hydrocarbon Solvents" (Adopted 1964), which are incorporated by reference. Copies are available from University Microfilms International, 300 N. Zeeb Rd., Ann Arbor, MI 48106, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408. * * *

Styrene-dimethylstyrene- α -methylstyrene copolymers * * * as determined by ASTM method D25003-67, "Standard Method of Test for Molecular Weight of Hydrocarbons by Thermoelectric Measurement of Vapor Pressure" (Revised 1967), which is incorporated by reference. Copies are available from University Microfilms International, 300 N. Zeeb Rd., Ann Arbor, MI 48106, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(d) * * *

(3) * * * described in "Official Methods of Analysis of the Association of Official Agricultural Chemists," 10th Ed. (1965), secs. 7.034-7.039, under "Exposing Flexible Barrier Materials for Extraction," (which is incorporated by reference; copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408); also described in ASTM method F34-63T, "Tentative Method for Exposing Flexible Barrier Materials to Liquids for Extraction" (Revised 1963) (which is incorporated by reference; copies are available from University Microfilms International, 300 N. Zeeb Rd., Ann Arbor, MI 48106, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408), except that

b. In § 176.180(b)(2) by revising under the "List of substance" column the item "*N,N*-Dioleylethylenediamine" to read as follows:

§ 176.180 Components of paper and paperboard in contact with dry foods.

(b) * * *

(2) * * *

List of substances	Limitations
<i>N,N</i> -Dioleylethylenediamine, <i>N,N</i> -dilinoleylethylenediamine, and <i>N</i> -oleoyl- <i>N</i> -linoleylethylenediamine mixture produced when tall oil fatty acids are made to react with ethylenediamine such that the finished mixture has a melting point of 212°-228° F, as determined by ASTM method D127-60, and an acid value of 10 maximum. ASTM Method D127-60 "Standard Method of Test for Melting Point of Petroleum and Microcrystalline Wax" (Revised 1960) is incorporated by reference. Copies are available from University Microfilms International, 300 N. Zeeb Rd., Ann Arbor, MI 48106, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.	

PART 177—INDIRECT FOOD ADDITIVES: POLYMERS

6. Part 177 is amended as follows:

a. In § 177.1020(b) by revising the item in the table; in (c)(2) by revising that portion of the paragraph beginning with "as determined"; and in (d)(2) by revising that portion of the paragraph beginning with "when analyzed", to read as follows:

§ 177.1020 Acrylonitrile/butadiene/styrene copolymer.

(b) * * *

Substance	Limitations
2-Mercaptoethanol.	The finished copolymer shall contain not more than 100 ppm 2-mercaptoethanol acrylonitrile adduct as determined by a method titled "Analysis of Cyclopentadiene Resin for Residual β -(2-Hydroxyethylmercapto) propionitrile," which is incorporated by reference. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(c) * * *

(2) * * * as determined by a gas chromatographic method titled "Determination of Residual Acrylonitrile and Styrene Monomers-Gas Chromatographic Internal Standard Method," which is incorporated by reference. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(d) * * *

(2) * * * when analyzed by a polarographic method titled "Extracted Acrylonitrile by Differential Pulse Polarography," which is incorporated by reference. Copies are available from the

Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

b. In § 177.1030(b) by revising the item in the table; in (c)(2) by revising that portion of the paragraph beginning with "as determined"; and in (d)(2) by revising that portion of the paragraph beginning with "when analyzed" to read as follows:

§ 177.1030 Acrylonitrile/butadiene/styrene/methyl methacrylate copolymer.

(b) * * *

Substances	Limitations
2-Mercaptoethanol.	The finished copolymer shall contain not more than 800 ppm 2-mercaptoethanol acrylonitrile adduct as determined by a method titled "Analysis of Cyclopentadiene Resin for Residual β -(2-Hydroxyethylmercapto) propionitrile," which is incorporated by reference. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(c) * * *

(2) * * * as determined by a gas chromatographic method titled "Determination of Residual Acrylonitrile and Styrene Monomers-Gas Chromatographic Internal Standard Method," which is incorporated by reference. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(d) * * *

(2) * * * when analyzed by a polarographic method titled "Extracted Acrylonitrile by Differential Pulse Polarography," which is incorporated by reference. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

c. In § 177.1040(c) by revising the footnote to read as follows:

§ 177.1040 Acrylonitrile/styrene copolymer.

* * * * *

* Use methods for determination of residual acrylonitrile monomer content, maximum extractable fraction, number average molecular weight, and solution viscosity, titled: "Determination of Residual Acrylonitrile and Styrene Monomers-Gas Chromatographic Internal Standard Method"; "Infrared Spectrophotometric Determination of Polymer Extracted from Barex 210 Resin Pellets; "Procedure for the Determination of Molecular Weights of Acrylonitrile/Styrene Copolymers," and "Analytical Method for 10% Solution Viscosity of Tyrol," which are incorporated by reference. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

d. In § 177.1050(b) by revising the item in the table, in (c)(2) and (3) by revising the portion of each paragraph beginning with "as determined by", in the introductory text of (d) by revising the portion beginning with "are determined," and in (e)(4) by revising that portion of the paragraph beginning with "and analyzed" to read as follows:

§ 177.1050 Acrylonitrile/styrene copolymer modified with butadiene/styrene elastomer.

(b) * * *

Substances	Limitations
<i>n</i> -Dodecylmercaptan.	The finished copolymer shall contain not more than 500 parts per million (ppm) dodecylmercaptan as dodecylmercapto-propionitrile as determined by the method titled, "Determination of β -Dodecylmercapto-propionitrile in NR-16 Polymer," which is incorporated by reference. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(c) * * *

(2) * * * as determined by the method titled "Molecular Weight of Matrix Copolymer by Solution Viscosity," which is incorporated by reference. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(3) * * * as determined by a gas chromatographic method titled "Determination of Residual Acrylonitrile and Styrene Monomers-Gas Chromatographic Internal Standard Method," which is incorporated by

reference. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(d) *** are determined by an infrared spectrophotometric method titled "Infrared Spectrophotometric Determination of Polymer Extracted from Borex® 210 Resin Pellets," which is incorporated by reference. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(e) ***

(4) *** and analyzed for acrylonitrile monomer by a gas chromatographic method titled "Gas-Solid Chromatographic Procedure for Determining Acrylonitrile Monomer in Acrylonitrile-Containing Polymers and Food Simulating Solvents," which is incorporated by reference. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

e. In § 177.1200(c) by revising under the "List of substances" column that portion of item "N,N-Dioleoyethyl-enediamine" beginning with "as determined by" to read as follows:

§ 177.1200 Cellophane.

(c) ***

List of substances	Limitations ¹
N,N'-Dioleoyethylenediamine, "N,N'-diindoleylethylenediamine and N-oleoyl-N'-indoleylethylenediamine mixture" (as determined by ASTM method D127-60 ("Standard Method of Test for Melting Point of Petroleum and Microcrystalline Wax" (Revised 1969), which is incorporated by reference; copies are available from University Microfilms International, 300 N. Zeeb Rd., Ann Arbor, MI 48106, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408), and an acid value of 10 maximum.	

¹ Residue and limits of addition expressed as percent by weight of finished packaging cellophane.

f. In § 177.1320(c)(1)(iii) by revising that portion of the paragraph beginning

with "as determined by" to read as follows:

§ 177.1320 Ethylene-ethyl acrylate copolymers.

(c) ***

(1) ***

(iii) *** as determined by ASTM method D1505-68, "Test for Density of Plastic Gradient Technique" (Revised 1968), which is incorporated by reference. Copies are available from University Microfilms International, 300 N. Zeeb Rd., Ann Arbor, MI 48106, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

g. In § 177.1330 by revising paragraph (e)(4) to read as follows:

§ 177.1330 Ionomeric resins.

(e) ***

(4) *Selection of test method.* The finished food-contact articles shall be tested either by the extraction cell described in the *Journal of the Association of Official Agricultural Chemists*, Vol. 47, No. 1, p. 177-179 (February 1964), also described in ASTM method F34-76, "Standard Test Methods for Liquid Extraction of Flexible Barrier Materials" (Revised 1976), which are incorporated by reference, or by adapting the in-container methods described in § 175.300(e) of this chapter. Copies of the material incorporated by reference are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, and American Society for Testing and Materials (ASTM), 1916 Race St., Philadelphia, PA 19103, respectively, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

h. In § 177.1360 by revising the portion of the introductory text of paragraphs (b) and (c) beginning with "meet the following" to read as follows:

§ 177.1360 Ethylene-vinyl acetate-vinyl alcohol copolymers.

(b) ***

meet the following extractives limitation when tested by ASTM method F34-63T, "Exposing Flexible Barrier Materials to Liquids for Extraction" (issued 1963), which is incorporated by reference. Copies are available from University Microfilms International, 300 N. Zeeb Rd., Ann Arbor, MI 48106, or available for

inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(c) *** meet the following extractives limitation when tested by ASTM method F34-63T, "Exposing Flexible Barrier Materials to Liquids for Extraction" (issued 1963), which is incorporated by reference. Copies are available from University Microfilms International, 300 N. Zeeb Rd., Ann Arbor, MI 48106, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

i. In § 177.1390(c)(3)(i) by revising that portion of the paragraph beginning with "as determined by" to read as follows:

§ 177.1390 High temperature laminates.

(c) ***

(3) ***

(i) *** as determined by a method titled "Determination of Non-volatile Chloroform Soluble Residue in Retort Pouch Water Extracts," which is incorporated by reference. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-334), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

j. In § 177.1430(a)(1), (2), and (3) by revising the portion of the paragraphs beginning with "as determined by" to read as follows:

§ 177.1430 Isobutylene-butene copolymers.

(a) ***

(1) *** as determined by ASTM method D2503-67, "Standard Method of Test for Molecular Weight of Hydrocarbons by Thermoelectric Measurement of Vapor Pressure" (Revised 1967), which is incorporated by reference. Copies are available from University Microfilms International, 300 N. Zeeb Rd., Ann Arbor, MI 48106, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(2) *** as determined by ASTM method D445-74, "Test for Kinematic Viscosity of Transparent and Opaque Liquids" (Revised 1974), which is incorporated by reference. Copies are available from American Society for Testing and Materials (ASTM), 1916 Race Street, Philadelphia, PA 19103, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(3) * * * as determined by ASTM method D1492-60, "Standard Method of Test for Bromine Index of Aromatic Hydrocarbons by Coulometric Titration" (Reapproved 1960), which is incorporated by reference. Copies are available from University Microfilms International, 300 N. Zeeb Rd., Ann Arbor, MI 48106, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

k. In § 177.1480, by revising paragraph (b)(1)(ii) and the introductory text of (b)(2) to read as follows:

§ 177.1480 Nitrile rubber modified acrylonitrile-methyl acrylate copolymers.

(b) * * *

(1) * * *

(ii) Intrinsic viscosity in acetonitrile at 25° C is not less than 0.29 deciliter per gram as determined by ASTM method D1243-60, "Standard Method of Test for Dilute Solution Viscosity of Vinyl Chloride Polymers" (Reapproved 1961), which is incorporated by reference. Copies are available from University Microfilms International, 300 N. Zeeb Rd., Ann Arbor, MI 48106, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(2) *Extractives limitations.* The following extractive limitations are determined by an infrared spectrophotometric method titled, "Infrared Spectrophotometric Determination of Polymer Extracted from Borex® 210 Resin Pellets," which is incorporated by reference. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-334), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

1. In § 177.1520, by revising paragraph (d)(1), (2) (i) and (ii), and the introductory text in (d)(5) and the first sentence in (d)(6) to read as follows:

§ 177.1520 Olefin polymers.

(d) * * *

(1) *Density.* Density shall be determined by ASTM method D1505-68, "Test for Density of Plastics-Gradient Technique" (Revised 1968), which is incorporated by reference. Copies are available from University Microfilms International, 300 N. Zeeb Rd., Ann Arbor, MI 48106, or available for inspection at the Office of the Federal

Register, 1100 L St. NW., Washington, DC 20408.

(2) * * * (i) *Melting point.* The melting point shall be determined by ASTM method D2117-62T, "Tentative Method of Test for Melting Point of Semicrystalline Polymers" (issued 1962), which is incorporated by reference. Copies are available from University Microfilms International, 300 N. Zeeb Rd., Ann Arbor, MI 48106, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(ii) *Softening point.* The softening point shall be determined by ASTM method E28-58T, "Tentative Method of Test for Softening Point by Ring and Ball Apparatus" (Revised 1958), which is incorporated by reference. Copies are available from University Microfilms International, 300 N. Zeeb Rd., Ann Arbor, MI 48106, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(5) * * * The viscosity average molecular weight shall be determined from the kinematic viscosity (using ASTM method D445-74, "Test for Kinematic Viscosity of Transparent and Opaque Liquids" (Revised 1974), which is incorporated by reference; copies are available from American Society for Testing and Materials (ASTM), 1916 Race Street, Philadelphia, PA 19103, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408) of solutions of the copolymers in solvents and at temperatures as follows:

(6) * * * Mooney viscosity is determined by ASTM method D1646-63, "Standard Method of Test for Viscosity and Curing Characteristic of Rubber by the Shearing Disc Viscometer" (Revised 1963), which is incorporated by reference (copies are available from University Microfilms International, 300 N. Zeeb Rd., Ann Arbor, MI 48106, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408), using the large rotor at a temperature of 212° F, except that a temperature of 260° F shall be used for those copolymers whose Mooney viscosity cannot be determined at 212° F.

m. In § 177.1550, by revising the first sentence of paragraph (d) (2) and (3) and by adding a new sentence immediately after each and by revising footnote "2" in paragraph (e) to read as follows:

§ 177.1550 Perfluorocarbon resins.

* * * * *

(d) * * *

(2) * * * Perfluorocarbon resins have a melt viscosity of not less than 10⁴ poises at 380° C as determined by ASTM method D 1238-57T, "Standard Method of Test for Melt Viscosity in Perfluorocarbon" (Revised 1957), which is incorporated by reference. Copies are available from University Microfilms International, 300 N. Zeeb Rd., Ann Arbor, MI 48106, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408. * * *

(3) * * * The thermal instability index of the tetrafluoroethylene homopolymer shall not exceed 50 as determined by ASTM method D1457-56T, "Test for Thermal Instability index of Tetrafluoroethylene Homopolymer" (Revised 1956), which is incorporated by reference. Copies are available from University Microfilms International, 300 N. Zeeb Rd., Ann Arbor, MI 48106, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408. * * *

(e) *Limitations.* * * * * *

² A more detailed procedure of extraction conditions is entitled, "Preparation of Extracts," which is incorporated by reference. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

n. In § 177.1570(b)(1) (ii), (iii), and (iv) by revising that portion of the paragraphs beginning with "as determined by" to read as follows:

§ 177.1570 Poly-1-butene resins and butene-ethylene copolymers.

* * * * *

(b) * * *

(1) * * *

(ii) * * * as determined by ASTM method D1601-61, "Standard Method of Test for Dilute Solution Viscosity of Ethylene Polymers," (Revised 1961), which is incorporated by reference. Copies are available from University Microfilms International, 300 N. Zeeb Rd., Ann Arbor, MI 48106, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(iii) * * * as determined by ASTM method D1505-68, "Test for Density of Plastics-Gradient Technique" (Revised 1968), which is incorporated by reference. Copies are available from University Microfilms International, 300

N. Zeeb Rd., Ann Arbor, MI 48106, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(iv) * * * as determined by ASTM method D1238-73, condition E, "Standard Method of Measuring Flow Rates of Thermoplastics by Extrusion Plastometer" (Approved 1973), which is incorporated by reference. Copies are available from University Microfilms International, 300 N. Zeeb Rd., Ann Arbor, MI 48106, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

o. In § 177.1590, by revising the first portion of paragraph (c) ending with "using No. 50 emery abrasive" to read as follows:

§ 177.1590 Polyester elastomers.

(c) An appropriate sample of the finished polyester elastomer in the form in which it contacts food when subjected to method 6191 in Federal Test Method Standard No. 141, published in "Varnish, Lacquer, and Related Materials—Methods of Inspection and Sampling," which is incorporated by reference (copies are available from General Services Administration, Washington, DC 20507; also from Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408), using No. 50 emery abrasive * * *

p. In § 177.1610(a) by revising that portion of the paragraph beginning with "as determined by ASTM Method D1303-55" and ending with "and has a 7.0" to read as follows:

§ 177.1610 Polyethylene, chlorinated.

(a) * * * as determined by ASTM method D1303-55 ("Standard Method of Test for Total Chlorine in Vinyl Chloride Polymers and Copolymers" (Reapproved 1961), which is incorporated by reference (copies are available from University Microfilms International, 300 N. Zeeb Rd., Ann Arbor MI 48106, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408), and has a 7.0

q. In § 177.1630(e)(4)(iii), under the entry for "Ethylene azelate-terephthalate copolymer" by revising

that portion of the text beginning with "as determined by" and ending with "Total residual" to read as follows:

§ 177.1630 Polyethylene phthalate polymers.

(e) * * *
(4) * * *
(iii) * * * as determined by a method title "General Procedure of Determining the Relative Viscosity of Resin Polymers," which is incorporated by reference. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection, at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408. Total residual * * *

r. In § 177.1650(c) by revising that portion of the paragraph beginning with "when subjected" and ending with "using No. 50" to read as follows:

§ 177.1650 Polysulfide polymer-polyepoxy resins.

(c) * * * when subjected to method 6191 in Federal Test Method Standard No. 141, published in "Varnish, Lacquer, and Related Materials—Methods of Inspection and Sampling," which is incorporated by reference (copies are available from General Services Administration, Washington, DC 20507; also from Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408), using No. 50

s. In § 177.1670(b) by revising the end of the paragraph beginning with "when tested by" to read as follows:

§ 177.1670 Polyvinyl alcohol film.

(b) * * * when tested by ASTM method F34-63T, "Tentative Method for Exposing Flexible Barrier Materials to Liquids for Extraction" (issued 1963), which is incorporated by reference. Copies are available from University Microfilms International, 300 N. Zeeb Rd., Ann Arbor, MI 48106, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

t. In § 177.1680(c), by revising that portion of the paragraph beginning with "when subjected to" and ending with "using No. 50" to read as follows:

§ 177.1680 Polyurethane resins.

(c) * * * when subjected to "Method 6191 in Federal Test Method Standard No. 141," published in "Varnish, Lacquer, and Related Materials—Methods of Inspection and Sampling," which is incorporated by reference (copies are available from General Services Administration, Washington, DC 20507; also from Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408), using No. 50 * * *

u. In § 177.1810(c)(2)(i), by revising the beginning of the paragraph ending with "modified by" and by revising the beginning of (c)(2)(ii) ending with "by which the glass" to read as follows:

§ 177.1810 Styrene block polymers.

(c) * * *
(2) * * *
(i) ASTM method D2236-70 ("Standard Method of Test for Dynamic Mechanical Properties of Plastics by Means of Torsional Pendulum," which is incorporated by reference; copies are available from American Society for Testing and Materials (ASTM), 1916 Race Street, Philadelphia, PA 19103, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408) modified by

(ii) Direct reading viscoelastometric method titled "Direct Reading Viscoelastometric Method for Determining Glass Transition Points of Styrene Block Polymers" (which is incorporated by reference; copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408), by which the glass * * *

v. In § 177.1820(c)(3) by revising that portion of the paragraph beginning with "shall be determined" to read as follows:

§ 177.1820 Styrene-maleic anhydride copolymers.

(c) * * *
(3) * * * shall be determined by a gas chromatographic method titled "Determination of Residual Maleic Anhydride in Polymers by Gas

Chromatography," which is incorporated by reference. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

w. In § 177.1950(c)(1)(ii) by revising that portion of the paragraph beginning with "as determined by" to read as follows:

§ 177.1950 Vinyl chloride-ethylene copolymers.

(c) * * *

(1) * * *

(ii) * * * as determined by ASTM method D1243-60, "Standard Method of Test for Dilute Solution Viscosity of Vinyl Chloride Polymers" (Revised 1960), which is incorporated by reference. Copies are available from University Microfilms International, 300 N. Zeeb Rd., Ann Arbor, MI 48106, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

x. In § 177.1960(b)(1)(ii), by revising that portion of the paragraph beginning with "as determined by" to read as follows:

§ 177.1960 Vinyl chloride-hexene-1 copolymers.

(b) * * *

(1) * * *

(ii) * * * as determined by ASTM method D1243-66, "Standard Method of Test for Dilute Solution Viscosity of Vinyl Chloride Polymers" (Revised 1966), which is incorporated by reference. Copies are available from University Microfilms International, 300 N. Zeeb Rd., Ann Arbor, MI 48106, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

y. In § 177.1970(c)(1)(ii), by revising that portion of the paragraph beginning with "as determined by" to read as follows:

§ 177.1970 Vinyl chloride-lauryl vinyl ether copolymers.

(c) * * *

(1) * * *

(ii) * * * as determined by ASTM method D1243-60, "Standard Method of Test for Dilute Solution Viscosity of Vinyl Chloride Polymers" (Revised 1960), which is incorporated by

reference. Copies are available from University Microfilms International, 300 N. Zeeb Rd., Ann Arbor, MI 48106, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

z. In § 177.1980(c)(1)(ii), by revising that portion of the paragraph beginning with "as determined by" to read as follows:

§ 177.1980 Vinyl chloride-propylene copolymers.

(c) * * *

(1) * * *

(ii) * * * as determined by ASTM method D1243-60, "Standard Method of Test for Dilute Solution Viscosity of Vinyl Chloride Polymers" (Revised 1960), which is incorporated by reference. Copies are available from University Microfilms International, 300 N. Zeeb Rd., Ann Arbor, MI 48106, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

aa. In § 177.2210, by revising the undesignated portion at the end of paragraph (b) to read as follows:

§ 177.2210 Ethylene polymer, chlorosulfonated.

(b) * * *

Methods for the specifications in this paragraph (b), titled "Chlorine and Bromine—Coulometric Titration Method by Aminco Chloridometer," "Hypolon® Synthetic Rubber—Determination of Sulfur by Parr Bomb," and ASTM method D2857-70, "Standard Method of Test for Dilute Solution Viscosity of Polymers", are incorporated by reference. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

bb. In § 177.2440(a), by revising the end of the paragraph beginning with "in accordance with" to read as follows:

§ 177.2440 Polyethersulfone resins.

(a) * * * in accordance with ASTM method D2857-70, "Standard Method of Test for Dilute Solution Viscosity of Polymers" (Reapproved 1977), which is incorporated by reference. Copies are available from American Society for Testing and Materials (ASTM), 1916 Race St., Philadelphia, PA 19103, or

available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

cc. In § 177.2450, by revising the introductory text of paragraph (b), that portion of (b)(1) beginning with "as set forth", and (b) (2) and (3) to read as follows:

§ 177.2450 Polyamide-imide resins.

(b) *Specifications.* Polyamide-imide resins identified in paragraph (a) of this section shall conform to the following specifications:

(1) * * * as set forth in "Official Method of Analysis of the Association of Official Analytical Chemists," 11th Ed. (1970), page 123, secs. 7.017 to 7.024, which is incorporated by reference. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(2) Solution viscosity: not less than 1.200 as determined by a method titled "Solution Viscosity," which is incorporated by reference. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(3) Residual monomers as determined by gas chromatography (the gas chromatographic method titled "Amide-Imide Polymer Analysis—Analysis of Monomer Content," is incorporated by reference; copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408), in the polyamide-imide resin, heat cured at 600° F for 15 minutes; *p,p'*-diphenylmethane diisocyanate, not more than 100 parts per million; trimellitic anhydride, not more than 500 parts per million.

dd. In § 177.2460 in the introductory text of paragraph (c)(1) by revising that portion of the paragraph beginning with "as determined by", and in paragraph (c)(1)(iv) by revising the beginning of the paragraph ending with "with the reduced viscosity" to read as follows:

§ 177.2460 Poly(2,6-dimethyl-1,4-phenylene) oxide resins.

(c) * * *

(1) * * * as determined by ASTM method D1243-66, "Standard Method of Test for Dilute Solution Viscosity of Vinyl Chloride Polymers" (Revised 1966), modified as follows, which is incorporated by reference. Copies are available from University Microfilms International, 300 N. Zeeb Rd., Ann Arbor, MI 48106, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(iv) Calculation: The calculation method used is that described in Appendix A1.2.2 (ASTM method D1243-66, cited and incorporated by reference in paragraph (c)(1) of this section) with the reduced viscosity * * *

ee. In § 177.2470(c)(2) by revising that portion of the paragraph beginning with "as determined by" to read as follows:

§ 177.2470 Polyoxymethylene copolymer.

(c) * * *

(2) * * * as determined by a method titled "Number Average Molecular Weight," which is incorporated by reference. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

ff. In § 177.2480(c) (3) and (4) and (d)(2)(i) by revising that portion of the paragraphs beginning with "as determined by" to read as follows:

§ 177.2480 Polyoxymethylene homopolymers.

(c) * * *

(3) * * * as determined by ASTM method D1505-68, "Test for Density of Plastics—Gradient Technique" (Revised 1968), which is incorporated by reference. Copies are available from University Microfilms International, 300 N. Zeeb Rd., Ann Arbor, MI 48106, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(4) * * * as determined by ASTM method D2133-66, "Specifications for Acetal Resin Injection Molding and Extrusion Materials" (Revised 1966), which is incorporated by reference.

Copies are available from American Society for Testing and Materials (ASTM), 1916 Race Street, Philadelphia, PA 19103, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(d) * * *

(2) * * *

(i) * * * as determined by a method titled "Formaldehyde Release and Formaldehyde Analysis," which is incorporated by reference. Copies are available from Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

gg. In § 177.2490(a) introductory text beginning with "as determined by" is revised to read as follows:

§ 177.2490 Polyphenylene sulfide resins.

(a) * * * as determined by methods titled "Oxygen Flask Combustion-Gravimetric Method for Determination of Sulfur in Organic Compounds," "Determination of the Inherent Viscosity of Polyphenylene Sulfide," and "Analysis for Dichlorobenzene in Ryton Polyphenylene Sulfide," which are incorporated by reference. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

hh. In § 177.2600(c)(4)(i) by revising the item "Silicone basic polymers" to read as follows:

§ 177.2600 Rubber articles intended for repeated use.

(c) * * *

(4) * * *

(i) * * * Silicone basic polymer as described in ASTM D1418-61T, "Tentative Recommended Practice for Nomenclature for Synthetic Elastomers and Latices" (Adopted 1961), which is incorporated by reference. Copies are available from University Microfilms International, 300 N. Zeeb Rd., Ann Arbor, MI 48106, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

PART 178—INDIRECT FOOD ADDITIVES: ADJUVANTS, PRODUCTION AIDS, AND SANITIZERS

7. Part 178 is amended as follows:

a. In § 178.1005(c) by revising that portion of the paragraph beginning with "Food Chemical Codex" and ending with "and the United States Pharmacopeia" to read as follows:

§ 178.1005 Hydrogen peroxide solution.

(c) * * * "Food Chemicals Codex," 2d Ed. (1972), under "hydrogen peroxide," which is incorporated by reference (copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408), and the United States Pharmacopeia * * *

b. In § 178.2010(b) by revising under the "Substances" column that portion of items "Butylated, styrenated cresols," "Dicetyl thiopropionate," and "Dimyristyl thiodipropionate" beginning with "as determined by" to read as follows:

§ 178.2010 Antioxidants and/or stabilizers for polymers.

(b) * * *

Substances	Limitations
Butylated styrenated cresols * * * as determined by ASTM method D1218-61, "Standard Method for Measurement of Refractive Index and Refractive Dispersion of Hydrocarbon Liquids" (Adopted 1961), which is incorporated by reference. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.	
Dicetyl thiopropionate * * * as determined by ASTM method E324-69, "Relative Initials and Final Melting Points and the Melting Range of Organic Chemicals" (Revised 1969), and a saponification value in the range 176-183 as determined by ASTM method 1962-67, "Saponification Value of Drying Oils, Fatty Acids, and Polymerized Fatty Acids" (Revised 1967), which are incorporated by reference. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.	

Substances

Limitations

Dimyristyl thiodipropionate * * * as determined by ASTM method E324-69, "Relative Initials and Final Melting Points and the Melting Range of Organic Chemicals" (Revised 1969), and a saponification equivalent in the range 280-290 as determined by ASTM method D1962-67, "Saponification Values of Drying Oils, Fatty Acids, and Polymerized Fatty Acids," (Revised 1967), which are incorporated by reference. Copies are available from University Microfilms International, 300 N. Zeeb Rd., Ann Arbor, MI 48106, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

c. In § 178.2650(b)(1)(ii) by revising the end of the paragraph beginning with "as determined by" to read as follows:

§ 178.2650 Octyltin stabilizers in vinyl chloride plastics.

(b) * * *

(1) * * *

(ii) * * * as determined by an analytical method titled "Atomic Absorption Spectrometric Determination of Subpart-per-Million Quantities of Tin in Extracts and Biological Materials with Graphite Furnace," *Analytical Chemistry*, Vol. 49, pages 1090-1093, 1977, which is incorporated by reference. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

d. In § 178.3480(c) by revising the introductory text beginning with "as determined by" to read as follows:

§ 178.3480 Fatty alcohols, synthetic.

(c) * * * as determined by a method titled "Diols in Monohydroxy Alcohol by Miniature Thin Layer Chromatography (MTLC)," which is incorporated by reference. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

e. In § 178.3530(a) by revising the entry for "Boiling point" and that portion of the entry for "Synthetic isoparaffinic petroleum hydrocarbons" beginning with "under 'Specifications'" to read as follows:

§ 178.3530 Isoparaffinic petroleum hydrocarbons, synthetic.

(a) * * *

Boiling point 145°-500° F, as determined by ASTM method D86-62, "Standard Method of Test for Distillation of Petroleum Products" (Revised 1962), which is incorporated by reference. Copies are available from University Microfilms International, 300 N. Zeeb Rd., Ann Arbor, MI 48106, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

Synthetic isoparaffinic petroleum hydrocarbons * * * under "Specifications" on page 66 of the *Journal of the Association of Official Agricultural Chemists*, Vol. 45 (February 1962), which is incorporated by reference, disregarding the last sentence of that procedure. For hydrocarbons boiling below 250° F, the nonvolatile residue shall be determined by ASTM procedure D1353-64, "Standard Method of Test for Nonvolatile Matter in Volatile Solvents for Use in Paint, Varnish, Lacquer, and Related Products" (Revised 1964), for those boiling above 250° F, ASTM procedure D381-6, "Standard Method of Test for Existent Gum in Fuels for Jet Evaporation" (Adopted 1964), which are incorporated by reference. Copies of the material incorporated by reference are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

f. In § 178.3610(a) by revising that portion beginning with "as determined by" to read as follows:

§ 178.3610 α -Methylstyrene-vinyltoluene resins, hydrogenated.

(a) * * * as determined by methods titled "Determination of Softening Point (Drop Method)" and "Determination of Unsaturation of Resin 1977," which are incorporated by reference. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

g. In § 178.3620, by revising (b)(1)(i); by revising that portion of (b)(1)(ii) beginning with "under 'Specification'"

and ending with "disregarding the last"; by revising (c)(1)(ii); by revising the text of footnote "1" in (c)(3); by revising that portion of (d)(1)(i) beginning with "as determined by"; and by revising that portion of Paragraph (d)(3) item V.B. 19.b. beginning with "technique described in" and ending with "Correct each" to read as follows:

§ 178.3620 Mineral oil.

(b) * * *

(1) * * *

(i) Saybolt color 20 minimum as determined by ASTM method D156-64, "Standard Method of Test for Saybolt Color of Petroleum Products" (Adopted 1964), which is incorporated by reference. Copies are available from University Microfilms International, 300 N. Zeeb Rd., Ann Arbor, MI 48106, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(ii) * * * under "Specification" on page 66 of the *Journal of the Association of Official Agricultural Chemists*, Volume 45 (February 1962) (which is incorporated by reference; copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408), disregarding the last * * *

(c) * * *

(1) * * *

(ii) Color 5.5 maximum as determined by ASTM Method D1500-64, "Standard Method of Test for ASTM Color of Petroleum Products" (Revised 1964), which is incorporated by reference. Copies are available from University Microfilms International, 300 N. Zeeb Rd., Ann Arbor, MI 48106, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

¹ As determined by procedure using potassium chromate for reference standard and described in National Bureau of Standards Circular 484, Spectrophotometry, U.S. Department of Commerce (1949). The accuracy is to be determined by comparison with the standard values at 290, 345, and 400 millimicrons. Circular 484 is incorporated by reference. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(d) * * *

(1) * * *

(i) * * * as determined by ASTM method D86-67; IP123/68 "Standard Method of Test for Distillation of Petroleum Products" (Revised 1968), which is incorporated by reference. Copies are available from University Microfilms International, 300 N. Zeeb Rd., Ann Arbor, MI 48106, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(3) * * *

V. * * *

B. * * *

19. * * *

b. * * * technique described in ASTM method E169-60T, "Tentative Recommended Practices for General Techniques of Ultraviolet Quantitative Analysis" (Issued 1960), which is incorporated by reference. Copies are available from University Microfilms International, 300 N. Zeeb Rd., Ann Arbor, MI 48106, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408. Correct each * * *

h. In § 178.3690(b)(1), (2), (3), and (4) by revising that portion of the paragraph beginning with "as determined by" to read as follows:

§ 178.3690 Pentaerythritol adipate-stearate.

(b) * * *

(1) * * * as determined by ASTM method D566-76, "Standard Test Method for Dropping Point of Lubricating Grease" (Revised 1976), which is incorporated by reference. Copies are available from American Society for Testing and Materials (ASTM), 1916 Race Street, Philadelphia, PA 19103, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(2) * * * as determined by ASTM method D1386-78, "Standard Test Method for Saponification Number (Empirical) of Synthetic and Natural Waxes" (Revised 1978), which is incorporated by reference. Copies are available from American Society for Testing and Materials (ASTM), 1916 Race Street, Philadelphia, PA 19103, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(3) * * * as determined by ASTM method D1387-78, "Standard Test Method for Acid Number (Empirical) of Synthetic and Natural Waxes" (Revised 1978), which is incorporated by reference. Copies are available from American Society for Testing and Materials (ASTM), 1916 Race Street, Philadelphia, PA 19103, or available for inspection at the Office of the Federal

Register, 1100 L St. NW., Washington, DC 20408.

(4) * * * as determined by Iodine Absorption Number, Hanus Method, of the "Official Methods of Analysis of the Association of Official Analytical Chemists," sec. 28.019, 12th Ed. (1975), which is incorporated by reference. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

i. In § 178.3740(b) by revising in the table under the "Substances" column the item "Polybutene, hydrogenated" to read as follows:

§ 178.3740 Plasticizers in polymeric substances.

(b) * * *

Substances	Limitations
Polybutene, hydrogenated (minimum viscosity at 210°F. 39 Saybolt Universal seconds, as determined by ASTM method D445-74 ("Test for Kinematic Viscosity of Transparent and Opaque Liquids" (Revised 1974)) and D2161-86 ("Standard Method of Test for Conversion of Kinematic Viscosity of Saybolt Universal Viscosity or to Saybolt Furol Viscosity" (Adopted 1968)), and bromine number of 3 or less, as determined by ASTM method D1492-60 ("Standard Method of Test for Bromine Index of Aromatic Hydrocarbons by Coulometric Titration" (Reapproved 1960)), which are incorporated by reference. Copies are available from American Society for Testing and Materials, 1916 Race Street, Philadelphia, PA 19103 (for method D445-74) and University Microfilms International, 300 N. Zeeb Rd., Ann Arbor, MI 48106 (for methods D1492-60 and D2161-86), or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408 * * *	

j. In § 178.3770, by revising paragraphs (a)(1), (2), and (3); by revising footnote "1" in (a)(4); and by revising (b)(1), (2), and (3) to read as follows:

§ 178.3770 Polyhydric alcohol diesters of oxidatively refined (Gersthoffen process) montan wax acids.

(a) * * *

(1) Dropping point 76°-105° C, as determined by ASTM method D566-76, "Standard Method for Dropping Point of Lubricating Grease" (Revised 1976), which is incorporated by reference. Copies are available from American Society for Testing and Materials (ASTM), 1916 Race Street, Philadelphia, PA 19103, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(2) Acid value 10-20, as determined by ASTM method D1386-78 ("Standard Test Method for Saponification Number (Empirical) of Synthetic and Natural Waxes" (Revised 1978), which is incorporated by reference; copies are available from American Society for Testing and Materials (ASTM), 1916 Race Street, Philadelphia, PA 19103, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408) using as solvent xylene-ethyl alcohol in a 2:1 ratio instead of toluene-ethyl alcohol in a 2:1 ratio.

(3) Saponification value 100-160, as determined by ASTM method D1387-78 ("Standard Test Method for Acid Number (Empirical) of Synthetic and Natural Waxes" (Revised 1978), which is incorporated by reference; copies are available from American Society for Testing and Materials (ASTM), 1916 Race Street, Philadelphia, PA 19103, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408) using xylene-ethyl alcohol in a 2:1 ratio instead of ethyl alcohol in preparation of potassium hydroxide solution.

(4) * * *

¹ As determined by procedure using potassium chromate for reference standard and described in National Bureau of Standards Circular 484, Spectrometry, U.S. Department of Commerce (1949). The accuracy is to be determined by comparison with the standard values at 290, 345, and 400 millimicrons. Circular 484 is incorporated by reference. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(b) * * *

(1) Dropping point 77°-82° C, as determined by ASTM method D566-76, "Standard Method for Dropping Point of Lubricating Grease" (Revised 1976), which is incorporated by reference. Copies are available from American Society for Testing and Materials (ASTM), 1916 Race Street, Philadelphia, PA 19103, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(2) Acid value 25-35, as determined by ASTM method D1386-78 ("Standard Test Method for Saponification Number (Empirical) of Synthetic and Natural Waxes" (Revised 1978), which is incorporated by reference; copies are available from American Society for Testing and Materials (ASTM), 1916 Race Street, Philadelphia, PA 19103, or available for inspection at the Office of the Federal Register, 1100 L St. NW.,

Washington, DC 20408) using as solvent xylene-ethyl alcohol in a 2:1 ratio instead of toluene-ethyl alcohol in a 1:2 ratio.

(3) Saponification value 135-150, as determined by ASTM method D1387-78 ("Standard Test Method for Acid Number (Empirical) of Synthetic and Natural Waxes" (Revised 1978), which is incorporated by reference; copies are available from American Society for Testing and Materials (ASTM), 1916 Race Street, Philadelphia, PA 19103, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408) using xylene-ethyl alcohol in a 2:1 ratio instead of ethyl alcohol in preparation of potassium hydroxide solution.

k. In § 178.3780(b) (1), (2), and (3) by revising the portion of the paragraphs beginning with "as determined by" to read as follows:

§ 178.3780 Polyhydric alcohol esters of long chain monobasic acids.

(1) * * * as determined by the Fisher Johns method as described in "Semimicro Qualitative Organic Analysis—The Systematic Identification of Organic Compounds," by Cheronis and Entrikin, 2d Ed., Interscience Publishers, NY, which is incorporated by reference. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-334), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(2) * * * as determined by the A.O.C.S. method Trla-64T "Titer Test," which is incorporated by reference. Copies are available from American Association of Oil Chemists, 36 East Wacker Drive, Chicago, IL 60601, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408. The method is modified to use as the acid solvent a 1:1 volume mixture of anhydrous isopropyl alcohol and toluene. The solution is titrated with 0.1N methanolic sodium hydroxide.

(3) * * * as determined the A.O.C.S. method Trla-64T "Saponification Value," which is incorporated by reference. Copies are available from American Association of Oil Chemists, 36 East Wacker Drive, Chicago, IL 60601, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

l. In § 178.3870, by revising that portion of paragraph (f) (1), (2), (3), (4),

and (5) beginning with "as determined by", and by revising that portion of (f)(6) beginning with "specifications not listed" to read as follows:

§ 178.3870 Rosin and rosin derivatives.

(f) * * *
(1) * * * as determined by ASTM method D509-55, "Standard Method of Sampling and Grading Rosin" (Revised 1955), which is incorporated by reference. Copies are available from University Microfilms International, 300 N. Zeeb Rd., Ann Arbor, MI 48106, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(2) * * * as determined by ASTM method D1747-62, "Standard Method for Refractive Index of Viscous Materials" (Reapproved 1978), which is incorporated by reference. Copies are available from University Microfilms International, 300 N. Zeeb Rd., Ann Arbor, MI 48106, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(3) * * * as determined by ASTM method D465-59, "Standard Test Method of Test for Acid Number of Rosin" (Revised 1959), which is incorporated by reference. Copies are available from University Microfilms International, 300 N. Zeeb Rd., Ann Arbor, MI 48106, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(4) * * * as determined by ASTM method D1824-66, "Standard Test Method for Apparent Viscosity of Plastics" (Revised 1966), and in Saybolt seconds by ASTM method D88-56, "Standard Method of Test for Saybolt Viscosity" (Revised 1956), which are incorporated by reference. Copies are available from University Microfilms International, 300 N. Zeeb Rd., Ann Arbor, MI 48106, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(5) * * * as determined by ASTM method E28-67, "Standard Test Method for Softening Point by Ring and Ball Apparatus" (Reapproved 1977), which is incorporated by reference. Copies are available from American Society for Testing and Materials (ASTM), 1916 Race St., Philadelphia, PA 19103, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(6) * * * specifications not listed under paragraph (f)(1) through (5) of this section, titled: (i) "Determination of Abietic Acid and Dehydroabietic Acid

in Rosins"; (ii) "Determination of Softening Point of Solid Resins"; (iii) "Determination of Saponification Number of Rosin Esters," and (iv) "Determination of Phenolic Modification of Rosin Derivatives," which are incorporated by reference. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

m. In § 178.3910 by revising that portion of paragraph (a)(4)(i)(a), (b), and (c) beginning with "as determined by" and by revising footnote "1" in (a)(4)(iii) to read as follows:

§ 178.3910 Surface lubricants used in the manufacture of metallic articles.

(a) * * *
(4) * * *
(i) * * *

(a) * * * as determined by ASTM method D88-62, "Standard Method of Test for Distillation of Petroleum Products" (Revised 1962), which is incorporated by reference. Copies are available from University Microfilms International, 300 N. Zeeb Rd., Ann Arbor, MI 48106, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(b) * * * as determined by ASTM method D381-64, "Standard Method of Test for Existent Gum in Fuels by Jet Evaporation" (Adopted 1964), when the final boiling point is 250° F or above and by ASTM method D1353-64, "Standard Method of Test for Nonvolatile Matter in Volatile Solvents for Use in Paint, Varnish, Lacquer, and Related Products" (Revised 1964), when the final boiling point is below 250° F, which are incorporated by reference. Copies are available from University Microfilms International, 300 N. Zeeb Rd., Ann Arbor, MI 48106, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(c) * * * as determined by ASTM method D156-64, "Standard Method of Test for Saybolt Color of Petroleum Products: Saybolt Chromometer Method" (Adopted 1964), which is incorporated by reference. Copies are available from University Microfilms International, 300 N. Zeeb Rd., Ann Arbor, MI 48106, or available for inspection at the Office of the Federal

Register, 1100 L St. NW., Washington, DC 20408.

(iii) * * *

¹ As determined by procedure using potassium chromate for reference standard and described in National Bureau of Standards Circular 484, Spectrometry, U.S. Department of Commerce (1949), which is incorporated by reference. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408. The accuracy is to be determined by comparison with the standard values at 210, 345, and 400 millimicrons.

PART 179—IRRADIATION IN THE PRODUCTION, PROCESSING AND HANDLING OF FOODS

8. Part 179 is amended in § 179.45(b)(9) and (c)(2)(iv) by revising the first sentence beginning with "determined by" and adding a new sentence to read as follows:

§ 179.45 Packaging materials for use during the irradiation of prepackaged foods.

(b) * * *

(9) * * * determined by ASTM method D729-57, "Standard Specifications for Vinylidene Chloride Molding Compounds (Revised 1957), which is incorporated by reference. Copies are available from University Microfilms International, 300 N. Zeeb Rd., Ann Arbor, MI 48106, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(c) * * *

(2) * * *

(iv) * * * determined by ASTM method D1243-60, "Standard Method of Test for Dilute Solution Viscosity of Vinyl Chloride Polymers" (Revised 1960) Method A, which is incorporated by reference. Copies are available from University Microfilms International, 300 N. Zeeb Rd., Ann Arbor, MI 48106, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

PART 180—FOOD ADDITIVES PERMITTED IN FOOD ON AN INTERIM BASIS OR IN CONTACT WITH FOOD PENDING ADDITIONAL STUDY

9. Part 180 is amended as follows:

a. In § 180.22, by revising that portion of the introductory text of paragraph (a)

beginning with "determined by" and by revising that portion of (b) beginning with "Analytical methods" to read as follows:

§ 180.22 Acrylonitrile copolymers.

(a) * * * determined by a method of analysis titled "Gas-Solid Chromatographic Procedure for Determining Acrylonitrile Monomer in Acrylonitrile-Containing Polymers and Food Simulating Solvents," which is incorporated by reference. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(b) * * * Analytical methods for the determination of acrylonitrile complexes with *n*-dodecyl-mercaptan, *n*-octyl mercaptan, and 2-mercaptoethanol, titled "Determination of β -Dodecyl-mercaptanpropionitrile in NR-16R Aqueous Extracts" and "Measurement of β -(2-Hydroxyethylmercapto) Propionitrile in Heptane Food-Simulating Solvent," are incorporated by reference. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

b. In § 180.25, by revising paragraph (b) to read as follows:

§ 180.25 Mannitol.

(b) The ingredient meets the specifications of the "Food Chemicals Codex," 2d Ed. (1972), under "Mannitol," which is incorporated by reference. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

c. In § 180.30 by revising paragraph (a) to read as follows:

§ 180.30 Brominated vegetable oil.

(a) The additive complies with specifications prescribed in "Food Chemicals Codex," 1st Ed. (1966), under "Brominated vegetable oil," which is incorporated by reference, except that

free fatty acids (as oleic) shall not exceed 2.5 percent and iodine value shall not exceed 16. Copies of the material incorporated by reference are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

d. In § 180.37, by revising paragraph (b) to read as follows:

§ 180.37 Saccharin, ammonium saccharin, calcium saccharin, and sodium saccharin.

(b) The Food additives meet the specifications of the "Food Chemicals Codex," 2d Ed. (1972), under "Saccharin," which is incorporated by reference. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

PART 181—PRIOR-SANCTIONED FOOD INGREDIENTS

10. Part 181 is amended in § 181.32(b) by revising that portion of the paragraph beginning with "determined by" to read as follows:

§ 181.32 Acrylonitrile copolymers and resins.

(b) * * * determined by using the method of analysis titled "Gas-Solid Chromatographic Procedure for Determining Acrylonitrile Monomer in Acrylonitrile-Containing Polymers and Food-Simulating Solvents," which is incorporated by reference. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

PART 184—DIRECT FOOD SUBSTANCES AFFIRMED AS GENERALLY RECOGNIZED AS SAFE

11. Part 184 is amended as follows:

a. In § 184.1007(b)(1), (6), and (7) by revising that portion of the paragraphs beginning with "Food Chemicals Codex" to read as follows:

§ 184.1007 Aconitic acid.

(b) * * *

(1) * * * "Food Chemicals Codex," 2d Ed. (1972), test for citric acid, which is incorporated by reference, and a molecular weight of 174.11. Copies of the material incorporated by reference are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(6) * * * "Food Chemicals Codex," 2d Ed. (1972), test for citric acid, which is incorporated by reference. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(7) * * * "Food Chemicals Codex," 2d Ed. (1972), test for citric acid, which is incorporated by reference. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

b. In § 184.1021, by revising paragraph (b) to read as follows:

§ 184.1021 Benzoic acid.

(b) The ingredient meets the specifications of the "Food Chemicals Codex," 2d Ed. (1972), under "Benzoic acid," which is incorporated by reference. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

c. In § 184.1025 by revising paragraph (b) to read as follows:

§ 184.1025 Caprylic acid.

(b) The ingredient meets the specifications of the "Food Chemicals Codex," 2d Ed. (1972), under "Caprylic acid," which is incorporated by reference. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW.,

Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

d. In § 184.1069 by revising paragraph (b) to read as follows:

§ 184.1069 Malic acid.

(b) The ingredient meets the specifications of the "Food Chemicals Codex," 2d Ed. (1972), as amended by the Second Supplement (1975), under "Malic acid," which is incorporated by reference. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

e. In § 184.1091 by revising paragraph (b) to read as follows:

§ 184.1091 Succinic acid.

(b) The ingredient meets specifications of the "Food Chemicals Codex," 2d Ed. (1972), under "Succinic acid," which is incorporated by reference. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

f. In § 184.1095 by revising paragraph (b) to read as follows:

§ 184.1095 Sulfuric acid.

(b) The ingredient meets the specifications of the "Food Chemicals Codex," 2d Ed. (1972), under "Sulfuric acid," which is incorporated by reference. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

g. In § 184.1115 by revising paragraph (b) to read as follows:

§ 184.1115 Agar-agar.

(b) The ingredient meets the specifications of the "Food Chemicals Codex," 2d Ed. (1972), under "Agar-agar," which is incorporated by

reference. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

h. In § 184.1143 by revising paragraph (b) to read as follows:

§ 184.1143 Ammonium sulfate.

(b) The ingredient meets the specifications of the "Food Chemicals Codex," 2d Ed. (1972), as amended by the First Supplement (1974), under "Ammonium sulfate," which is incorporated by reference. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

i. In § 184.1206 by revising paragraph (b) to read as follows:

§ 184.1206 Calcium iodate.

(b) The ingredient meets the specifications of the "Food Chemicals Codex," 2d Ed. (1972), under "Calcium iodate," which is incorporated by reference. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

j. In § 184.1230 by revising paragraph (b) to read as follows:

§ 184.1230 Calcium sulfate.

(b) The ingredient meets the specifications of the "Food Chemicals Codex," 2d Ed. (1972), as amended by the First Supplement (1974), under "Calcium sulfate," which are incorporated by reference. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

k. In § 184.1257(b) by revising that portion of the beginning with "Food

Chemicals Codex" and ending with "As determined by" to read as follows:

§ 184.1257 Clove and its derivatives.

(b) * * * "Food Chemicals Codex," 2d Ed. (1972), under "Clove leaf oil," "Clove oil," and "Clove stem oil," which is incorporated by reference. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408. As determined by * * *

l. In § 184.1259(b) (3) and (6) by removing the footnote and revising the parenthetical text to read as follows:

§ 184.1259 Cocoa butter substitute from palm oil.

(b) * * *
(3) * * * [see page 920 of "Food Chemicals Codex," 2d Ed. (1972), under "Heavy metal test," which is incorporated by reference; copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408].

(6) * * * ("Official Methods of Analysis of the Association of Analytical Chemists," 12th Ed. (1975), which is incorporated by reference, residual fluorine; limit of detection 0.2 part per million F; multiply fluoride result by 2.63 to convert to residual catalyst. Copies of the material incorporated by reference are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.) * * *

m. In § 184.1271(b) by revising that portion of the text beginning with "Food Chemicals Codex" to read as follows:

§ 184.1271 L-cysteine.

(b) * * * "Food Chemicals Codex," 2d Ed. (1972), under "L-cysteine monohydrochloride," which is incorporated by reference. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or

available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

n. In § 184.1272(b) by revising that portion of the paragraph beginning with "Food Chemicals Codex" to read as follows:

§ 184.1272 L-cysteine monohydrochloride.

(b) * * * "Food Chemicals Codex," 2d Ed. (1972), under "L-cysteine monohydrochloride," which is incorporated by reference. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-220), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

o. In § 184.1282(b) by revising that portion of the paragraph beginning with "Food Chemicals Codex" to read as follows:

§ 184.1282 Dill and its derivatives.

(b) * * * "Food Chemicals Codex," 2d Ed. (1972), under "Dill Seed oils," which is incorporated by reference. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

p. In § 184.1272(b) by revising that portion beginning with "Food Chemicals Codex" to read as follows:

§ 184.1293 Ethyl alcohol.

(b) * * * "Food Chemicals Codex," 2d Ed. (1972), under "Ethyl alcohol," which is incorporated by reference. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-220), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

q. In § 184.1295(b) by revising that portion of the paragraph beginning with "Food Chemicals Codex" to read as follows:

§ 184.1295 Ethyl formate.

(b) * * * "Food Chemicals Codex," 2d Ed. (1972), under "Ethyl formate,"

which is incorporated by reference. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

r. In § 184.1317(b) by revising that portion of the paragraph beginning with "Food Chemicals Codex" to read as follows:

§ 184.1317 Garlic and its derivatives.

(b) * * * "Food Chemicals Codex," 2d Ed. (1972), under "Garlic oil," which is incorporated by reference. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

s. In § 184.1330(b) by revising that portion of the paragraph beginning with "Food Chemicals Codex" to read as follows:

§ 184.1330 Acacia (gum arabic).

(b) * * * "Food Chemicals Codex," 2d Ed. (1972), under "Acacia (gum arabic)," which is incorporated by reference. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

t. In § 184.1333(b)(4) by revising the first portion of the paragraph ending with "to 5 ml of a cold" to read as follows:

§ 184.1333 Gum ghatti.

(b) * * *
(4) *Identification test.* Add 0.2 ml of diluted lead acetate (basic lead acetate, Official Methods of Analysis of the Association of Official Analytical Chemists, 12th Ed. (1975), sec. 31.164(b), which is incorporated by reference; (copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal

Register, 1100 L St. NW., Washington, DC 20408), to 5 ml of a cold * * *

u. In § 184.1339 by revising paragraph (b), to read as follows:

§ 184.1339 Guar gum.

(b) The ingredient meets specifications of the "Food Chemicals Codex," 2d Ed. (1972), under "Guar gum," which is incorporated by reference. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

v. In § 184.1343(b) by revising that portion beginning with "Food Chemicals Codex" to read as follows:

§ 184.1343 Locust (carob) bean gum.

(b) * * * "Food Chemicals Codex," 2d Ed. (1972), under "Locust bean gum," which is incorporated by reference. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

w. In § 184.1349(b) by revising that portion of the paragraph beginning with "Food Chemicals Codex" to read as follows:

§ 184.1349 Karaya gum (sterculia gum).

(b) * * * "Food Chemicals Codex," 2d Ed. (1972), under "Karaya gum," which is incorporated by reference. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

x. In § 184.1351(b) by revising that portion of the paragraph beginning with "Food Chemicals Codex" to read as follows:

§ 184.1351 Gum tragacanth.

(b) * * * "Food Chemicals Codex," 2d Ed. (1972), under "Tragacanth," which is incorporated by reference. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-

330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

y. In § 184.1490(b) by revising that portion of the paragraph beginning with "Food Chemicals Codex" to read as follows:

§ 184.1490 Methylparaben.

(b) * * * "Food Chemicals Codex," 2d Ed. (1972), under "Methylparaben," which is incorporated by reference. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

z. In § 184.1555(b)(2) by revising the first sentence and adding a new sentence to read as follows:

§ 184.1555 Rapeseed oil.

(b) * * *
(2) The ingredient meets the specifications of the "Food Chemicals Codex," 2d Ed. (1972), relating to mono- and diglycerides, which is incorporated by reference. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408. * * *

aa. In § 184.1634(b) by revising that portion of the paragraph beginning with "Food Chemicals Codex" to read as follows:

§ 184.1634 Potassium iodide.

(b) * * * "Food Chemicals Codex," 2d Ed. (1972), under "Potassium iodide," which is incorporated by reference. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

bb. In § 184.1635(b) by revising that portion of the paragraph beginning with "Food Chemicals Codex" to read as follows:

§ 184.1635 Potassium iodate.

(b) * * * "Food Chemicals Codex," 2d Ed. (1972), under "Potassium iodate," which is incorporated by reference. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

cc. In § 184.1643(b) by revising that portion of the paragraph beginning with "Food Chemicals Codex" to read as follows:

§ 184.1643 Potassium sulfate.

(b) * * * "Food Chemicals Codex," 2d Ed. (1972) as amended by the First Supplement (1974), under "Potassium sulfate," which is incorporated by reference. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

dd. In § 184.1660(b) by revising that portion of the paragraph beginning with "Food Chemicals Codex" to read as follows:

§ 184.1660 Propyl gallate.

(b) * * * "Food Chemicals Codex," 2d Ed. (1972), under "Propyl gallate," which is incorporated by reference. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

ee. In § 184.1670(b) by revising that portion of the paragraph beginning with "Food Chemicals Codex" to read as follows:

§ 184.1670 Propylparaben.

(b) * * * "Food Chemicals Codex," 2d Ed. (1972), under "Propylparaben," which is incorporated by reference. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal

Register, 1100 L St. NW., Washington, DC 20408.

ff. In § 184.1699(b) by revising that portion of the paragraph beginning with "Food Chemicals Codex" to read as follows:

§ 184.1699 Oil of rue.

(b) * * * "Food Chemicals Codex," 2d Ed. (1972), under "Rue oil," which is incorporated by reference. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

gg. In § 184.1733(b) by revising that portion of the paragraph beginning with "Food Chemicals Codex" to read as follows:

§ 184.1733 Sodium benzoate.

(b) * * * "Food Chemicals Codex," 2d Ed. (1972), under "Sodium benzoate," which is incorporated by reference. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

hh. In § 184.1807(b) by revising that portion of the paragraph beginning with "Food Chemicals Codex" to read as follows:

§ 184.1807 Sodium thiosulfate.

(b) * * * "Food Chemicals Codex," 2d Ed. (1972), as amended by the First Supplement (1974), under "Sodium thiosulfate," which is incorporated by reference. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

ii. In § 184.1835(b) by revising that portion of the paragraph beginning with "Food Chemicals Codex" to read as follows:

§ 184.1835 Sorbitol.

(b) * * * "Food Chemicals Codex," 2d Ed. (1972), under "Sorbitol," which are

incorporated by reference. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

jj. In § 184.1973(b) by revising that portion of the paragraph beginning with "Food Chemicals Codex" to read as follows:

§ 184.1973 Beeswax (yellow and white).

(b) * * * "Food Chemicals Codex," 2d Ed. (1972), under "Beeswax, yellow," and "Beeswax, white," which is incorporated by reference. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

PART 186—INDIRECT FOOD SUBSTANCES AFFIRMED AS GENERALLY RECOGNIZED AS SAFE

12. Part 186 is amended as follows:

a. In § 186.1025(b) by revising that portion of the paragraph beginning with "Food Chemicals Codex" to read as follows:

§ 186.1025 Caprylic acid.

(b) * * * "Food Chemicals Codex," 2d Ed. (1972), under "Caprylic acid," which is incorporated by reference. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

b. In § 186.1330(b) by revising that portion of the paragraph beginning with "Food Chemicals Codex" to read as follows:

§ 186.1330 Acacia (gum arabic).

(b) * * * "Food Chemicals Codex," 2d Ed. (1972), under "Acacia (gum arabic)," which is incorporated by reference. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for

inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

c. In § 186.1339(a) by revising the end of the paragraph beginning with "Food Chemicals Codex" to read as follows:

§ 186.1339 Guar gum (technical grade).

(a) * * * "Food Chemicals Codex," 2d Ed. (1972), under "Guar gum," which is incorporated by reference. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

d. In § 186.1343(a) by revising that portion of the paragraph beginning with "Food Chemicals Codex" to read as follows:

§ 186.1343 Locust (carob) bean gum.

(a) * * * "Food Chemicals Codex," 2d Ed. (1972), under "Locust bean gum," which is incorporated by reference. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

§ 186.1551 [Amended]

e. In § 186.1551 by removing footnote "1" and its text from paragraph (b).

f. In § 186.1807(b) by revising that portion of the paragraph beginning with "Food Chemicals Codex" to read as follows:

§ 186.1807 Sodium thiosulfate

(b) * * * "Food Chemicals Codex," 2d Ed. (1972), as amended by the First Supplement (1974), under "Sodium thiosulfate," which is incorporated by reference. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

PART 189—SUBSTANCES PROHIBITED FROM USE IN HUMAN FOOD

13. Part 189 is amended as follows:

a. In § 189.110(c) by revising that portion of the paragraph beginning with "in the" to read as follows:

§ 189.110 Calamus and its derivatives.

(c) * * * in the *Journal of the Association of Official Analytical Chemists*, Volume 56, (Number 5), pages 1281 to 1283, September 1973, which is incorporated by reference. Copies are available from the Association of Official Analytical Chemists, P.O. Box 540, Benjamin Franklin Station, Washington, DC 20044, also from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

b. In § 189.130(c) by revising that portion of the paragraph beginning with "are in §§ 19.014 through 19.023" to read as follows:

§ 189.130 Coumarin.

(c) * * * are in secs. 19.014 through 19.023 of the "Official Methods of Analysis of the Association of Official Analytical Chemists," 11th Ed. (1970), which is incorporated by reference. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

c. In § 189.135(c) by revising that portion of the paragraph beginning with "are in secs. 20.127 through 20.132" to read as follows:

§ 189.135 Cyclamate and its derivatives.

(c) * * * are in secs. 20.127 through 20.132 of the "Official Methods of Analysis of the Association of Official Analytical Chemists," 11th Ed. (1970), which is incorporated by reference. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal

Register, 1100 L St. NW., Washington, DC 20408.

d. In § 189.145(c) by revising that portion of the paragraph beginning with "are in secs. 20.133 through 20.136" to read as follows:

§ 189.145 Dulcin.

(c) * * * are in secs. 20.133 through 20.136 of the "Official Methods of Analysis of the Association of Official Analytical Chemists," which is incorporated by reference. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

e. In § 189.155(c) by revising that portion of the paragraph beginning with "are in §§ 20.057 through 20.062" to read as follows:

§ 189.155 Monochloroacetic acid.

(c) * * * are in secs. 20.057 through 20.062 of the "Official Methods of Analysis of the Association of Official Analytical Chemists," 11th Ed. (1970), which is incorporated by reference. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

f. In § 189.165 by revising paragraph (c) to read as follows:

§ 189.165 Nordihydroguaiaretic acid (NDGA).

(c) The analytical method used for detecting NDGA in food is in sec. 20.008 of the "Official Methods of Analysis of the Association of Official Analytical Chemists," 11th Ed. (1970), which is incorporated by reference. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

g. In § 189.175 by revising paragraph (c) to read as follows:

§ 189.175 P-4000.

(c) The analytical methods used for detecting P-4000 in food are in secs. 20.137 through 20.141 of the "Official Methods of Analysis of the Association of Official Analytical Chemists," 11th Ed. (1970), which is incorporated by reference. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

h. In § 189.180(c) by revising that portion of the paragraph beginning with "is in the" to read as follows:

§ 189.180 Safrole.

(c) * * * is in the *Journal of the Association of Official Analytical Chemists*, Volume 54 (Number 4), pages 900 to 902, July 1971, which is incorporated by reference. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

i. In § 189.190(c) by revising that portion of the paragraph beginning with "are in §§ 20.099 through 20.100" to read as follows:

§ 189.190 Thiourea.

(c) * * * are in secs. 20.099 through 20.100 of the "Official Methods of Analysis of the Association of Official Analytical Chemists," 11th Ed. (1970), which is incorporated by reference. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

The agency has determined that because these amendments do not make any substantive changes in the regulations but merely are editorial, bringing the incorporation by reference text into compliance with drafting requirements of 1 CFR 51.6, 51.7, and 51.8, notice and public procedure and delayed effective date are unnecessary. However, interested persons may, on or before April 19, 1982 submit to the Dockets Management Branch (address above), written comments regarding

these amendments. Two copies of any comments are to be submitted, except individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. If the agency determines by the comments received that the amended text should be modified, a notice containing those modifications will be published in the *Federal Register*. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 1, 1982.

William F. Randolph,
Acting Associate Commissioner for
Regulatory Affairs.

[FR Doc. 82-7179 Filed 3-18-82; 8:45 am]

BILLING CODE 4160-01-M

21 CFR Parts 436 and 442

[Docket No. 81N-0407]

Antibiotic Drugs; Cephadrine Dihydrate Capsules

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the antibiotic drug regulations to provide for the certification of a new antibiotic drug, cephadrine dihydrate capsules. The manufacturer has supplied sufficient data and information to establish its safety and efficacy.

DATES: Effective March 19, 1982; comments, notice of participation, and request for hearing by April 19, 1982; data, information, and analyses to justify a hearing by May 18, 1982.

ADDRESS: Written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Joan Eckert, Bureau of Drugs (HFD-140), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4290.

SUPPLEMENTARY INFORMATION: FDA has evaluated data submitted in accordance with regulations promulgated under section 507 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 357), as amended, with respect to providing for the certification of a new antibiotic drug, cephadrine dihydrate capsules. The agency has concluded that the data supplied by the manufacturer concerning this antibiotic drug are adequate to establish its safety and efficacy when used as directed in the labeling and that the regulations should

be amended in Parts 436 and 442 (21 CFR Parts 436 and 442) to provide for its certification.

The agency has determined pursuant to 21 CFR 25.24(b)(22) (proposed December 11, 1979; 44 FR 71742) that this action is of a type that does not individually or cumulatively have a significant impact on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Therefore, under the Federal Food, Drug and Cosmetic Act (secs. 507, 701 (f) and (g), 52 Stat. 1055-1056 as amended, 59 Stat. 463 as amended (21 U.S.C. 357,

371 (f) and (g))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10 (formerly 5.1; see 46 FR 26052; May 11, 1981)), Parts 436 and 442 are amended as follows:

PART 436—TESTS AND METHODS OF ASSAY OF ANTIBIOTIC AND ANTIBIOTIC-CONTAINING DRUGS

1. Part 436 is amended:

a. In § 436.33(b) by alphabetically adding a new item in the table as follows:

§ 436.33 Safety test.

* * * * *

(b) * * *

Antibiotic drug	Diluent (diluent number as listed in § 436.31)	Test dose		Route of administration as described in paragraph (c) of this section
		Concentration in units or milligram of activity per milliliter	Volume in milliliters to be administered to each mouse	
Cephadrine dihydrate	10	40 mg	0.5	Oral.

§ 436.541 Dissolution test.

* * * * *

(b) * * *

b. In § 436.541, by amending paragraph (b) by alphabetically adding a new item into the table and by adding new paragraph (c)(5), to read as follows:

Dosage form	Dissolution medium	Stirring blade ¹	Sampling time(s) (minutes)
Cephadrine dihydrate capsules	900 mL 0.12N hydrochloric acid	75	60

* * * * *

(c) * * *

(5) *Cephadrine dihydrate*—(i) *Preparation of working standard solution.* Accurately weigh approximately 40 milligrams of cephadrine working standard into a suitable-sized volumetric flask. Dissolve and dilute to volume with 0.12N hydrochloric acid. Further dilute with a buffer solution (prepared by dissolving 27.2 grams of sodium acetate trihydrate in a mixture of 12 milliliters of glacial acetic acid and sufficient distilled water to make 2 liters) to obtain a known concentration of 0.01 to 0.03 milligram of cephadrine per milliliter.

(ii) *Preparation of sample solution.* Filter the sample and dilute an accurately measured portion of the filtrate with sufficient buffer solution, described in paragraph (c)(5)(i) of this section, to obtain a concentration of 0.01 to 0.03 milligram of cephadrine per milliliter (estimated).

(iii) Proceed as directed in paragraph (c)(1) (iii) and (iv) of this section, except measure the absorbance at the absorption peak at approximately 262 nanometers.

PART 442—CEPHA ANTIBIOTIC DRUGS

2. Part 442 is amended:

a. By adding new § 442.41, to read as follows:

§ 442.41 Cephadrine dihydrate.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Cephadrine dihydrate is the dihydrate form of (6R,7R)-7-[(R)-2-amino-2-[1,4-cyclohexadien-1-yl]acetamido]-3-methyl-8-oxo-5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylic acid. It is so purified and dried that:

(i) Its potency is not less than 900 micrograms and not more than 1,050 micrograms of cephadrine per milligram on an anhydrous basis.