

(10) Attracting any white shark in that part of the Sanctuary out to the seaward limit of State waters. For the purposes of this prohibition, the seaward limit of State waters is a line three nautical miles distant from the coastline of the State, where the coastline is the line of ordinary low water along the portion of the coast in direct contact with the open sea. The coastline for Monterey Bay, which is inland waters, is the straight line marking the seaward limit of the Bay, determined by connecting the following two points: 36°57'6" N, 121°01'45" W and 36°38'16" N, 121°56'3" W.

* * * * *

[FR Doc. 96-32111 Filed 12-18-96; 8:45 am]

BILLING CODE 3510-08-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 178

[Docket No. 96F-0205]

Indirect Food Additives: Adjuvants, Production Aids, and Sanitizers

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the additional safe use of 3,9-bis[2-{3-(3-*tert*-butyl-4-hydroxy-5-methylphenyl)propionyloxy}-1,1-dimethylethyl]-2,4,8,10-tetraoxaspiro[5.5]undecane as an antioxidant and/or stabilizer in propylene homopolymer and high-propylene olefin copolymer articles intended for use in contact with food. This action is in response to a petition filed by Sumitomo Chemical America, Inc.

DATES: Effective December 19, 1996; written objections and requests for a hearing by January 21, 1997.

ADDRESSES: Submit written objections to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Vir D. Anand, Center for Food Safety and

Applied Nutrition (HFS-216), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3081.

SUPPLEMENTARY INFORMATION: In a notice published in the Federal Register of July 3, 1996 (61 FR 34853), FDA announced that a food additive petition (FAP 6B4510) had been filed by Sumitomo Chemical America, Inc., c/o Keller and Heckman, 1001 G St. NW., suite 500 West, Washington, DC 20001. The petition proposed to amend the food additive regulations in § 178.2010 *Antioxidants and/or stabilizers for polymers* (21 CFR 178.2010) to provide for the additional safe use of 3,9-bis[2-{3-(3-*tert*-butyl-4-hydroxy-5-methylphenyl)propionyloxy}-1,1-dimethylethyl]-2,4,8,10-tetraoxaspiro[5.5]undecane intended for use in contact with food.

FDA has evaluated the data in the petition and other relevant material. The agency concludes that the proposed use of the additive is safe, that the food additive will have the intended technical effect, and therefore, that the regulations in § 178.2010 should be amended as set forth below.

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the information contact person listed above. As provided in § 171.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

Any person who will be adversely affected by this regulation may at any time on or before January 21, 1997, file with the Dockets Management Branch (address above) written objections thereto. Each objection shall be

separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 178

Food additives, Food packaging.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Director, Center for Food Safety and Applied Nutrition, 21 CFR part 178 is amended as follows:

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

1. The authority citation for 21 CFR part 178 continues to read as follows:

Authority: Secs. 201, 402, 409, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 348, 379e).

2. Section 178.2010 is amended in the table in paragraph (b) for the entry "3,9-Bis[2-{3-(3-*tert*-butyl-4-hydroxy-5-methylphenyl)propionyloxy}-1,1-dimethylethyl]-2,4,8,10-tetraoxaspiro[5.5]undecane" by adding a new entry "3." under the heading "Limitations" to read as follows:

§ 178.2010 Antioxidants and/or stabilizers for polymers.

* * * * *

(b) * * *

Substances	Limitations
<p>* * *</p> <p>3,9-Bis[2-{3-(3-<i>tert</i>-butyl-4-hydroxy-5-methylphenyl)propionyloxy}-1,1-dimethylethyl]-2,4,8,10-tetraoxaspiro[5.5]undecane (CAS Reg. No. 90498-90-1).</p> <p>* * *</p>	<p>* * *</p> <p>3. At levels not to exceed 0.3 percent by weight of olefin polymers complying with § 177.1520(c) of this chapter, items 1.1, 3.1, and 3.2, where the copolymers complying with items 3.1 and 3.2 contain not less than 85 weight percent of polymer units derived from propylene. The finished polymer is to be used in contact with food of types I, II, IV-B, VI-A, VI-B, VI-C, VII-B, and VIII under conditions of use A through H described in Tables 1 and 2 of § 176.170(c) of this chapter.</p> <p>* * *</p>

Dated: December 4, 1996.

Fred R. Shank,
Director, Center for Safety and Applied
Nutrition.

[FR Doc. 96-32126 Filed 12-18-96; 8:45 am]

BILLING CODE 4160-01-F

Food and Drug Administration

21 CFR Parts 606 and 610

[Docket No. 91N-0152]

RIN 0910-AA05

Current Good Manufacturing Practices for Blood and Blood Components: Notification of Consignees Receiving Blood and Blood Components at Increased Risk for Transmitting HIV Infection; Correction of Effective Date

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; correction of effective date.

SUMMARY: The Food and Drug Administration (FDA) is correcting a final rule on current good manufacturing practices for blood and blood components, that appeared in the Federal Register of September 9, 1996 (61 FR 47413). The document was published with an incorrect effective date. The effective date had been inadvertently switched with the comment deadline for the information collection requirements. This document corrects those errors.

DATES: Effective September 9, 1996, the effective date of the regulation published at 61 FR 47413 is corrected to February 7, 1997. The deadline for written comments on the information collection requirements of the final rule published at 61 FR 47413 is corrected to November 8, 1996.

ADDRESSES: Submit written comments on the information collection requirements to the Dockets

Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm 1-23, Rockville MD 20857.

FOR FURTHER INFORMATION CONTACT: Sharon Carayiannis, Center for Biologics Evaluation and Research (HFM-630), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, 301-594-3074.

SUPPLEMENTARY INFORMATION:

In FR Doc. 96-22709, appearing at page 47413 in the Federal Register of Monday, September 9, 1996, the following correction is made: On page 47413, in the 3d column, in the "DATES" section, in the 2d line "November 8, 1996" is corrected to read "February 7, 1997"; and in the 5th line, "February 7, 1997" is corrected to read "November 8, 1996."

Dated: December 12, 1996.

William K. Hubbard,
Associate Commissioner for Policy
Coordination.

[FR Doc. 96-32271 Filed 12-18-96; 8:45 am]

BILLING CODE 4160-01-F

Health Care Financing Administration

42 CFR Parts 412, 413, and 489

[BPD-847-FCN]

RIN 0938-AH34

Medicare Program; Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 1997 Rates; Corrections

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Final rule; correction.

SUMMARY: In the August 30, 1996 issue of the Federal Register (61 FR 46166), we published a final rule revising the Medicare hospital inpatient prospective payment systems for operating costs and capital-related costs to implement

necessary changes arising from our continuing experience with the system. In the addendum to that final rule, we announced the amounts and factors for determining prospective payment rates for Medicare hospital inpatient services for operating costs and capital-related costs applicable to discharges occurring on or after October 1, 1996, and set forth rate-of-increase limits for hospitals and hospital units excluded from the prospective payment systems. This document corrects errors made in that document.

EFFECTIVE DATE: October 1, 1996.

FOR FURTHER INFORMATION CONTACT: Stephen Phillips, (410) 786-4548.

SUPPLEMENTARY INFORMATION: In publishing Table 3C of the Addendum to the August 30, 1996 final rule (61 FR 46166), we inadvertently failed to incorporate a number of wage data revisions that had been transmitted to the Hospital Cost Report Information System (HCRIS) before mid-August 1996 as part of the process for verifying wage data. This document corrects the published average hourly wages for affected hospitals. Also, in the final rule, we indicated that if a hospital believes its wage index value was incorrect as a result of an intermediary or HCFA error that the hospital could not have known about before reviewing data made available in mid-August, the hospital must notify the intermediary and HCFA in writing, to be received no later than September 16, 1996 (see 61 FR 46179). As a result of this process, we have corrected the wage data for seven hospitals. Accordingly, the wage index values for several areas have changed and are corrected in this document.

The August 30, 1996 final rule also contained other technical and typographical errors. Therefore, we are making the following corrections to the final rule: