## PART 142—ENTRY PROCESS

■ 4. The authority citation for part 142 continues to read as follows:

**Authority:** 19 U.S.C. 66, 1448, 1484, 1624.

■ 5. Section 142.21 is amended by:
■ a. Removing the term ''Customs'' wherever it appears and in its place adding the term ''CBP'';
■ b. Revising the heading of paragraph (e)(1);
■ c. Removing the second sentence in paragraph (e)(1) and adding in its place two new sentences;
■ d. Revising the heading of paragraph (e)(2);
■ e. Removing the second sentence in paragraph (e)(2) and adding in its place two new sentences;
■ f. Revising paragraph (g);
■ g. Redesignating paragraph (h) as paragraph (i);
■ h. Adding a new paragraph (h), and
■ i. Revising newly designated paragraph (i).

The additions and revisions read as follows:

**§ 142.21 Merchandise eligible for special permit for immediate delivery.**

* * * * *

(e) *Quota-class merchandise*—(1) *Tariff rate quotas.* * * * However, merchandise subject to a tariff-rate quota may not be incrementally released under a special permit for immediate delivery as provided in paragraphs (g) and (h) of this section. Nor is such merchandise eligible for release under a special permit pursuant to 19 CFR 141.58(d)(1). * * *

(2) *Absolute quotas.* * * * However, merchandise subject to an absolute quota under this paragraph may not be incrementally released under a special permit for immediate delivery as provided in paragraphs (g) and (h) of this section. Nor is such merchandise eligible for release under a special permit pursuant to § 141.58(d)(1) of this chapter. * * *

* * * * *

(g) *Split shipments.* Merchandise subject to § 141.57(d)(2) of this chapter, which is invoiced and delivered to the carrier as a single shipment, but which, due to the carrier's inability to accommodate the merchandise on a single conveyance, is shipped by the carrier in separate portions to the same port of entry in the United States as listed on the original bill of lading, may be released incrementally under a special permit. Incremental release means releasing each portion of such shipments separately as they arrive.

(h) *Entities shipped unassembled or disassembled on multiple conveyances.* Merchandise subject to § 141.58(d)(2) of this chapter, which is purchased, invoiced, and classified as a single entity under the Harmonized Tariff Schedule of the United States (HTSUS), and which is shipped in separate portions because its size or nature prevents shipping the entity on a single conveyance, may be released incrementally under a special permit.

(i) *When authorized by Headquarters.* Headquarters may authorize the release of merchandise under the immediate delivery procedure in circumstances other than those described in § 142.21(a) through (h) provided a bond on CBP Form 301 containing the bond conditions set forth in § 113.62 of this chapter is on file.

■ 6. Section 142.22 is amended by:
■ a. Removing the term ''Customs'' wherever it appears and in its place adding the term ''CBP''; and
■ b. Revising the first sentence in paragraph (a) to read as follows:

**§ 142.22 Application for special permit for immediate delivery.**

(a) *Form.* An application for a special permit for immediate delivery will be made on CBP Form 3461, supported by the documentation provided for in § 142.3. * * *

* * * * *

**Deborah J. Spero,**

*Acting Commissioner, Bureau of Customs and Border Protection.*

Dated: May 26, 2006.

**Timothy E. Skud,**

*Deputy Assistant Secretary of the Treasury.*

[FR Doc. E6–8498 Filed 6–1–06; 8:45 am]

**BILLING CODE 9111–14–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### 21 CFR Part 73

**[Docket No. 1998C–0790] (formerly 98C–0790)**

## Listing of Color Additives Exempt From Certification; Mica-Based Pearlescent Pigments

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is amending the color additive regulations to provide for the safe use of titanium dioxide coated mica-based pearlescent pigments as color additives in food. This action is in partial response to a petition filed by EM Industries, Inc.

**DATES:** This rule is effective July 5, 2006. Submit written or electronic objections and requests for a hearing by July 3, 2006. See section VIII of the **SUPPLEMENTARY INFORMATION** section 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. 1998C–0790, by any of the following methods:

*Electronic Submissions*

Submit electronic comments in the following ways:

- Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments.
- Agency Web site: *http://www.fda.gov/dockets/ecomments*. Follow the instructions for submitting comments on the agency Web site.

*Written Submissions*

Submit written submissions 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.

To ensure more timely processing of comments, FDA is no longer accepting comments submitted to the agency by e-mail. FDA encourages you to continue to submit electronic comments by using the Federal eRulemaking Portal or the agency Web site, as described in the *Electronic Submissions* portion of this paragraph.

*Instructions*: All submissions received must include the agency name and Docket No(s). and Regulatory Information Number (RIN) (if a RIN number has been assigned) for this rulemaking. All objections received will be posted without change to *http://www.fda.gov/ohrms/dockets/default.htm*, 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.fda.gov/ohrms/dockets/default.htm* 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:** Paul C. DeLeo, Center for Food Safety and Applied Nutrition (HFS–265), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740–3835, 301–436–1302.

**SUPPLEMENTARY INFORMATION:**

## I. Introduction

In a notice published in the **Federal Register** of September 25, 1998 (63 FR 51359), FDA announced that a color additive petition (CAP 8C0262) had been filed by EM Industries, Inc., 7 Skyline Dr., Hawthorne, NY 10532 (now EMD Chemicals, Inc.). The petition proposed to amend the color additive regulations to provide for the safe use of synthetic iron oxide and mica to color food and to provide for the safe use of titanium dioxide to color food at levels higher than the current limit. At the time of the filing of the petition, FDA considered the pigments that are the subjects of this petition to be color additive mixtures of synthetic iron oxide, mica, and titanium dioxide. During its subsequent review of the petition, the agency determined that these pigments are composite pigments, not color additive mixtures. Therefore, the agency published an amended filing notice in the **Federal Register** of June 21, 1999 (64 FR 33097), to indicate that the petition proposed to amend the color additive regulations to provide for the safe use of composite pigments prepared from synthetic iron oxide, mica, and titanium dioxide to color food. This final rule is a partial response to the petition and addresses only the composite pigments prepared from mica and titanium dioxide to color food. The remaining composite pigments containing synthetic iron oxide included in the petition remain under review.

The petitioner is seeking approval for a maximum use level of the resulting pigments of up to 1.25 percent by weight in food. The categories of food identified in the petition to which mica-based pearlescent pigments would be added are cereals, confections and frostings, gelatin desserts, hard and soft candies (including lozenges), nutritional supplement tablets and gelatin capsules, and chewing gum.

## II. Manufacturing and Nomenclature

The subject color additive is manufactured by preparing a suspension of mica platelets, then adding a solution of soluble salts of titanium and a basic solution to precipitate titanium hydroxide onto the mica platelets. These particles are then heated (calcined) at temperatures up to 900 °C. During the calcination, titanium hydroxide is converted into titanium dioxide. The agency has reviewed the relevant data and information in the petition relating to the manufacture and identity of the subject color additive (Ref. 1), and to the proposed uses of and estimated exposure to the subject color additive (Refs. 2, 3, and 4).

In a final rule published in the **Federal Register** of October 24, 2002 (67 FR 65311), the agency listed the color additives based on titanium or iron salts and mica platelets for use in contact lenses in § 73.3128 (21 CFR 73.3128). In the same final rule, the agency collectively identified these color additives as mica-based pearlescent pigments. In addition, in the **Federal Register** of July 22, 2005 (70 FR 42271), the agency published a final rule to amend the color additive regulations to provide for the use of mica-based pearlescent pigments as color additives, in amounts up to 3 percent by weight, in ingested drugs by adding § 73.1128 (21 CFR 73.1128). To be consistent with these actions, the agency is using the same name for the color additive that is the subject of the present rule.

## III. Safety Evaluation

To evaluate the safety of the proposed use of titanium dioxide coated mica-based pearlescent pigments for coloring food, the agency reviewed the toxicological data and information submitted in the petition as well as other information contained in agency files (Ref. 5).

To determine whether a color additive in food is safe under its proposed conditions of use, FDA considers the projected human dietary intake of the additive, toxicological data on the additive, and other relevant information (such as published literature) available to the agency. FDA compares an individual's estimated daily intake (EDI) of the additive from all sources to an acceptable daily intake (ADI) established by toxicological data. The EDI is determined by projections based on the amount of the additive proposed for use in particular foods and on data regarding the amount consumed from all sources of the additive. The agency commonly uses the EDI of the additive from consumption of food at the 90th percentile as a measure of high chronic dietary intake.

FDA estimates the EDI of mica-based pearlescent pigments from all the petitioned uses in food (except nutritional supplements in tablet and gelatin capsule form) for consumers aged 2 years or more at the 90th percentile to be 0.86 grams per person per day (g/p/d) (Ref. 3). The agency also considered the exposure to the color additive from its uses in ingested drugs, nutritional supplements in tablet and gelatin capsule form, and contact lenses. The estimated intake of the pigments from their use in ingested drugs and nutritional supplements is approximately one-eighth of the intake from their proposed use in food (Ref. 4). The exposure to the components of mica-based pearlescent pigments from the use of the pigments in contact lenses is negligible compared to the intake from their use in ingested drugs or food (Ref. 5).

As part of the FDA's safety evaluation, the agency selected a life-time rodent bioassay submitted with the petition as the pivotal study. During the study, a blend of two titanium dioxide-coated mica-based pearlescent pigments was fed to rats at levels up to 5 percent in the feed for up to 2 years (Ref. 5). The agency determined that the results of the study showed no indications of adverse effects in rats from the prolonged consumption of the pigments at any of the doses tested. FDA concluded that the no-observed-effect level (NOEL) based on the highest dose tested in this study is over 3,000 mg/kg body-weight/day. By applying a 100-fold safety factor to this NOEL, the agency calculated the ADI for titanium dioxide-coated mica-based pearlescent pigments for a 60 kg human as 1.8 g/p/d. Therefore, taking into account the available safety information, and the conservative estimates of intake of the additives, the agency concludes that the proposed use of titanium dioxide-coated mica-based pearlescent pigments to color food is safe.

## IV. Conclusion

Based on the data and information in the petition and other relevant material, FDA concludes that the petitioned use of mica-based pearlescent pigments prepared from titanium salts and mica to color food is safe. The agency further concludes that the additive will achieve its intended technical effect, and is suitable for use in coloring food. The agency also concludes that 21 CFR part 73 of the color additive regulations 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 these titanium dioxide-coated mica-based pearlescent pigments is not necessary for the protection of the public health.

## V. Inspection of Documents

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 are available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the information contact person (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.

### VI. Environmental Impact

The agency has previously considered the environmental effects of this rule as announced in the notice of filing and amended filing notice for CAP 8C0262 (63 FR 51359 and 64 FR 33097). No new information or comments have been received that would affect the agency's previous determination that there is no significant impact on the human environment and that an environmental impact statement is not required.

### VII. Paperwork Reduction Act of 1995

This final rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

### VIII. 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 file with the Division of Dockets Management (see **ADDRESSES**) written or electronic 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**.

### IX. 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 Jensen, Chemistry Review Team, Division of Product Manufacture and Use, to Orstan, Division of Petition Control, January 22, 1999.

2. Memorandum from Lee, Chemistry Review Group, Division of Petition Review, to Orstan, Regulatory Group II, Division of Petition Review, April 16, 2003.

3. Memorandum from Lee, Chemistry Review Group, Division of Petition Review, to DeLeo, Regulatory Group II, Division of Petition Review, March 1, 2005.

4. Memorandum from Lee, Chemistry Review Group, Division of Petition Review, to Orstan, Regulatory Group II, Division of Petition Review, January 30, 2003.

5. Memorandum from Park, Toxicology Review Group I, Division of Petition Review, to DeLeo, Division of Petition Review, December 14, 2005.

### List of Subjects in 21 CFR Part 73

Color additives, Cosmetics, Drugs, Medical devices.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act (the act) and under the 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 73.350 is added to subpart A to read as follows:

#### § 73.350 Mica-based pearlescent pigments.

(a) *Identity.* (1) The color additive is formed by depositing titanium salts onto mica, followed by heating to produce titanium dioxide on mica. Mica used to manufacture the color additive shall conform in identity to the requirements of § 73.1496(a)(1).

(2) Color additive mixtures for food use made with mica-based pearlescent pigments may contain only those diluents listed in this subpart as safe and suitable for use in color additive mixtures for coloring food.

(b) *Specifications.* Mica-based pearlescent pigments shall conform to the following specifications and shall be free from impurities other than those named to the extent that such other impurities may be avoided by good manufacturing practice:

(1) Lead (as Pb), not more than 4 parts per million (ppm).

(2) Arsenic (as As), not more than 3 ppm.

(3) Mercury (as Hg), not more than 1 ppm.

(c) *Uses and restrictions.* (1) The substance listed in paragraph (a) of this section may be safely used as a color additive in amounts up to 1.25 percent, by weight, in the following foods:

(i) Cereals.

(ii) Confections and frostings.

(iii) Gelatin desserts.

(iv) Hard and soft candies (including lozenges).

(v) Nutritional supplement tablets and gelatin capsules.

(vi) Chewing gum.

(2) The color additive may not be used to color foods for which standards of identity have been issued under section 401 of the act, unless the use of the added color is authorized by such standards.

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

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health and therefore batches thereof are exempt from the certification requirements of section 721(c) of the act.

Dated: May 25, 2006.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. E6–8575 Filed 6–1–06; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF LABOR

### Office of Labor-Management Standards

### 29 CFR Part 458

**RIN 1215–AB48**

### Standards of Conduct for Federal Sector Labor Organizations

**AGENCY:** Office of Labor-Management Standards, Employment Standards Administration, Department of Labor.

**ACTION:** Final rule.

**SUMMARY:** The Department of Labor (Department) proposed to revise the regulations applicable to Federal sector labor organizations subject to the Civil Service Reform Act of 1978 (CSRA), the