to further flight. Do all actions in accordance with the Accomplishment Instructions of Boeing Special Attention Service Bulletin 747–53–2493, dated July 3, 2003.

Note 1: For the purposes of this AD, a detailed inspection is: ''An intensive examination of a specific item, installation, or assembly to detect damage, failure, or irregularity. Available lighting is normally supplemented with a direct source of good lighting at an intensity deemed appropriate. Inspection aids such as mirror, magnifying lenses, etc., may be necessary. Surface cleaning and elaborate procedures may be required.''

Alternative Methods of Compliance (AMOCs)

(g)(1) The Manager, Seattle Aircraft Certification Office (ACO), FAA, has the authority to approve AMOCs for this AD, if requested in accordance with the procedures found in 14 CFR 39.19.

(2) An AMOC that provides an acceptable level of safety may be used for any repair required by this AD, if it is approved by an Authorized Representative for the Boeing Delegation Option Authorization Organization who has been authorized by the Manager, Seattle ACO, to make those findings. For a repair method to be approved, the repair must meet the certification basis of the airplane, and the approval must specifically refer to this AD.

Material Incorporated by Reference

(h) You must use Boeing Special Attention Service Bulletin 747–53–2493, dated July 3, 2003, to perform the actions that are required by this AD, unless the AD specifies otherwise. The Director of the Federal Register approves the incorporation by reference of this document in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. To get copies of the service information, contact Boeing Commercial Airplanes, P.O. Box 3707, Seattle, Washington 98124–2207. To view the AD docket, go to the Docket Management Facility, U.S. Department of Transportation, 400 Seventh Street SW., room PL–401, Nassif Building, Washington, DC. To review copies of the service information, go to the National Archives and Records Administration (NARA). For information on the availability of this material at the NARA, call (202) 741–6030, or go to *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

Issued in Renton, Washington, on July 11, 2005.

Ali Bahrami,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 05–14174 Filed 7–21–05; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 73

[Docket No. 1998C–0431] (formerly 98C–0431)

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 mica-based pearlescent pigments as color additives in ingested drugs. This action is in response to a petition filed by EM Industries, Inc.

DATES: This rule is effective August 23, 2005. Submit written or electronic objections and requests for a hearing by August 22, 2005. 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–0431, by any of the following methods:

- 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.
- E-mail: *fdadockets@oc.fda.gov*. Include Docket No. 1998C–0431 in the subject line of your e-mail message.
- 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.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 comments 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: Aydin Örstan, Center for Food Safety and Applied Nutrition (HFS–255), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1301.

SUPPLEMENTARY INFORMATION:

I. Introduction

In a notice published in the **Federal Register** of June 22, 1998 (63 FR 33934), FDA announced that a color additive petition (CAP 8C0257) had been filed by EM Industries, Inc., 7 Skyline Dr., Hawthorne, NY 10532 (now EMD Industries, Inc.). The petition proposed to amend the color additive regulations to provide for the safe use of synthetic iron oxide to color ingested drugs at levels higher than the current limit and to provide for the safe use of mica to color ingested drugs. 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. FDA did not include titanium dioxide in the filing notice, because that color additive was already listed for use in ingested drugs. 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 29, 1999 (64 FR 34816), 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 ingested drugs.

The petitioner is seeking approval for a maximum use level of the resulting pigments of up to 3 percent by weight in the finished drug product, and a maximum iron oxide content no greater than 55 percent in those pigments containing iron oxide.

II. Manufacturing and Nomenclature

The subject color additives are manufactured by preparing a suspension of mica platelets, adding a solution of soluble salts of titanium, of iron, or of both, and a base to precipitate titanium hydroxide, iron hydroxide, or both onto the mica platelets. These particles are then heated (calcined) at temperatures up to 900 °C. During the calcination, titanium hydroxide and

iron hydroxide are converted into titanium dioxide, and iron oxide, respectively. The agency has reviewed the relevant data and information in the petition relating to the manufacturing and identity of the subject color additives (Ref. 1), and to the proposed uses of and estimated exposures to (Ref. 2) the subject color additives.

In a final rule published in the **Federal Register** of October 24, 2002 (67 FR 65311), the agency listed in § 73.3128 (21 CFR 73.3128) the color additives based on the first two combinations given above (titanium or iron salts and mica platelets) for use in contact lenses. In the same final rule, the agency collectively identified these color additives as mica-based pearlescent pigments. To be consistent with § 73.3128, the agency is using the same name for the color additives that are the subjects of the present rule.

III. Safety Evaluation

To evaluate the safety of the proposed uses of mica-based pearlescent pigments for coloring ingested drugs, the agency reviewed the toxicological data and information submitted in the petition as well as other information contained in agency files (Ref. 3). In conjunction with this review the agency notes that, based on the chemical nature of these inorganic pigments and their individual components, as well as the available solubility data contained in the petition, the solubility of mica-based pearlescent pigments in media relevant to human health (e.g., digestive fluids in the gastrointestinal tract) is expected to be very low. As such, the bioavailability of these pigments and/or their individual components when ingested is also expected to be low. Considering the chemical nature of the pigments, and their expected low solubility and bioavailability, the agency concludes that there is no toxic potential when ingested at levels estimated by the agency, based on their proposed use in coloring ingested drugs. The agency also notes that it has previously reviewed various color additive uses of iron oxide, titanium dioxide, and mica where the additives would be ingested and found such uses to be safe (§§ 73.200, 73.575, 73.1200, 73.1496, 73.1575, 73.2250, 73.2496, and 73.2575).

Therefore, taking into account the available safety information, the insoluble nature of the subject color additives, and the conservative estimates of intake of the additives, the agency concludes that the proposed use of mica-based pearlescent pigments to color ingested drugs is safe (Ref. 3).

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 synthetic iron oxide, mica, and titanium dioxide to color ingested drugs is safe. The agency further concludes that the additives will achieve their intended technical effect, and are suitable for use in coloring ingested drugs. The agency also concludes that 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 mica-based pearlescent pigments is not necessary for the protection of the public health.

V. Inspection of Documents

In accordance with § 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 for CAP 8C0257 (63 FR 33934). 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. Jensen, E., Memorandum entitled ''Use of Pearlescent Pigments as a Color Additive in Tablets and Other Pharmaceutical Preparations,'' from the Division of Product Manufacture and Use (HFS–246) to the Division of Petition Control (HFS–215), Center for Food Safety and Applied Nutrition, FDA, January 21, 1999.

2. Lee, H. S., Memorandum entitled ''Update of Intake Estimates,'' from the Division of Petition Review (HFS–265) to the Division of Petition Review (HFS–265), Center for Food Safety and Applied Nutrition, FDA, November 24, 2004.

3. Taras, T. L., Memorandum entitled ''Comprehensive Final Toxicology Evaluation Memorandum: CAP 8C0257'' from the Division of Petition Review (HFS–265) to the Division of Petition Review (HFS–265), Center for Food Safety and Applied Nutrition, FDA, December 20, 2004.

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 73.1128 is added to subpart B to read as follows:

§ 73.1128 Mica-based pearlescent pigments.

(a) *Identity.* (1) The color additive is formed by depositing titanium and/or iron salts onto mica, followed by heating to produce one of the following combinations: Titanium dioxide on mica; iron oxide on mica; titanium dioxide and iron oxide 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 drug 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 ingested drugs.

(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.* Mica-based pearlescent pigments may be safely used to color ingested drugs in amounts up to 3 percent, by weight, of the final drug product. The maximum amount of iron oxide to be used in producing said pigments is not to exceed 55 percent, by weight, in the finished pigment.

(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 Federal Food, Drug, and Cosmetic Act.

Dated: July 13, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–14457 Filed 7–21–05; 8:45 am]

BILLING CODE 4160–01–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 271

[FRL–7942–9]

Idaho: Final Authorization of State Hazardous Waste Management Program Revision

AGENCY: Environmental Protection Agency.

ACTION: Final rule.

SUMMARY: Idaho applied to the United States Environmental Protection Agency (EPA) for final authorization of changes to its hazardous waste program under the Resource Conservation and Recovery Act (RCRA). On May 16, 2005, EPA published a proposed rule to authorize the changes and opened a public comment period. The comment period closed on June 15, 2005. EPA has decided that these revisions to the Idaho hazardous waste management program satisfy all of the requirements necessary to qualify for final authorization and is authorizing these revisions to Idaho's authorized hazardous waste management program in today's final rule.

DATES: Final authorization for the revisions to the hazardous waste program in Idaho shall be effective at 1 p.m. E.S.T. on July 22, 2005.

FOR FURTHER INFORMATION CONTACT: Jeff Hunt, Mail Stop AWT–122, U.S. EPA Region 10, Office of Air, Waste, and Toxics, 1200 Sixth Avenue, Seattle, Washington 98101, phone (206) 553–0256. E-mail: *hunt.jeff@epa.gov.*

SUPPLEMENTARY INFORMATION:

A. Why Are Revisions to State Programs Necessary?

States which have received final authorization from EPA under RCRA section 3006(b), 42 U.S.C. 6926(b), must maintain a hazardous waste program that is equivalent to and consistent with the Federal program. States are required to have enforcement authority which is adequate to enforce compliance with the requirements of the hazardous waste program. Under RCRA Section 3009, States are not allowed to impose any requirements which are less stringent than the Federal program. Changes to State programs may be necessary when Federal or State statutory or regulatory authority is modified or when certain other changes occur. Most commonly, States must change their programs because of changes to EPA's regulations in title 40 of the Code of Federal Regulations (CFR) parts 124, 260 through 266, 268, 270, 273 and 279.

Idaho's hazardous waste management program received final authorization effective on April 9, 1990 (55 FR 11015, March 29, 1990). EPA also granted authorization for revisions to Idaho's program effective on June 5, 1992 (57 FR 11580, April 6, 1992), on August 10, 1992 (57 FR 24757, June 11, 1992), on June 11, 1995 (60 FR 18549, April 12, 1995), on January 19, 1999 (63 FR 56086, October 21, 1998), on July 1, 2002 (67 FR 44069, July 1, 2002), and on March 10, 2004 (69 FR 11322).

Today's final rule addresses a program revision application that Idaho submitted to EPA in September 2004, in accordance with 40 CFR 271.21, seeking authorization of changes to the State program. On May 16, 2005, EPA published a proposed rule announcing its intent to grant Idaho final authorization for revisions to Idaho's hazardous waste program and provided a period of time for the receipt of public comments. The proposed rule can be found at 70 FR 25798.

B. What Were the Comments to EPA's Proposed Rule?

EPA received two letters during the public comment period. One letter was dated June 3, 2005, from Mr. Chuck Broscious on behalf of the Environmental Defense Institute and a second letter was dated June 14, 2005, from Mr. Chuck Broscious on behalf of the Environmental Defense Institute, Keep Yellowstone Nuclear Free, and David B. McCoy, collectively the commenters.

The comment letters focused on issues originally raised in petitions submitted to EPA on August 8, 2000, and September 13, 2001, and on numerous follow up letters and correspondence related to those petitions. The petitions themselves centered on issues related to specific units located at the Idaho National Laboratory (INL) in Idaho Falls, Idaho. The comment letters also raised a concern about nuclear defense activities at the same INL facility. In response to this aspect of the commenters' letter EPA observes that defense activities related to nuclear production and propulsion programs will generally not meet the definition of solid waste under the RCRA regulations and may be regulated by other federal authorities. With respect to mixed waste, Idaho's hazardous waste program is authorized for mixed waste.

In the September 13, 2001, petition which commenters refer to in their current comments, the commenters as petitioners sought EPA's withdrawal of Idaho's authorization to implement the hazardous waste program under RCRA