on State or local governments, as discussed above, no consultations with State and local governments on this rule were necessary.

List of Subjects in 14 CFR Part 255

Air carriers, Antitrust, Consumer protection, Reporting and recordkeeping requirements, Travel agents.

Accordingly, the Department of Transportation amends 14 CFR Part 255 as follows:

PART 255—[AMENDED]

1. The authority citation for Part 255 continues to read as follows:

Authority: 49 U.S.C. 40101, 40102, 40105, 40113, 41712.

2. Section 255.12 is revised to read as follows:

§ 255.12. Termination.

The rules in this part terminate on March 31, 2002.

Issued in Washington, D.C. on March 27, 2001, under authority delegated by 49 CFR 1.56a (h) 2.

Susan McDermott,

Deputy Assistant Secretary for Aviation and International Affairs.

[FR Doc. 01–7978 Filed 3–28–01; 11:38 am]

BILLING CODE 4910–62–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 101, 102, 106, 107, 130, 146, 165, and 190

[Docket No. 01N–0134]

Foods, Infant Formulas, and Dietary Supplements; Technical Amendments

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendments.

SUMMARY: The Food and Drug Administration (FDA) is making technical amendments to its regulations that address food labeling, common or usual names for nonstandardized foods, infant formulas, food standards, and dietary supplements. The purpose of the amendments is to update the names, addresses, and phone numbers for FDA offices and professional organizations, to correct minor errors and inadvertent omissions in the Code of Federal Regulations (CFR), and to delete obsolete information. The technical amendments made by this final rule are editorial in nature and are intended to provide accuracy and clarity to the agency's regulations.

DATES: This rule is effective March 30, 2001.

FOR FURTHER INFORMATION CONTACT: Rhonda Rhoda Kane, Office of Nutritional Products, Labeling and Dietary Supplements (HFS–821), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–4168.

SUPPLEMENTARY INFORMATION: FDA is making technical amendments in its regulations under parts 101, 102, 106, 107, 130, 146, 165, and 190 (21 CFR parts 101, 102, 106, 107, 130, 146, 165, and 190). Specifically, as a result of an FDA reorganization in 2000, the Office of Special Nutritionals and the Office of Food Labeling were combined to form the Office of Nutritional Products, Labeling and Dietary Supplements. Therefore, this rule updates the name and mail codes for this new office in FDA regulations on food labeling (part 101), common or usual name for nonstandardized foods (part 102), infant formula quality control procedures (part 106), infant formula (part 107), food standards (part 130), and new dietary ingredient notification requirements for dietary supplements (part 190). In parts 106 and 107, pertaining to infant formulas, this rule also corrects FDA emergency phone numbers and a regulation section citation for FDA district offices. Similarly, this rule updates the names, addresses, and other contact information for several professional organizations cited in FDA regulations on food labeling (part 101) and requirements for standardized foods (part 146). In addition, FDA discovered that minor errors and omissions were inadvertently published in the CFR affecting its regulations on food labeling (part 101), infant formulas (parts 106 and 107), and requirements for standardized foods (part 165). This rule makes the needed corrections. Finally, due to the passage of time, certain food labeling provisions for juices (§ 101.17) are now obsolete and are removed from FDA regulations by this rule.

This final regulation makes the noted technical amendments. The final rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required. The changes addressed in this final rule are as follows:

1. FDA's recent reorganization resulted in changes in the names of several of its offices, mail codes, phone numbers, and staff contacts cited in its regulations. This rule amends parts 101, 102, 106, 107, 130, and 190 to incorporate all of these types of changes and other minor corrections as noted below:

- Throughout part 101, pertaining to food labeling, the Office of Food Labeling (HFS–150) or the Center for Food Safety and Applied Nutrition (HFS–150) is cited as the FDA office responsible for this part's provisions. The new name and mail code for the Office of Food Labeling are the Office of Nutritional Products, Labeling and Dietary Supplements (HFS–800). The new mail code for the Center for Food Safety and Applied Nutrition pertaining to part 101 is (HFS–800). The new FDA office name and mail code are substituted for the old ones wherever they appear in part 101.
- In § 101.93(a)(1), dietary supplement manufacturers, packers or distributors are required to notify FDA no later than 30 days post marketing about any structure or function claims made on the labeling of their dietary supplements. The name and mail code of the FDA office to contact for this purpose are changed from Office of Special Nutritionals (HFS–450) to the Office of Nutritional Products, Labeling and Dietary Supplements (HFS–810).
- In § 102.23(c)(5), pertaining to requirements for peanut spreads, the FDA mail code for the Center for Food Safety and Applied Nutrition is changed from (HFS–150) to (HFS–800).
- In § 106.120(a), pertaining to notification requirements for new formulations and reformulations of infant formulas, the FDA mail code for the Center for Food Safety and Applied Nutrition is changed from (HFS–450) to (HFS–830).
- In § 106.20(b), the FDA emergency phone number for manufacturers to call to report adulterated or misbranded infant formulas is changed from 202–737–0448 to 301–443–1240. Also in § 106.120(b), the regulatory section citation for a list of FDA district offices for manufacturers to contact to report this infant formula problem is currently erroneously stated in two places as § 5.115 and is corrected to read § 5.215.
- In § 107.50(e)(1), pertaining to notification requirements for exempt infant formulas, the FDA mail code for the Center for Food Safety and Applied Nutrition is changed from (HFS–450) to (HFS–830).
- In § 107.50(e)(2), the FDA emergency phone number for manufacturers to call to report adulterated or misbranded exempt infant formulas is changed from 202–737–0448 to 301–443–1240. Also in § 107.50(e)(2), the regulatory section citation for a list of FDA district offices for manufacturers to contact to report this problem is currently erroneously

stated in two places as § 5.115 and is corrected to read § 5.215.

• In §§ 107.230(e), 170.240(b), and 107.250, pertaining to infant formula recalls, notification requirements for violative infant formulas, and the termination of an infant formula recall, respectively, the regulatory section citation for a list of FDA district offices for manufacturers to contact to report these situations is currently erroneously stated one or more times as § 5.115 and is corrected to read § 5.215. Also, in § 107.240(b), the FDA emergency phone number for manufacturers to call to report violative infant formula is changed from 202–857–8400 to 301–443–1240.

• In § 130.17(c), the regulations currently state the Chief, Food Standards Branch, Office of Food Labeling, Center for Food Safety and Applied Nutrition (HFS–158) as the FDA contact to whom a request for a temporary permit must be filed. This temporary permit is for interstate shipment of experimental packs of food varying from the requirements of definitions and standards of identity. The new FDA contact for filing such a permit is the Team Leader, Conventional Foods Team, Division of Standards and Labeling Regulations, Office of Nutritional Products, Labeling and Dietary Supplements, Center for Food Safety and Applied Nutrition (HFS–822).

• In 190.6(a), the FDA name and mail code for manufacturers or distributors to submit a premarket notification for a dietary supplement containing a new dietary ingredient are changed from the Office of Special Nutritionals (HFS–450) to the Office of Nutritional Products, Labeling and Dietary Supplements (HFS–820).

2. A final rule, published in the **Federal Register** on September 23, 1997 (62 FR 49825), amended FDA's food labeling regulations to establish requirements for the identification of dietary supplements and for their nutrition labeling and ingredient labeling in § 101.4. Section 101.4(h) requires that the product label for dietary supplements that contain dietary ingredients that are botanicals to state the common or usual names of these ingredients. Current regulations also require that the common or usual names stated on the label for these ingredients be consistent with the names standardized in *Herbs of Commerce*, 1992 edition, which was incorporated by reference. The address for the American Herbal Products Association, the publisher and source of copies of the *Herbs of Commerce*, has changed from 4733 Bethesda Ave., suite 345, Bethesda, MD 20814 to 8484 Georgia Ave., suite 370, Silver Spring, MD 20910. This rule amends the address cited in § 101.4(h) for the American Herbal Products Association and includes the following phone and facsimile numbers and electronic mail address as additional ways to contact the association: phone: 301–588–1171, FAX: 301–588–1174, and e-mail: ahpa@ahpa.org.

3. A final rule, published in the **Federal Register** on September 23, 1997 (62 FR 49859), revised FDA's regulations on nutrient content claims and health claims for conventional foods and dietary supplements. FDA discovered two inadvertent errors from that rulemaking that affect §§ 101.14 and 101.54. Old § 101.14(a)(4) was removed and old § 101.14(a)(5) was redesignated as the new § 101.14(a)(4). At that time, FDA did not realize that § 101.14(e)(3) referenced the original § 101.14(a)(5), which is now paragraph (a)(4). Therefore, this rule amends § 101.14(e)(3) by referring to § 101.14(a)(4) and not (a)(5). In addition, when § 101.54(e)(1) was revised, FDA inadvertently omitted the terms ''extra'' and ''plus'' as synonyms for the nutrient content claim ''more.'' Consequently, this rule reinserts the additional terms for ''more'' in § 101.54(e)(1).

4. In an amendment to § 101.17 published in the **Federal Register** on July 8, 1998 (63 FR 37030), FDA allowed, for a specified period of time, the warning statements required in the labeling of juices to be displayed on signs and placards located near products sold in stores as an alternative to having this information included on the product labels themselves. Section 101.17(g)(4)(i) and (g)(4)(ii), respectively, stated that the dates for this labeling flexibility were September 8, 1999, for apple juice or apple cider and November 5, 1999, for all other juices. Since these dates have passed, these sections of the regulations are no longer needed. This rule deletes these two paragraphs as well as the words ''except that'' from that end of the sentence in the introductory § 101.17(g)(4) directly preceding § 101.17(g)(4)(i) and (g)(4)(ii).

5. A final rule, published in the **Federal Register** on March 24, 1998 (63 FR 14035), amended FDA's regulations to reflect a change in the name and address for the association of Official Analytical Chemists. The association's old address was P.O. Box 540, Benjamin Franklin Station, Washington, DC 20044. The association's new name and address are AOAC INTERNATIONAL, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877–2504. FDA discovered that there are two instances in parts 101 and 146 where this change was inadvertently overlooked. Therefore, this rule amends § 101.100(a)(4), pertaining to exemptions from food labeling requirements, and § 146.132(a)(1), pertaining to food standard requirements for canned grapefruit juice, to reflect the current name and address for AOAC INTERNATIONAL.

6. In § 165.110(b)(2) and (b)(4)(i)(C), pertaining to the microbiological and chemical quality testing of bottled water, the regulations currently state the address for the American Public Health Association as 1015 15th (or Fifteenth) St. NW., Washington, DC 20005. The American Public Health Association is the source of copies of a resource incorporated by reference for analyzing the quality of water. The new address for the American Public Health Association is 800 I St. NW., Washington, DC 20001. This rule amends part 165 to reflect the new address of the American Public Health Association.

7. In § 165.110(b)(4)(iii)(E), (b)(4)(iii)(E)(*1*)(*ii*), and (b)(4)(iii)(E)(*11*)(*i*), pertaining to the requirements for bottled water, current regulations mistakenly state the address for the National Technical Information Service (NTIS), U.S. Department of Commerce as 5825 Port Royal Rd., Springfield, VA 22161. NTIS is the source of copies of a resource incorporated by reference for analyzing trace minerals in water. The correct street address is 5285 Port Royal Rd., Springfield, VA 22161. In addition, these paragraphs inconsistently refer to the National Technical Information Service by either including or excluding the acronym (NTIS) with the name or by using the acronym without the name spelled out. This rule amends part 165 to consistently and correctly cite the name and address for the National Technical Information Service (NTIS).

Publication of this document constitutes final action of these changes under the Administrative Procedure Act (5 U.S.C. 553). FDA has determined that notice and public comment are unnecessary because these amendments are merely correcting nonsubstantive errors.

List of Subjects

21 CFR Part 101

Food labeling, Nutrition, Reporting and recordkeeping requirements.

21 CFR Part 102

Beverages, Food grades and standards, Food labeling, Frozen foods, Oils and fats, Onions, Potatoes, Seafood.

21 CFR Part 106

Food grades and standards, Infants and children, Nutrition, Reporting and recordkeeping requirements.

21 CFR Part 107

Food labeling, Infants and children, Nutrition, Reporting and recordkeeping requirements, Signs and symbols.

21 CFR Part 130

Food additives, Food grades and standards.

21 CFR Part 146

Food grades and standards, Fruit juices.

21 CFR Part 165

Beverages, Bottled water, Food grades and standards.

21 CFR Part 190

Food additives, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 101, 102, 106, 107, 130, 146, 165, and 190 are amended as follows:

PART 101—FOOD LABELING

1. The authority citation for 21 CFR part 101 continues to read as follows:

Authority: 15 U.S.C. 1453, 1454, 1455; 21 U.S.C. 321, 331, 342, 343, 348, 371; 42 U.S.C. 243, 264, 271.

Part 101 [Amended]

2. Part 101 is amended by removing the words ''Office of Food Labeling (HFS–150)'' wherever they appear and by adding in their place ''Office of Nutritional Products, Labeling and Dietary Supplements (HFS–800)'', and by removing the old mail code ''(HFS–150)'' after the Center for Food Safety and Applied Nutrition wherever it appears and by adding in its place the new mail code ''(HFS–800)''.

§ 101.4 [Amended]

3. Section 101.4 *Food; designation of ingredients* is amended in paragraph (h) by removing the address for American Herbal Products Association ''4733 Bethesda Ave., suite 345, Bethesda, MD 20814'' and by adding in its place ''8484 Georgia Ave., suite 370, Silver Spring, MD 20910, 301–588–1171, FAX 301–588–1174, e-mail: ahpa@ahpa.org''.

§ 101.14 [Amended]

4. Section 101.14 *Health claims: general requirements* is amended in paragraph (e)(3) by removing the words ''paragraph (a)(5)'' and by adding in their place ''paragraph (a)(4)''.

§ 101.17 [Amended]

5. Section 101.17 *Food labeling warning and notice statements* is amended in paragraph (g)(4) by removing the words '', except that:'' from the end of the sentence in the introductory paragraph, and by adding in their place a period after the word ''container'', and by removing paragraphs (g)(4)(i) and (g)(4)(ii).

§ 101.54 [Amended]

6. Section 101.54 *Nutrient content claims for ''good source,'' ''high,'' ''more,'' and ''high potency''* is amended in paragraph (e)(1) by removing the words 'and ''added'' ' and by adding, in their place the words ' ''added,'' ''extra,'' and ''plus'' '.

§ 101.93 [Amended]

7. Section 101.93 *Certain types of statements for dietary supplements* is amended in paragraph (a)(1) by removing the words ''Office of Special Nutritionals (HFS–450)'' and by adding in their place ''Office of Nutritional Products, Labeling and Dietary Supplements (HFS–810)''.

§ 101.100 [Amended]

8. Section 101.100 *Food; exemptions from labeling* is amended in paragraph (a)(4) by removing the words ''Association of Official Analytical Chemists, P.O. Box 540, Benjamin Franklin Station, Washington, DC 20044'' and by adding in their place ''AOAC INTERNATIONAL, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877–2504''.

PART 102—COMMON OR USUAL NAME FOR NONSTANDARDIZED FOODS

9. The authority citation for 21 CFR part 102 continues to read as follows:

Authority: 21 U.S.C. 321, 343, 371.

§ 102.23 [Amended]

10. Section 102.23 *Peanut spreads* is amended in paragraph (c)(5) by removing the mail code ''(HFS–150)'' after the words ''Center for Food Safety and Applied Nutrition'' and by adding in its place ''(HFS–800)''.

PART 106—INFANT FORMULA QUALITY CONTROL PROCEDURES

11. The authority citation for 21 CFR part 106 continues to read as follows:

Authority: 21 U.S.C. 321, 350a, 371.

12. Section 106.120 is amended in paragraph (a) by removing the mail code ''(HFS–450)'' after the words ''Center for Food Safety and Applied Nutrition'' and by adding in its place the new mail code ''(HFS–830)'', and in paragraph (b) by revising the second and third sentences to read as follows:

§ 106.120 New formulations and reformulations.

* * * * *

(b) * * * This notification shall be made, by telephone, to the Director of the appropriate Food and Drug Administration district office specified in § 5.215 of this chapter. After normal business hours (8 a.m. to 4:30 p.m.) the FDA emergency number, 301–443–1240, shall be used. The manufacturer shall send a followup written confirmation to the Center for Food Safety and Applied Nutrition (HFS–605), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, and to the appropriate Food and Drug Administration district office specified in §5.215.

PART 107—INFANT FORMULA

13. The authority citation for 21 CFR part 107 continues to read as follows:

Authority: 21 U.S.C. 321, 343, 350a, 371.

14. Section 107.50 is amended in paragraph (e)(1) by removing the mail code ''(HFS–450)'' after the words ''Center for Food Safety and Applied Nutrition'' and by adding in its place the new mail code ''(HFS–830)'', and in paragraph (e)(2) by revising the second and third sentences to read as follows:

§ 107.50 Terms and conditions.

* * * * *

(e) * * *

(2) * * * This notification shall be made, by telephone, to the Director of the appropriate FDA district office specified in § 5.215 of this chapter. After normal business hours (8 a.m. to 4:30 p.m.), the FDA emergency number, 301–443–1240, shall be used. The manufacturer shall send a followup written confirmation to the Center for Food Safety and Applied Nutrition (HFS–605), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, and to the appropriate FDA district office specified in § 5.215.

§ 107.230 [Amended]

15. Section 107.230 *Elements of an infant formula recall* is amended in paragraph (e) by removing the reference to ''§ 5.115'' and by adding in its place ''§ 5.215''.

16. Section 107.240 *Notification requirements* is amended in paragraph (b) by removing the reference to ''§ 5.115'' and by adding in its place ''§ 5.215'', and by removing the old emergency phone number ''202–857–8400'' and by adding in its place the new emergency phone number ''301–443–1240''.

§ 107.250 [Amended]

17. Section 107.250 *Termination of an infant formula recall* is amended in the introductory paragraph by removing the reference to ''§ 5.115'' and by adding in its place ''§ 5.215''.

PART 130—FOOD STANDARDS: GENERAL

18. The authority citation for 21 CFR part 130 continues to read as follows:

Authority: 21 U.S.C. 321, 336, 341, 343, 371.

§ 130.17 [Amended]

19. Section 130.17 *Temporary permits for interstate shipment of experimental packs of food varying from the requirements of definitions and standards of identity* is amended in paragraph (c) by removing the words ''Chief, Food Standards Branch, Office of Food Labeling, Center for Food Safety and Applied Nutrition (HFS–158)'' and by adding in their place ''Team Leader, Conventional Foods Team, Division of Standards and Labeling Regulations, Office of Nutritional Products, Labeling and Dietary Supplements, Center for Food Safety and Applied Nutrition (HFS–822)''.

PART 146—CANNED FRUIT JUICES

20. The authority citation for 21 CFR part 146 continues to read as follows:

Authority: 21 U.S.C. 321, 341, 343, 348, 371, 379e.

§ 146.132 [Amended]

21. Section 146.132 *Grapefruit juice* is amended in paragraph (a)(1) by removing the words ''Association of Official Analytical Chemists International, 1111 N. 19th St., Suite 210, Arlington, VA 22209'' and by adding in their place ''AOAC INTERNATIONAL, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877–2504''.

PART 165—BEVERAGES

22. The authority citation for 21 CFR part 165 continues to read as follows:

Authority: 21 U.S.C. 321, 341, 343, 343–1, 348, 349, 371, 379e.

§ 165.110 [Amended]

23. Section 165.110 *Bottled water* is amended as follows:

a. In paragraph (b)(2) by removing the words ''American Public Health Association, 1015 15th St. NW., Washington, DC 20005'' and by adding in their place ''American Public Health Association, 800 I St. NW., Washington, DC 20001'';

b. In paragraph (b)(4)(i)(C) by removing the words ''American Public Health Association, 1015 Fifteenth St. NW., Washington, DC 20005'' and by adding in their place ''American Public Health Association, 800 I St. NW., Washington, DC 20001'';

c. In paragraph (b)(4)(iii)(E) by removing the words ''National Technical Information Service (NTIS), U.S. Department of Commerce, 5825 Port Royal Rd., Springfield, VA 22161'' and by adding in their place ''National Technical Information Service (NTIS), U.S. Department of Commerce, 5285 Port Royal Rd., Springfield, VA 22161'';

d. In paragraph (b)(4)(iii)(E)(*1*)(*ii*) by removing the words ''National Technical Information Service, U.S. Department of Commerce, 5825 Port Royal Rd., Springfield, VA 22161'' and by adding in their place ''National Technical Information Service (NTIS), U.S. Department of Commerce, 5285 Port Royal Rd., Springfield, VA 22161''; and

e. In paragraph (b)(4)(iii)(E)(*11*)(*i*) by removing the words ''NTIS, U.S. Department of Commerce, 5825 Port Royal Rd., Springfield, VA 22161'' and by adding in their place ''National Technical Information Service (NTIS), U.S. Department of Commerce, 5285 Port Royal Rd., Springfield, VA 22161''.

PART 190—DIETARY SUPPLEMENTS

24. The authority citation for 21 CFR part 190 continues to read as follows:

Authority: Secs. 201(ff), 301, 402, 413, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(ff), 331, 342, 350b, 371).

§ 190.6 [Amended]

25. Section 190.6 *Requirement for premarket notification* is amended in paragraph (a) by removing the words ''Office of Special Nutritionals (HFS–450)'' and by adding in their place ''Office of Nutritional Products, Labeling and Dietary Supplements (HFS–820)''.

Dated: March 27, 2001.

Ann M. Witt,

Acting Associate Commissioner for Policy.

[FR Doc. 01–7980 Filed 3–29–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 809 and 864

[Docket No. 97N–0135]

Hematology and Pathology Devices; Reclassification; Restricted Devices; OTC Test Sample Collection Systems for Drugs of Abuse Testing; Delay of Effective Date

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; delay of effective date.

SUMMARY: In accordance with the memorandum of January 20, 2001, from the Assistant to the President and Chief of Staff, entitled ''Regulatory Review Plan,'' published in the **Federal Register** on January 24, 2001 (66 FR 7702), this action temporarily delays for 60 days the effective date of the rule entitled ''Hematology and Pathology Devices; Reclassification; Restricted Devices; OTC Test Sample Collection Systems for Drugs of Abuse Testing,'' published in the **Federal Register** on April 7, 2000 (65 FR 18230).

DATES: The effective date of the ''Hematology and Pathology Devices; Reclassification; Restricted Devices; OTC Test Sample Collection Systems for Drugs of Abuse Testing,'' amending 21 CFR parts 809 and 864 published in the **Federal Register** on April 7, 2000 (65 FR 18230), is delayed for 60 days, from April 9, 2001, to a new effective date of June 8, 2001.

FOR FURTHER INFORMATION CONTACT: Joseph M. Sheehan, Center for Devices and Radiological Health (HFZ–215), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–827–2974.

SUPPLEMENTARY INFORMATION: The rule: (1) Reclassifies over-the-counter (OTC) test sample collection systems for drugs of abuse testing from class III (premarket approval) into class I (general controls) and exempts them from premarket notification (510(k)) and current good manufacturing practice requirements; (2) designates OTC test sample collection systems for drugs of abuse testing as restricted devices under the Federal Food, Drug, and Cosmetic Act; and (3) establishes restrictions intended to assure consumers that: The underlying laboratory test(s) are accurate and reliable, the laboratory performing the test(s) has adequate expertise and competency, and the product has adequate labeling and