DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 73

[Docket No. 00C–1321]

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 contact lenses. This action is in response to a petition filed by Wesley Jessen Corp.

DATES: This regulation is effective November 26, 2002. Submit written or electronic objections and requests for a hearing by November 25, 2002. See Section VIII of the **SUPPLEMENTARY INFORMATION** section of this document for information on the filing of objections.

ADDRESSES: Submit written or electronic objections to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments.

FOR FURTHER INFORMATION CONTACT: Aydin Örstan, Center for Food Safety and Applied Nutrition (HFS–265), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 202–418–3076.

SUPPLEMENTARY INFORMATION:

I. Introduction

In a notice published in the **Federal Register** of June 7, 2000 (65 FR 36148), FDA announced that a color additive petition (CAP 0C0271) had been filed by Wesley Jessen, Corp., 333 East Howard Ave., Des Plaines, IL 60018 (now Ciba Vision Corp., 11460 Johns Creek Pkwy., Duluth, GA 30097–1556). The petition proposed to amend the color additive regulations in part 73 (21 CFR part 73 subpart D—Medical Devices) to provide for the safe use of mica to color contact lenses. During its subsequent review of the petition, the agency determined that the subject color additives are composite pigments composed of mica coated with iron oxides or mica coated with titanium dioxide. Therefore, in the **Federal Register** of May 20, 2002 (67 FR 35551), the agency published an amended filing notice to state that the petition proposes that the color additive regulations be amended to provide for the safe use of mica coated with iron oxides or mica coated with titanium dioxide, collectively identified as mica-based pearlescent pigments, in contact lenses.

II. Identity and Manufacturing

Mica-based pearlescent pigments consist of either mica platelets coated with titanium dioxide or mica platelets coated with iron oxides. These color additives are manufactured by preparing a suspension of mica platelets, and then adding a solution of a soluble salt of titanium or of iron, and a base to precipitate titanium hydroxide or iron hydroxide onto the mica platelets. These particles are heated (calcined) at 800 to 900 °C to obtain mica coated with titanium dioxide or mica coated with iron oxides. These color additives create a pearlescent effect and are known commonly as pearlescent pigments. Therefore, the agency is establishing mica-based pearlescent pigments as the common or usual name of the color additives.

III. Safety Evaluation

During its review of the safety of the use of mica-based pearlescent pigments in contact lenses, the agency considered the exposure to the color additives from the petitioned use. The agency notes that it is highly unlikely that the color additives or their components would migrate out of the contact lens into the aqueous environment of the eye, because: (1) These pigments are insoluble in aqueous media, and (2) they are an integral part of the contact lens. Therefore, the agency concludes that the exposure to the components of the color additives, including any impurities that may be present in them, from the petitioned use would be negligible (Ref. 1).

The agency notes that two of the components of the color additives, iron oxides (§ 73.3125) and titanium dioxide (§ 73.3126), already are listed for use as color additives in contact lenses. Therefore, the agency concludes that the use of iron oxides or titanium dioxide in mica-based pearlescent pigments does not present a safety concern (Ref. 2).

Although mica currently is not regulated for use as a color additive in contact lenses, it has been approved for safe use in coloring cosmetics generally, including those applied to the area of the eye, including the eyeball (§§ 73.2496 and 70.3(s)). Generally, the toxicological tests the agency requires to demonstrate that a color additive is safe for use in coloring cosmetics applied to the eye area are adequate to support the safety of a color additive used in contact lenses. In both cases, the tests must show that the color additive is safe and not expected to cause adverse effects under the conditions of use. This is reflected in the agency's current guidance document for contact lens manufacturers (Ref. 3).

In this case, the toxicological data which supported the approval of mica for use in eye area cosmetics are sufficient to support the safe use of mica in contact lenses. These data showed that instillation of a solution containing 5-percent mica directly into the eyes of rabbits did not produce any evidence of ocular or iridial irritation (Ref. 4). In contrast to this exaggerated and direct exposure to mica in the eye, the exposure to mica from its proposed use in contact lenses would be negligible, and if any incidental exposure to mica were to occur, it would not be a safety concern. Therefore, the agency concludes that mica also may be used safely to color contact lenses (Ref. 2).

The regulations listing mica for use in coloring drugs (§ 73.1496) and cosmetics (§ 73.2496) provide specifications to ensure the safe use of mica in those products. To ensure that the mica used in the manufacture of mica-based pearlescent pigments is of comparable purity to the already regulated mica, the agency is requiring in new § 73.3128 that mica used to manufacture the color additives meet the identity and specifications for mica in § 73.1496. The agency also has considered the need to establish purity specifications for the mica-based pearlescent pigments. As noted previously, the agency has determined that the exposure to the components of mica-based pearlescent pigments, including any impurities that may be present in them from the petitioned use, would be negligible. Given the negligible exposure to the color additive and the specifications that are being established for the mica component of the color additive, the agency concludes that it is not necessary to establish separate specifications for the mica-based pearlescent pigments in new § 73.3128.

IV. Conclusion

Based on the data in the petition and other relevant material, FDA concludes that the petitioned use of mica-based pearlescent pigments as color additives in contact lenses is safe, the additives will achieve their intended technical effects, and thus, are suitable for this use. The agency concludes that part 73 should be amended as set forth in this document. In addition, based upon the factors listed in 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 (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. 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 0C0271 (65 FR 36148, June 7, 2000). 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

Any person who will be adversely affected by this regulation may file with the Dockets Management Branch (see **ADDRESSES**) written objections by (see **DATES**). 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. FDA will publish notice of the objections that the agency has received or lack thereof in the **Federal Register**.

IX. References

1. Carberry, S. E., memorandum entitled ''Use of Mica-Based Pearlescent Pigments as Colorants for Contact Lenses'' from the Division of Petition Review (HFS–265) to the Division of Petition Review (HFS–265), Center for Food Safety and Applied Nutrition, FDA, March 28, 2002.

2. Johnson, C. B., memorandum entitled ''Use of Mica-Based Pearlescent Pigments to Color Contact Lenses: Toxicology Review'' from the Division of Petition Review (HFS–225) to the Division of Petition Review (HFS–215), Center for Food Safety and Applied Nutrition, FDA, November 9, 2001.

3. Center for Devices and Radiological Health, Premarket Notification (510(k)) Guidance Document for Daily Wear Contact Lenses, Addendum to Chemistry Guidance for Listing Color Additives in Contact Lenses, Part 5, p.149, (http://www.fda.gov/cdrh/ode/conta.html) May 1994.

4. Gittes, H. R., memorandum entitled ''Eye Area Studies'' from the Division of Toxicology (HFF–152) to the Petitions Control Branch (HFF–334), Center for Food Safety and Applied Nutrition, FDA, May 17, 1977.

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 73.3128 is added to subpart D to read as follows:

§ 73.3128 Mica-based pearlescent pigments.

(a) *Identity and specifications.* The color additive is formed by depositing titanium or iron salts from a basic solution onto mica, followed by calcination to produce titanium dioxide or iron oxides on mica. Mica used to manufacture the color additive shall conform in identity and specifications to the requirements of § 73.1496(a)(1) and (b).

(b) *Uses and restrictions.* (1) Mica-based pearlescent pigments listed in paragraph (a) of this section may be used as a color additive in contact lenses in amounts not to exceed the minimum reasonably required to accomplish the intended coloring effect.

(2) Authorization and compliance with this use shall not be construed as waiving any of the requirements of sections 510(k), 515, and 520(g) of the Federal Food, Drug, and Cosmetic Act (the act) with respect to the contact lenses in which the additive is used.

(c) *Labeling.* The label of the color additive shall conform to the requirements in § 70.25 of this chapter.

(d) *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: September 30, 2002.

L. Robert Lake,

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

[FR Doc. 02–27048 Filed 10–23–02; 8:45 am]

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DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 8869]

RIN 1545–AU77

Subchapter S Subsidiaries; Correction

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Correcting amendment.

SUMMARY: This document contains corrections to final regulations (TD 8869), which were published in the **Federal Register** on Tuesday, January 25, 2000 (65 FR 3843), relating to the treatment of corporate subsidiaries of S corporations.

EFFECTIVE DATE: January 25, 2000.

FOR FURTHER INFORMATION CONTACT: Jeanne M. Sullivan (202) 622–3070 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

The final regulations that are the subject of this correction are under section 1361 of the Internal Revenue Code.