

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00C-1321]

Wesley Jessen Corp.; Filing of Color Additive Petition; Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

DmB

Display Date 5-17-02

Publication Date 5-20-02

Certifier G. Pressky

SUMMARY: The Food and Drug Administration (FDA) is amending the filing notice for a color additive petition filed by Wesley Jessen, Corp. (now Ciba Vision Corp.), to indicate that the petitioned additive is more appropriately identified as mica coated with iron oxides or mica coated with titanium dioxide for use in contact lenses. The previous filing notice indicated that the proposed additive was mica for use in contact lenses.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION: 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 to provide for the safe use of mica to color contact lenses.

During its review of the petition, the agency determined that the subject color additives are composite pigments, commonly known as pearlescent pigments, composed of mica coated with iron oxides or mica coated with titanium dioxide. Therefore, FDA is amending the filing notice of June 7, 2000, to state that the petition proposes that the color additive regulations in 21 CFR part 73 subpart D--Medical Devices 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.

The agency has determined under 21 CFR 25.32(l) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Dated: May 6, 2002
May 6, 2002.

Alan M. Rulis

Alan M. Rulis,
Director,
Office of Food Additive Safety,
Center for Food Safety and Applied Nutrition.

**CERTIFIED TO BE A TRUE
COPY OF THE ORIGINAL**

Gloria Lenkey