

7. Memorandum from M. DiNovi, FDA, to J. Wallwork, FDA, August 29, 1996.

8. Olsen, P. "Canthaxanthin," in *Toxicological Evaluation of Certain Food Additives and Contaminants in Food*. WHO Food Additive Series: 35, World Health Organization, Geneva, pp. 157-171, 1996.

9. Memorandum of April 17, 1997, FDA Meeting Regarding Canthaxanthin: JECFA's 1996 ADI.

10. Memorandum from C. Johnson, FDA, to J. Wallwork, FDA, September 10, 1996.

11. Bunnell, R. H., and B. Borenstein, "Canthaxanthin, A Potential New Food Color," *Food Technology*, 21: 13A-16A, 1967.

12. Memorandum of Telephone Conversation between J. Wallwork, FDA, and S. Turujman, FDA, July 8, 1996.

List of Subjects in 21 CFR Part 73

Color additives, Cosmetics, Drugs, Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 73 is amended as follows:

PART 73—LISTING OF COLOR ADDITIVES EXEMPT FROM CERTIFICATION

1. The authority citation for 21 CFR part 73 continues to read as follows:

Authority: 21 U.S.C. 321, 341, 342, 343, 348, 351, 352, 355, 361, 362, 371, 379e.

2. Section 73.75 is amended in paragraph (c)(1)(i) by removing the period at the end and by adding "; and" in its place, by adding paragraph (c)(3), and by revising paragraph (d) to read as follows:

§ 73.75 Canthaxanthin.

* * * * *

(c) * * *

(3) Canthaxanthin may be safely used in the feed of salmonid fish in accordance with the following prescribed conditions:

(i) Canthaxanthin may be added to the fish feed only in the form of a stabilized color additive mixture;

(ii) The color additive is used to enhance the pink to orange-red color of the flesh of salmonid fish; and

(iii) The quantity of color additive in feed shall not exceed 80 milligrams per kilogram (72 grams per ton) of finished feed.

(d) *Labeling requirements.* (1) The labeling of the color additive and any mixture prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(2) For purposes of coloring fish, the labeling of the color additive and any premixes prepared therefrom shall bear

expiration dates (established through generally accepted stability testing methods) for the sealed and open container, other information required by § 70.25 of this chapter, and adequate directions to prepare a final product complying with the limitations prescribed in paragraph (c)(3) of this section.

(3) The presence of the color additive in finished fish feed prepared according to paragraph (c)(3) of this section shall be declared in accordance with § 501.4 of this chapter.

(4) The presence of the color additive in salmonid fish that have been fed feeds containing canthaxanthin shall be declared in accordance with §§ 101.22(b), (c), and (k)(2), and 101.100(a)(2) of this chapter.

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Dated: March 19, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98-8127 Filed 3-26-98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 101, 104, and 135

Foods and Drugs; Technical Amendments

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendments.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations to correct certain errors that have become incorporated into the food labeling regulations. This action is being taken to improve the accuracy and clarity of the regulations.

EFFECTIVE DATE: March 27, 1998

FOR FURTHER INFORMATION CONTACT: Theresa L. Thomas, Center for Food Safety and Applied Nutrition (HFS-150), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-205-4561.

SUPPLEMENTARY INFORMATION: FDA has discovered that certain errors have become incorporated into the agency's codified regulations on food labeling. FDA is correcting these nonsubstantive errors.

In the **Federal Register** of June 3, 1996 (61 FR 27771), FDA published a final rule entitled "Revocation of Certain Regulations Affecting Food." The final rule, among other things, revoked

§ 100.130 (21 CFR 100.130). However, in issuing the rule, the agency inadvertently neglected to remove the cross-reference to § 100.130 in § 101.2. Also in the **Federal Register** of January 6, 1993 (58 FR 2079), FDA published a final rule entitled "Food Labeling: Mandatory Status of Nutrition Labeling and Nutrient Content Revision, Format for Nutrition Label." The 1993 final rule, among other things, revised § 101.9 (21 CFR 101.9) in its entirety. However, in issuing the 1993 final rule, the agency inadvertently neglected to revise the reference to "§ 101.9(e)" that appeared in §§ 101.12 and 104.5 (21 CFR 101.12 and 104.5) to read "§ 101.9(g)." In this order, FDA is amending §§ 101.2, 101.12, and 104.5 to correct these inadvertent omissions.

In addition to these modifications, FDA is making a number of other minor corrections involving spelling and punctuation errors.

Publication of this document constitutes final action on these changes under the Administrative Procedure Act (5 U.S.C. 553). Notice and public procedure are unnecessary because FDA is merely correcting nonsubstantive errors.

Lists of Subjects

21 CFR Part 101

Food labeling, Nutrition, Reporting and recordkeeping requirements.

21 CFR Part 104

Food grades and standards, Frozen foods, Nutrition.

21 CFR Part 135

Food grades and standards, Food labeling, Frozen foods, Ice cream.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 101, 104, and 135 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.

§ 101.2 [Amended]

2. Section 101.2 *Information panel of package form food* is amended by removing paragraph (c)(1)(ii)(B)(3)(i) and by redesignating paragraphs (c)(1)(ii)(B)(3)(ii), (c)(1)(ii)(B)(3)(iii), and (c)(1)(ii)(B)(3)(iv) as paragraphs (c)(1)(ii)(B)(3)(i), (c)(1)(ii)(B)(3)(ii), and (c)(1)(ii)(B)(3)(iii), respectively.

§ 101.12 [Amended]

3. Section 101.12 *Reference amounts customarily consumed per eating occasion* is amended in paragraph (e)(2) by removing the citation “§ 101.9(e)” and adding in its place “§ 101.9(g).”

§ 101.13 [Amended]

4. Section 101.13 *Nutrient content claims—general principles* is amended in paragraph (q)(8) by revising the words “fluoridated fluoride added” to read “fluoridated, fluoride added.”

§ 101.22 [Amended]

5. Section 101.22 *Foods; labeling of spices, flavorings, colorings and chemical preservatives* is amended in the third sentence of paragraph (i)(4) by removing the phrase “A flavor used” and adding in its place the phrase “A flavor user”.

PART 104—NUTRITIONAL QUALITY GUIDELINES FOR FOODS

6. The authority citation for 21 CFR part 104 continues to read as follows:

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

§ 104.5 [Amended]

7. Section 104.5 *General principles* is amended in paragraph (e) by removing the citation “§ 101.9(e)” and adding in its place “§ 101.9(g)”.

PART 135—FROZEN DESSERTS

8. The authority citation for 21 CFR part 135 continues to read as follows:

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

§ 135.110 [Amended]

9. Section 135.110 *Ice cream and frozen custard* is amended in paragraph (f)(3)(i) by removing the citation to paragraph “(e)(2)(ii)” and adding in its place “(f)(2)(ii)”.

Dated: March 19, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98-7983 Filed 3-26-98; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration****21 CFR Part 522****Implantation or Injectable Dosage Form New Animal Drugs; Tilimicosin Phosphate Injection; Correction**

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a final rule that appeared in the **Federal Register** of February 17, 1998 (63 FR 7701). The document amended the drug regulations to reflect approval of a supplemental new animal drug application filed by Elanco Animal Health, A Division of Eli Lilly and Co. The document was published with an error. This document corrects that error.

EFFECTIVE DATE: February 17, 1998.

FOR FURTHER INFORMATION CONTACT: Lajuana D. Caldwell, Office of Policy (HF-27), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-2994.

In FR Doc. 98-3897, appearing on page 7701, in the **Federal Register** of Tuesday, February 17, 1998, the following correction is made:

§ 522.2471 [Corrected]

1. On page 7701, in the third column, in amendment no. 2, in line four, “13th and 14th” is corrected to read “14th and 15th”.

Dated: March 19, 1998.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 98-7982 Filed 3-26-98; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF TRANSPORTATION**Coast Guard****33 CFR Part 100**

[CGD 05-98-013]

RIN 2115-AE46

Special Local Regulations for Marine Events; Whitbread Chesapeake, Chesapeake Bay, Maryland

AGENCY: Coast Guard, DOT.

ACTION: Temporary final rule.

SUMMARY: Temporary special local regulations are being adopted for the Chesapeake Bay portion of the Whitbread Round-the-World Offshore Yacht Race. Three marine events held as part of the Whitbread Round-the-World Race will take place in the waters of the Chesapeake Bay and Patapsco River. The dates for these activities are April 22 through May 3, 1998. These regulations are needed to allow Whitbread Chesapeake, Inc. to protect boaters, spectators and participants from the dangers associated with the events.

DATES: This temporary final rule is effective from 6 a.m. EDT (Eastern Daylight Time) on April 22, 1998 to 6

a.m. EDT on April 23, from 9 a.m. EDT to 12 p.m. EDT on April 30, 1998, and from 10 a.m. EDT to 2:30 p.m. EDT on May 3, 1998.

FOR FURTHER INFORMATION CONTACT: Lieutenant James Driscoll, Marine Events Coordinator, Commander, Coast Guard Activities Baltimore, 2401 Hawkins Point Road, Baltimore, Maryland 21226-1791, telephone number (410) 576-2676.

SUPPLEMENTARY INFORMATION:**Regulatory History**

In accordance with 5 U.S.C. 553, a notice of proposed rulemaking was not published for this regulation. Following normal rulemaking procedures would have been impractical since there is not sufficient time remaining to publish a proposed rule in advance of the event or to provide for a delayed effective date. Immediate action is needed to protect vessel traffic from the potential hazards associated with congested waterways.

Background and Purpose

Whitbread Chesapeake, Inc. has submitted three marine event permit applications to the U.S. Coast Guard for events to be held as part of the Whitbread Round-the-World Offshore Yacht Race. On April 22, 1998, Whitbread Chesapeake, Inc. will sponsor the Whitbread Chesapeake Leg 7 finish. This event will consist of 10 offshore sailing vessels conducting race finish line approaches, finish line crossings and preparations for mooring on the waters of the Patapsco River and Northwest Harbor. On April 30, 1998, Whitbread Chesapeake, Inc. will sponsor the Whitbread Chesapeake parade of sail. This event will consist of 10 offshore sailing vessels conducting organized transit on the waters of the Patapsco River and Chesapeake Bay from Baltimore Inner Harbor to Annapolis Harbor. On May 3, 1998, Whitbread Chesapeake, Inc. will sponsor the Whitbread Chesapeake Leg 8 start. This event will consist of 10 offshore sailing vessels conducting race start preparations, start box maneuvering, corridor racing and gate area approaches on the waters of the Chesapeake Bay. A large fleet of spectator vessels is anticipated for each event. Due to the need for vessel control during the races and parade of sail, vessel traffic will be temporarily restricted to provide for the safety of spectators, participants and transiting vessels.

Discussion of Regulations

The Coast Guard will establish temporary special local regulations on specified waters of the Chesapeake Bay