

FDC Date	State	City	Airport	FDC No.	Subject
10/04/02	AR	Batesville	Batesville Regional	2/0517	NDB or GPS Rwy 7, Amdt 5C
10/04/02	NH	Manchester	Manchester	2/0521	ILS Rwy 6, Orig-A
10/04/02	WA	Spokane	Spokane Intl	2/0561	ILS Rwy 3 (Cat I, II, III), Amdt 4
10/04/02	WA	Spokane	Spokane Intl	2/0562	RNAV (GPS) Rwy 3, Orig-B
10/04/02	MA	Westfield	Barnes Muni	2/0576	GPS Rwy 2, Orig
10/04/02	MA	Westfield	Barnes Muni	2/0577	GPS Rwy 20, Orig
10/04/02	MA	Westfield	Barnes Muni	2/0578	ILS Rwy 20, Amdt 5
10/04/02	MA	Westfield	Barnes Muni	2/0579	NDB Rwy 20, Amdt 15
10/04/02	MA	Westfield	Barnes Muni	2/0580	VOR Rwy 20, Amdt 20
10/04/02	MA	Westfield	Barnes Muni	2/0581	VOR Or Tacan Rwy 2, Amdt 4
10/04/02	OK	Oklahoma City	Will Rogers World	2/0587	LOC BC Rwy 35L, Amdt 10D
10/07/02	WA	Spokane	Spokane Intl	2/0626	VOR Rwy 3, Amdt 12
10/07/02	WA	Seattle	Boeing Field/King County Intl	2/0627	ILS Rwy 13R, Amdt 28A
10/07/02	WA	Seattle	Boeing Field/King County Intl	2/0627	ILS Rwy 13R, Amdt 28A
10/07/02	MS	Jackson	Hawkins Field	2/0631	NDB Rwy 16, Amdt 5

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FEDERAL TRADE COMMISSION

16 CFR Part 305

Rule Concerning Disclosures Regarding Energy Consumption and Water Use of Certain Home Appliances and Other Products Required Under the Energy Policy and Conservation Act ("Appliance Labeling Rule")

AGENCY: Federal Trade Commission.

ACTION: Final rule.

SUMMARY: The Federal Trade Commission ("Commission") announces that, because ranges of comparability have not changed significantly, the current ranges of comparability for refrigerators, refrigerator-freezers, and freezers will remain in effect until further notice.

EFFECTIVE DATE: January 22, 2003.

FOR FURTHER INFORMATION CONTACT: Hampton Newsome, Attorney, Division of Enforcement, Federal Trade Commission, Washington, DC 20580 (202-326-2889); *hnewsome@ftc.gov*.

SUPPLEMENTARY INFORMATION: The rule was issued by the Commission in 1979, 44 FR 66466 (Nov. 19, 1979), in response to a directive in the Energy Policy and Conservation Act of 1975 ("EPCA").¹ The rule covers several categories of major household appliances including refrigerators, refrigerator-freezers, and freezers.

I. Background

The rule requires manufacturers of all covered appliances to disclose specific

¹ 42 U.S.C. 6294. The statute also requires the Department of Energy ("DOE") to develop test procedures that measure how much energy the appliances use, and to determine the representative average cost a consumer pays for the different types of energy available.

energy consumption or efficiency information (derived from the DOE test procedures) at the point of sale in the form of an "EnergyGuide" label, fact sheets (for some appliances), and in catalogs. The rule requires manufacturers to include, on labels and fact sheets, an energy consumption or efficiency figure and a "range of comparability." This range shows the highest and lowest energy consumption or efficiencies for all comparable appliance models so consumers can compare the energy consumption or efficiency of other models similar to the labeled model. The rule also requires manufacturers to include, on labels for some products, including those that are the subject of this notice, a secondary energy usage disclosure in the form of an estimated annual operating cost based on a specified DOE national average cost for the fuel the appliance uses.

Section 305.8(b) of the rule requires manufacturers, after filing an initial report, to report certain information annually to the Commission by specified dates for each product type.² These reports, which are to assist the Commission in preparing the ranges of comparability, contain the estimated annual energy consumption or energy efficiency ratings for the appliances derived from tests performed pursuant to the DOE test procedures. Because manufacturers regularly add new models to their lines, improve existing models, and drop others, the data base from which the ranges of comparability are calculated is constantly changing. To keep the required information on labels consistent with these changes, the Commission will publish new ranges if an analysis of the new information indicates that the upper or lower limits of the ranges have changed by more than 15%. Otherwise, the Commission

² Reports for refrigerators, refrigerator-freezers, and freezers are due August 1.

will publish a statement that the prior ranges remain in effect for the next year.

II. 2002 Refrigerator Information

The annual submissions of data for refrigerators, refrigerator-freezers, and freezers have been made and analyzed by the Commission. The ranges of comparability for the products have not changed significantly for these products.³ Therefore, the current ranges for these products (16 CFR Part 305, Appendices A1 through A8 and B1 through B3) will remain in effect until further notice.⁴

List of Subjects in 16 CFR Part 305

Advertising, Energy conservation, Household appliances, Labeling, Reporting and recordkeeping requirements.

The authority citation for Part 305 continues to read as follows:

Authority: 42 U.S.C. 6294.

By direction of the Commission.

Donald S. Clark,
Secretary.

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³ The Commission's analysis excluded models with energy consumption figures that do not meet the current DOE energy conservation standards. See 62 FR 23102 (April 28, 1997).

⁴ See November 19, 2001 (66 FR 57867), November 26, 2001 (66 FR 59050), December 10, 2001 (66 FR 63749), and January 29, 2002 (67 FR 4173).

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