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DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 1207

[Doc. No. AMS–FV–09–0024; FV–09–706C]

Potato Research and Promotion Plan

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Correcting amendments.

SUMMARY: The Agricultural Marketing Service is making corrections to its Potato Research and Promotion plan regulations to reflect the modification of the Harmonized Tariff Schedule for imported potatoes by U.S. Customs and Border Protection (Customs). This document also corrects Customs' name within 7 CFR part 1207.

DATES: Effective March 26, 2010.

FOR FURTHER INFORMATION CONTACT: Deborah Simmons, Marketing Specialist, Research and Promotion Branch, Fruit and Vegetable Programs, AMS, USDA, 1400 Independence Avenue, SW., Room 0632, Stop 0244, Washington, DC 20250–0244; telephone: (202) 720–9915; or fax: (202) 205–2800; or e-mail: *Deborah.simmons@ams.usda.gov*.

SUPPLEMENTARY INFORMATION: This amendment corrects 7 CFR part 1207, section 1207.510 Levy of Assessments paragraphs (b)(1) to correct the name of U.S. Customs and Border Protection and update HTS codes in the table that appears in paragraph (b)(3).

List of Subjects in 7 CFR Part 1207

Administrative practice and procedure, Advertising, Consumer information, Marketing agreements, Potatoes, Promotion, Reporting and recordkeeping requirements.

■ Accordingly, 7 CFR part 1207 is amended by making the following correcting amendments:

PART 1207—POTATO RESEARCH AND PROMOTION PLAN

■ 1. The authority citation for 7 CFR part 1207 continues to read as follows:

Authority: 7 U.S.C. 2611–2627 and 7 U.S.C. 7401.

■ 2. Section 1207.510 is amended by revising paragraph (b)(1), and the table in paragraph (b)(3) to read as follows:

§ 1207.510 Levy of assessments.

* * * * *

(b) * * *

(1) An Assessment rate of 3 cents per hundredweight shall be levied on all tablestock potatoes imported into the United States for ultimate consumption by humans and all seed potatoes imported into the United States. An assessment rate of 3 cents per hundredweight shall be levied on the fresh weight equivalents of imported frozen or processed potatoes for ultimate consumption by humans. The importer of imported tablestock potatoes, potato products, or seed potatoes shall pay the assessment to the Board through the U.S. Customs and Border Protection at the time of entry or withdrawal for consumption of such potatoes and potato products into the United States.

* * * * *

(3) * * *

Tablestock potatoes, frozen or processed potatoes, and seed potatoes	Assessment	
	Cents/cwt	Cents/kg
0701.10.0020	3.0	0.066
0701.10.0040	3.0	0.066
0701.90.1000	3.0	0.066
0701.90.5015	3.0	0.066
0701.90.5025	3.0	0.066
0701.90.5035	3.0	0.066
0701.90.5045	3.0	0.066
0701.90.5055	3.0	0.066
0701.90.5065	3.0	0.066
0710.10.0000	6.0	0.132
2004.10.4000	6.0	0.132
2004.10.8020	6.0	0.132
2004.10.8040	6.0	0.132
2005.20.0070	4.716	0.104
0712.90.3000	21.429	0.472
1105.10.0000	21.429	0.472
1105.20.0000	21.429	0.472
2005.20.0040	21.429	0.472
2005.20.0020	12.240	0.27
1108.13.0010	27.0	0.595

* * * * *

Dated: March 16, 2010.

David R. Shipman,

Acting Administrator, Agricultural Marketing Service.

[FR Doc. 2010–6185 Filed 3–25–10; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 73

[Docket No. FDA–2008–C–0098]

Listing of Color Additives Exempt From Certification; Bismuth Citrate

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the color additive regulations to increase the permitted use level of bismuth citrate as a color additive in cosmetics intended for coloring hair on the scalp. This action is in response to a petition filed by Combe, Inc.

DATES: This rule is effective April 27, 2010; except as to any provisions that may be stayed by the filing of proper objections. Submit electronic or written objections and requests for a hearing by April 26, 2010. See section VII of this document for information on the filing of objections.

ADDRESSES: You may submit written or electronic objections and requests for a hearing, identified by Docket No. FDA–2008–C–0098, by any of the following methods:

Electronic Submissions

Submit electronic objections in the following way:

- Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments.

Written Submissions

Submit written objections in the following ways:

- FAX: 301–827–6870.
- Mail/Hand delivery/Courier [For paper, disk, or CD–ROM submissions]: Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the agency name and

docket number for this rulemaking. All objections received will be posted without change to *http://www.regulations.gov*, including any personal information provided. For detailed instructions on submitting objections, see the "Objections" heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or objections received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Felicia M. Ellison, Center for Food Safety and Applied Nutrition (HFS–265), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740–3835, 301–436–1264.

SUPPLEMENTARY INFORMATION:

I. Background

In a notice published in the **Federal Register** of February 25, 2008 (73 FR 10035), FDA announced that a color additive petition (CAP 8C0286) had been filed by Combe, Inc., c/o EAS Consulting Group, LLC, 1940 Duke St., suite 200, Alexandria, VA 22314. The petition proposed to amend the color additive regulations in § 73.2110 *Bismuth citrate* (21 CFR 73.2110) by increasing the maximum permitted use level of bismuth citrate as a color additive in cosmetics intended for coloring hair on the scalp from 0.5 percent (weight per volume (w/v)) to 2.0 percent (w/v).

II. Evaluation of Safety

A. Determination of Safety

Under section 721(b)(4) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 379e(b)(4)), a color additive may not be listed for a particular use unless a fair evaluation of the data and information available to FDA establishes that the color additive is safe for that use. FDA's color additive regulations at § 70.3(i) (21 CFR 70.3(i)) define safe as the existence of "convincing evidence that establishes with reasonable certainty that no harm will result from the intended use of the color additive."

B. Safety of the Petitioned Use of the Color Additive

The petition proposes to increase the level of bismuth citrate in cosmetics intended for coloring scalp hair to 2.0 percent (w/v) with no changes to the identity or to the specifications of the color additive listed in § 73.2110. Consequently, the agency's current review focused on whether there are any safety concerns from the proposed increased use level of the color additive.

To assess the safety from use of bismuth citrate at a level of 2.0 percent (w/v) in cosmetic hair coloring products, FDA estimated the potential exposure to the color additive based on conservative assumptions. Directions on a sample label for a hair coloring product containing the color additive recommend that the product be applied daily until the hair reaches the desired color (estimated by the petitioner to be 2 to 3 weeks), followed by a maintenance regimen where the product is applied several times a week. The petitioner contends that the maintenance regimen is most representative of long-term use of bismuth citrate for coloring hair. FDA agrees with the petitioner and used the maintenance regimen to estimate chronic exposure to the color additive. Information in the petition indicates that 10 milliliters of the hair cosmetic product applied three times per week represents the maximum recommended use for the maintenance regimen. Of the amount applied, 2.0 percent of the hair coloring product is expected to reach the scalp and of that, 2.71 percent of the product is expected to be absorbed through the skin, resulting in an estimated potential exposure to the color additive of 46.5 micrograms per person per day (Ref. 1).

To show that the requested increased use level of bismuth citrate would be safe, the petitioner provided results from a 90-day oral toxicity study on bismuth citrate in rats, genotoxicity studies, dermal penetration studies, and dermal photosensitization studies. The dermal penetration studies showed no evidence of detectable systemic absorption of bismuth citrate, and the in vitro (pig skin) dermal penetration study revealed only minimal (2.71 percent) absorption in the epidermis. Neither study showed any evidence that bismuth citrate was a dermal- or photosensitizer. The 90-day oral feeding study showed no evidence of toxicity at 30 milligrams per kilogram body weight per day, which is more than 38,000 times greater than the estimated level of exposure (Ref. 2). Based on the totality of data and information submitted by the petitioner, FDA concludes that the expected exposure to the color additive from the proposed increased use level is safe.

III. Conclusion

FDA reviewed data in the petition and other available relevant material to evaluate the safety of the use of bismuth citrate as a color additive in cosmetics intended for coloring hair on the scalp. Based on this information, the agency concludes that the proposed increased use level of the color additive is safe and that the color additive will achieve its intended technical effect. Therefore, the regulations in part 73 (21 CFR part 73) should be amended as set forth in this document. In addition, based upon the factors listed in § 71.20(b) (21 CFR 71.20(b)), the agency concludes that certification of bismuth citrate is not necessary for the protection of the public health.

IV. Public Disclosure

In accordance with § 71.15 (21 CFR 71.15), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition will be made available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the information contact person listed above (see **FOR FURTHER INFORMATION CONTACT**). As provided in § 71.15, the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

V. Environmental Impact

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 Division of Dockets Management (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday.

VI. Paperwork Reduction Act of 1995

This 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.

VII. Objections

This rule is effective as shown in the **DATES** section of this document, except as to any provisions that may be stayed by the filing of proper objections. Any person who will be adversely affected by this regulation may at any time file with the Division of Dockets Management (see **ADDRESSES**) electronic or written objections. 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 are to be submitted and are to 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 Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday. FDA will publish notice of the objections that the agency has received or lack thereof in the **Federal Register**.

VIII. References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Memorandum from D. Folmer, Division of Petition Review, to F. Ellison, Division of Petition Review, January 30, 2009.

2. Memorandum from A. Khan, Division of Petition Review, to F. Ellison, Division of Petition Review, April 23, 2009.

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 and redelegated to the Director, Center for Food Safety and Applied Nutrition, 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 73.2110 is amended by revising paragraph (c)(1) to read as follows:

§ 73.2110 Bismuth citrate.

* * * * *

(c) * * *

(1) The amount of bismuth citrate in the cosmetic shall not be in excess of 2.0 percent (w/v).

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Dated: March 17, 2010.

Leslye M. Fraser,

Director, Office of Regulations, Policy and Social Sciences, Center for Food Safety and Applied Nutrition.

[FR Doc. 2010–6731 Filed 3–25–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2010–0002]

RIN 1625–AA00

Safety Zone; Dive Platform, Pago Pago Harbor, American Samoa

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone around the USNS Sioux or M/V EL LOBO GRANDE II dive platform and the 332-foot Tanker Barge CAPELLA while they are performing operations in and around the CHEHALIS wreck. The safety zone is necessary to protect other vessels and the general public from hazards associated with pre-staging vessels and dive operations. Entry into or remaining in the safety zone during the effective period is prohibited unless authorized by the Captain of the Port Honolulu.

DATES: This rule is effective from 6 a.m. on March 25, 2010 through 8 p.m. on April 17, 2010.

ADDRESSES: Comments and material received from the public, as well as documents mentioned in this preamble as being available in the docket, are part of docket USCG–2010–0002 and are available online by going to *http://www.regulations.gov,* inserting USCG–2010–0002 in the "Keyword" box, and then clicking "Search." This material is also available for inspection or copying at the Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or e-mail Lieutenant Commander Marcella Granquist, Waterways Management Division, U.S. Coast Guard Sector Honolulu, telephone 808–842–2600, e-mail *Marcella.A.Granquist@uscg.mil.* If you have questions on viewing or submitting material to the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202–366–9826.

SUPPLEMENTARY INFORMATION:

Regulatory Information

On February 5, 2010, we published a notice of proposed rulemaking (NPRM) entitled Safety Zone; Dive Platform, Pago Pago Harbor, American Samoa in the **Federal Register** (75 FR 5907). We received no comments and no public meeting was requested or held.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Making this safety zone effective March 25, 2010 is essential to protect the public from the hazards associated with pre-staging large vessels for the planned diving operations in and around the CHEHALIS wreck.

Background and Purpose

On October 7, 1949 the 4,130-ton gasoline tanker CHEHALIS sank in Pago Pago Inner Harbor, in an estimated 160 feet of water, approximately 350-feet from the fuel dock located near Goat Island Point, Pago Pago, American Samoa. From April 23, 2009 to May 10, 2009, the U.S. Coast Guard performed dive operations on the CHEHALIS wreck to determine the wreck's potential pollution threat to the environment. In December 2009, the U.S. Coast Guard planned dive operations to mitigate the wreck's potential pollution threat with pre-staging vessels beginning March 25, 2010 and conducting diving operations from March 27, 2010 to April 17, 2010.

Discussion of Comments and Changes

No comments were received and no public meeting was held. Two changes from the proposed temporary rule to the final temporary rule are necessary to enact the safety zone during the pre-staging of the dive platform and associated 332-foot Tank Barge starting on March 25, 2010 to ensure dive operations finish by April 17, 2010. First, we are changing the effective date of the regulation to March 25, 2010 instead of March 29, 2010. Second, we are slightly enlarging the area of the safety zone to accommodate both the dive platform and the Tank Barge, from a proposed 200-foot radius to an area approximately 600 by 300 feet. We note