

date. This rule is also exempt from these APA requirements because it involves a foreign and military affairs function of the United States. Section 13(b) of the EAA does not require that this rule be published in proposed form because this rule does not impose a new control. Further, no other law requires that notice of proposed rulemaking and an opportunity for public comment be given for this rule.

3. Because a notice of proposed rulemaking and an opportunity for public comment are not required to be given for this rule by section 553 of the Administrative Procedure Act (5 U.S.C. 553), or by any other law, under sections 603(e) and 604(a) of the Regulatory Flexibility Act (5 U.S.C. 603(a) and 604(a)) no initial or final Regulatory Flexibility Analysis has to be or will be prepared.

4. This rule contains a collection of information subject to the requirements of the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*). This collection has been approved by the Office of Management and Budget under control number 0694-0015. Public reporting burden for notifying all foreign consignees whenever a foreign consignee is suspended, removed or revoked from a Distribution License is estimated to average 20 minutes per response. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to the Office of Administration, Bureau of Export Administration, Room 3689, Department of Commerce, Washington, DC 20230 and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503.

5. This rule does not contain policies with Federalism implications sufficient to warrant preparation of a Federalism assessment under Executive Order 12812.

Accordingly, this rule is being issued in final form. However, as with other Department of Commerce rules, comments from the public are always welcome. Written comments (six copies) should be submitted to: Joan Maguire, Regulations Branch, Bureau of Export Administration, Department of Commerce, P.O. Box 273, Washington, DC 20044.

List of Subjects in 15 CFR Part 773

Exports, Reporting and recordkeeping requirements.

Accordingly, 15 CFR Part 773 of the Export Administration Regulations is amended as follows:

PART 773—[AMENDED]

1. The authority citation for Part 773 continues to read as follows:

Authority: Pub. L. 96-72, 93 Stat. 503 (50 U.S.C. app. 2401 *et seq.*), as amended by Pub. L. 97-145 of December 29, 1981, by Pub. L. 99-64 of July 12, 1985, and Pub. L. 100-418 of August 23, 1988; E.O. 12525 of July 12, 1985 (50 FR 28757, July 16, 1985); Pub. L. 95-223 of December 28, 1977 (50 U.S.C. 1701 *et seq.*); E.O. 12532 of September 9, 1985 (50 FR 36861, September 10, 1985) as affected by notice of September 4, 1986 (51 FR 31925, September 8, 1986); Pub. L. 99-440 of October 2, 1986 (22 U.S.C. 5001 *et seq.*); and E.O. 12571, October 27, 1986 (51 FR 39505, October 29, 1986).

2. In § 773.3, paragraph (f)(3)(v) is amended by adding a parenthetical clause after the fourth sentence to read as set forth below and paragraph (1)(4)(ii) is amended by revising the paragraph heading and by adding three sentences to the end of the paragraph to read as follows:

§ 773.3 Distribution License.

(f) Action on license applications.

(3) * * *

(v) * * * (See § 773.3(1)(4)(ii) regarding specific notification procedures.) * * *

(1) Amendments of Distribution Licenses. * * *

(4) * * *

(ii) Deletion, suspension or revocation of consignees. * * * Whenever a license holder submits a Form ITA-685P deleting a consignee or whenever the licensee learns that the Office of Export Licensing has suspended or revoked the Distribution License consignee status of any of his Distribution License consignees, he must immediately notify all other consignees of the deletion, suspension or revocation. The notice must state that the deleted, suspended or revoked party is no longer eligible to receive goods or technical data under the licensee's Distribution License. It need not specify the reason for the suspension unless the consignee has been denied export privileges by the U.S. Department of Commerce.

Dated: October 14, 1988.

Michael E. Zacharis,

Assistant Secretary for Export Administration.

[FR Doc. 88-24408 Filed 10-20-88; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 73

[Docket No. 87C-0379]

Listing of Color Additives for Coloring Contact Lenses; Carbazole Violet

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the color additive regulations to provide for the safe use of carbazole violet for coloring contact lenses. This action is in response to a petition filed by Wesley-Jessen.

DATES: Effective November 22, 1988, except as to any provisions that may be stayed by the filing of proper objections; written objections and requests for a hearing by November 21, 1988.

ADDRESS: Written objections to the Docket Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Mary W. Lipien, Center for Food Safety and Applied Nutrition (HFF-335), Food and Drug Administration, 200 C Street SW., Washington, DC 20204, 202-472-5690.

SUPPLEMENTARY INFORMATION:

I. Introduction

In a notice published in the *Federal Register* of January 26, 1988 (53 FR 2093), FDA announced that a color additive petition (CAP 7C0210) had been filed by Wesley-Jessen, 400 West Superior St., Chicago, IL 60610, proposing that 21 CFR Part 73 of the color additive regulations be amended to provide for the safe use of carbazole violet (CAS Reg. No. 6358-30-1, Colour Index No. 51319) to color contact lenses. The petition was filed under section 706 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 376).

II. Applicability of the Act

With the passage of the Medical Device Amendments of 1976 to the act (Pub. L. 94-295), Congress mandated the listing of color additives for use in medical devices when the color additive comes in direct contact with the body for a significant period of time (21 U.S.C. 376(a)). The use of carbazole violet as a color additive in contact lenses is subject to this listing requirement. The color additive is added to contact lenses in such a way that at least some of the

color additive will come in contact with the eye when the lenses are worn. In addition, the lenses are intended to be placed on the eye for several hours a day, each day, for 1 year or more. Thus, the color additive will be in direct contact with the body for a significant period of time. Consequently, the use of the color additive currently before the agency is subject to the statutory listing requirement.

III. The Color Additive

The color additive carbazole violet (CAS Reg. No. 6358-30-1, Colour Index No. 51319) is prepared by reacting aminoethyl carbazole with chloranil in a high-boiling solvent (trichlorobenzene), followed by ring closure using benzene sulfonyl chloride. The product, which is composed of large particles, is filtered, washed, and dried. Particle size is reduced by mixing the crude product with an inorganic salt and a wetting agent which are then washed out during processing.

IV. Safety Evaluation

FDA concludes from the data submitted in the petition and from other relevant information that the upper limit of exposure to carbazole violet from its use in contact lenses is 280 nanograms per day. The agency-calculated upper limit was based on two factors. First, FDA has established a maximum practical use level of 50 micrograms per lens for color additives in contact lenses (Ref. 1). Second, the agency made two worst-case assumptions: (1) That a user will replace lenses tinted with carbazole violet once each year with a new pair of lenses tinted with the color additive at the maximum use level; and (2) that 100 percent of the color additive will migrate from the lenses into the eyes over the 1-year period. Because these assumptions are worst-case estimates, exposure to carbazole violet from its use for coloring contact lenses is likely to be far less than 280 nanograms per day.

To establish that the color additive carbazole violet is safe for use in coloring contact lenses, the petitioner conducted an in vitro cytotoxicity study on the color additive using L929 mouse fibroblast cells. The mouse cell cultures were exposed to 50,000 micrograms per milliliter of neat color additive. In this study, there were no changes in the morphology of cells that were in contact with the color additive. Thus, the study demonstrated that this concentration of the color additive is noncytotoxic by direct contact, and that the non-effect level for this color additive is greater than 50,000 micrograms per milliliter.

To relate this no-effect concentration for carbazole violet to the maximum

concentration level in the eye that would result from the use of this color additive in contact lenses, the agency estimated that the daily exposure of the color additive in each eye (140 nanograms) will be diluted by the average daily volume of tears produced in each eye (1.68 milliliters). This concentration is equal to a maximum daily concentration of 83 nanograms of color additive per milliliter in the tear flow and eye area. This concentration is more than 600,000 times less than the dose of carbazole violet that was shown to have no adverse effect in the cytotoxicity study.

Based upon the available toxicity data, the small amount of the color additive added to the contact lens, and the agency's exposure calculation, FDA finds that the color additive carbazole violet is safe for use in contact lenses. FDA further concludes that the safety margin is sufficiently large that a limitation on the amount of the color additive that may be present in the lens is not required beyond the limitation that only the amount necessary to accomplish the intended technical effect may be used. Batch certification is not required to ensure safety.

V. Conclusions

Based on data contained in the petition and other relevant material, FDA concludes that there is a reasonable certainty that no harm will result from the petitioned use of carbazole violet for coloring contact lenses, and that this color additive is safe for its intended use. In addition, based upon the data it considered, the agency finds that carbazole violet is suitable for use in coloring contact lenses.

VI. 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 listed above. As provided in 21 CFR 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.

VII. Environmental Impact

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no

significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday. This action was considered under FDA's final rule implementing the National Environmental Policy Act (21 CFR Part 25).

VIII. Reference

The following reference has been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Memorandum of February 19, 1985, from the Food Additive Chemistry Evaluation Branch to the Petitions Control Branch, Re: "Color Additives in Contact Lenses."

IX. Objections

Any person who will be adversely affected by this regulation may at any time on or before November 21, 1988 file with the Dockets Management Branch (address above) written objections thereto. 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.

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, 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: Secs. 701, 706, 52 Stat. 1055-1056 as amended, 74 Stat. 399-407 as amended (21 U.S.C. 371, 376); 21 CFR 5.10.

2. New § 73.3107 is added to Subpart D to read as follows:

§ 73.3107 Carbazole violet.

(a) *Identity.* The color additive is carbazole violet (Pigment Violet 23) (CAS Reg. No. 6358-30-1, Colour Index No. 51319).

(b) *Uses and restrictions.* (1) The substance 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 for 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 lens in which the color additive is used.

(c) *Labeling.* The label of the color additive shall conform to the requirements of § 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 the color additive is exempt from the certification requirements of section 706(c) of the act.

Dated: October 18, 1988.

John M. Taylor,

Associate Commissioner for Regulatory Affairs.

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21 CFR Part 73

[Docket No. 87C-0253]

Listing of Color Additives for Coloring Contact Lenses; Chromium-Cobalt-Aluminum Oxide

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the color additive regulations to provide for the safe use of chromium-cobalt-aluminum oxide for coloring contact lenses. This action is in response to a petition filed by CooperVision, Inc.

DATES: Effective November 22, 1988, except for any provisions that may be stayed by the filing of proper objections;

written objections and requests for a hearing by November 21, 1988.

ADDRESS: Written objections to the Dockets Management Branch (HFA-305), Food and Drug Administration, Room 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Mary W. Lipien, Center for Food Safety and Applied Nutrition (HFF-335), Food and Drug Administration, 200 C Street, SW., Washington, DC 20204, 202-472-5890.

SUPPLEMENTARY INFORMATION:

I. Introduction

In a notice published in the *Federal Register* of September 1, 1987 (52 FR 32965), FDA announced that a color additive petition (CAP 7C0209) had been filed by CooperVision, Inc., 2610 Orchard Parkway, San Jose, CA 95134, proposing that 21 CFR Part 73 of the color additive regulations be amended to provide for the safe use of chromium-cobalt-aluminum oxide to color contact lenses. The petition was filed under section 706 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 376).

II. Applicability of the Act

With the passage of the Medical Device Amendments of 1976 to the act (Pub. L. 94-295), Congress mandated the listing of color additives for use in medical devices when the color additive comes in direct contact with the body for a significant period of time (21 U.S.C. 376(a)). The use of chromium-cobalt-aluminum oxide as a color additive in contact lenses is subject to this listing requirement. The color additive is added to contact lenses in such a way that at least some of the color additive will come in contact with the eye when the lenses are worn. In addition, the lenses are intended to be placed on the eye for several hours a day, each day for 1 year or more. Thus, the color additive will be in direct contact with the body for a significant period of time. Consequently, the use of the color additive currently before the agency is subject to the statutory listing requirement.

III. The Color Additive

The chemical identity of the color additive chromium-cobalt-aluminum oxide (CAS Reg. No. 68187-11-1, Colour Index No. 77343) is the same as that described in 21 CFR 73.1015(a), which authorizes the use of the additive for coloring linear polyethylene sutures. The composition of the additive is identical to that described in 21 CFR 73.1015(b). The range of metal concentrations in the specifications under § 73.1015 occurs

because the additive is an inorganic pigment of varying chromium, cobalt, and aluminum composition, rather than a compound of precisely defined chemical composition.

IV. Safety Evaluation

FDA concludes from the data submitted in the petition and from other relevant information that the upper limit of exposure to chromium-cobalt-aluminum oxide from its use in contact lenses is 760 nanograms per day. The agency-calculated upper limit was based on two factors. First, from information submitted by the petitioner, FDA estimated that the maximum use level of the color additive is 138 micrograms per lens. Second, the agency made two worst-case assumptions: (1) That a user will replace lenses tinted with chromium-cobalt-aluminum oxide once each year with a new pair of lenses tinted with the color additive at the maximum use level; and (2) that 100 percent of the color additive will migrate from the lenses into the eyes over the 1-year period. Because these assumptions are worst-case estimates, exposure to chromium-cobalt-aluminum oxide from its use for coloring contact lenses is likely to be far less than 760 nanograms per day.

To establish that the color additive chromium-cobalt-aluminum oxide is safe for use in coloring contact lenses, the petitioner conducted an in vitro cytotoxicity study on the color additive using L929 mouse fibroblast cells. The cell cultures were exposed to the color additive at various levels. The study demonstrated that the maximum concentration of pigment tested, 300 micrograms per milliliter, and that the no-effect level is greater than 300 micrograms per milliliter.

To relate this no-effect concentration for chromium-cobalt-aluminum oxide to the maximum concentration level in the eye that would result from the use of this color additive in contact lenses, the agency estimated that the daily exposure of the color additive in each eye (380 nanograms) will be diluted by the average daily volume of tears produced in each eye (1.68 milliliters). This concentration is equal to a maximum daily concentration of 0.226 micrograms of color additive per milliliter in the tear flow and eye area. This concentration is more than 1,000 times less than the no-effect dose for chromium-cobalt-aluminum oxide found in the cytotoxicity study. Data from 5-day and 21-day ocular irritation studies in rabbits tested with the colored contact lenses showed no irritation or toxicity to the ocular environment.