guarantee, or secure a commodity contract unless, the commodity broker first furnishes the customer with the disclosure statement set forth in paragraph (c)(2) of this section in boldfaced print in at least ten point type, which may be provided as either a separate, written document or incorporated into the customer agreement.

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Issued in Washington, DC, on March 30, 1993, by the Commission.

Jean A. Webb,

Secretary of the Commission.

[FR Doc. 93–7727 Filed 4–2–93; 8:45 am]

BILLING CODE 6351–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 73

[Docket No. 89C–0203]

Listing of Color Additives for Coloring Contact Lenses; 1,4-Bis[4-(2-Methacryloxyethyl) Phenylamino]Anthraquinone Copolymers

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 the colored reaction product formed by copolymerizing 1,4-bis[4-(2-methacryloxyethyl) phenylamino]anthraquinone (C.I. Reactive Blue 246) with hydroxyethyl methacrylate and *N*-vinyl pyrrolidone to form contact lenses and to identify clearly the color additive as the reaction product of 1,4-bis[4-(2-methacryloxyethyl) phenylamino]anthraquinone copolymerized with other monomers. This action is in response to a petition filed by Bausch & Lomb, Inc.

DATES: Effective May 6, 1993, except as to any provisions that may be stayed by the filing of proper objections; written objections and requests for a hearing by May 5, 1993.

ADDRESSES: Submit written objections to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Helen R. Thorsheim, Center for Food Safety and Applied Nutrition (HFS–216), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–254–9511.

SUPPLEMENTARY INFORMATION:

I. Introduction

In a notice published in the **Federal Register** of December 19, 1990 (55 FR 52099), FDA announced that a color additive petition (CAP 1C0229) had been filed by Bausch & Lomb, Inc., 1400 North Goodman St., Rochester, NY 14692–0450. The petition proposed to amend § 73.3106 (21 CFR 73.3106) of the color additive regulations to provide for the safe use of 1,4-bis[4-(2-methacryloxyethyl) phenylamino]anthraquinone copolymerized with hydroxyethyl methacrylate/*N*-vinyl pyrrolidone copolymer to color contact lenses. The petition was filed under section 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 376).

In a notice published in the **Federal Register** of August 11, 1992 (57 FR 35832), FDA announced that Bausch & Lomb, Inc., had also requested that § 73.3106 be amended to list the color additive as the copolymer formed as the reaction product of 1,4-bis[4-(2-methacryloxyethyl) phenylamino]anthraquinone copolymerized with the contact lens monomers, either hydroxyethyl methacrylate or a blend of hydroxyethyl methacrylate and *N*-vinyl pyrrolidone.

II. Applicability of the Act

With the passage of the Medical Device Amendments of 1976 (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 the reaction product of 1,4-bis[4-(2-methacryloxyethyl) phenylamino]anthraquinone copolymerized with hydroxyethyl methacrylate and *N*-vinyl pyrrolidone as a color additive in manufacturing contact lenses is subject to this listing requirement. The color additive is formed into contact lenses in such a way that at least some of the color additive will come in contact with the eyes when lenses are worn. In addition, the lenses are intended to be placed on the eyes 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. Identity

The color additive is produced by copolymerizing 1,4-bis[4-(2-methacryloxyethyl) phenylamino]anthraquinone (CAS Reg. No. 121888–69–5) with hydroxyethyl methacrylate and *N*-vinyl pyrrolidone monomers. The resulting copolymeric product is formed into a contact lens.

IV. Safety Evaluation

The agency believes that because 1,4-bis[4-(2-methacryloxyethyl) phenylamino]anthraquinone has a significantly lower molecular weight than the subject copolymer, it would be more readily absorbed into the body than the subject copolymer and would thus be expected to show a greater toxic effect. Therefore, the safety evaluation of the subject color additive focused primarily on 1,4-bis[4-(2-methacryloxyethyl) phenylamino]anthraquinone.

FDA concludes from the data submitted in the petition and from other relevant information that the average daily exposure to 1,4-bis[4-(2-methacryloxyethyl) phenylamino]anthraquinone from this petitioned use in contact lenses would be no greater than 0.04 micrograms (µg) per person per day. The agency-calculated upper limit was based on two factors. First, the maximum use level anticipated by the petitioner is 100 parts per million of the lens material or 8 µg per lens of 1,4-bis[4-(2-methacryloxyethyl) phenylamino]anthraquinone in a contact lens (Ref. 1). Second, the agency made two worst-case assumptions: (1) The user will replace these lenses once each year with a new pair of identical lenses, and (2) 100 percent of the 1,4-bis[4-(2-methacryloxyethyl) phenylamino]anthraquinone will migrate from the lenses into the eyes over the 1-year period. Because these assumptions are worst-case estimates, exposure to 1,4-bis[4-(2-methacryloxyethyl) phenylamino]anthraquinone from this use is likely to be far less than 0.04 µg per person per day (Ref. 1).

To establish the safety of the subject additive, the petitioner conducted toxicity studies with 1,4-bis[4-(2-methacryloxyethyl) phenylamino]anthraquinone, colored lenses, and colored lens extracts. The studies included six in vitro cytotoxicity studies, four by the agar overlay method (with 1,4-bis[4-(2-methacryloxyethyl) phenylamino]anthraquinone, lens, and lens extract), and two by the direct-contact method (with 1,4-bis[4-(2-methacryloxyethyl)

phenylamino]anthraquinone and lens extract). The maximum noncytotoxic concentration of 1,4-bis[4-(2-methacryloxyethyl) phenylamino]anthraquinone was determined to be 1,810 µg per milliliter (mL) by the direct-contact method using mouse fibroblast cells. Both the lenses and lens extracts were found to be noncytotoxic to mouse fibroblast cells. A 21-day ocular irritation study with contact lenses in rabbits and a guinea pig maximization study (Kligman) with lens extracts were also conducted. These studies demonstrated no evidence of ocular irritation or an allergic response in the test animals.

To relate the 1,810 µg/mL no-effect level, established in the direct-contact cytotoxicity study for 1,4-bis[4-(2-methacryloxyethyl) phenylamino]anthraquinone, to the 0.04 µg per person per day exposure from wearing the colored lenses, the agency calculated the maximum concentration level in each eye that would result from the use of the contact lens. The agency estimated that the daily exposure in each eye would be 0.02 µg and that this would be diluted by the average daily tear film of 1.2 mL produced in each eye. This concentration is equal to a maximum daily concentration in the tear flow of the eye of 0.02 µg dye per mL. This concentration represents more than a 90,000 fold safety factor, for this proposed use of 1,4-bis[4-(2-methacryloxyethyl) phenylamino]anthraquinone.

Based upon the available toxicity data, the small amount of 1,4-bis[4-(2-methacryloxyethyl) phenylamino]anthraquinone used to form the color additive in the contact lenses, and the agency's exposure calculation for 1,4-bis[4-(2-methacryloxyethyl) phenylamino]anthraquinone, FDA finds that the reaction product formed by copolymerizing 1,4-bis[4-(2-methacryloxyethyl) phenylamino]anthraquinone with hydroxyethyl methacrylate and *N*-vinyl pyrrolidone, is safe for use as a color additive in contact lenses. FDA further concludes that the safety margin is sufficiently large that no limitation is required beyond the usual limitation that the reactants may be used in amounts not to exceed the minimum reasonably required to accomplish the intended technical effect. 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 the reaction product formed by copolymerizing 1,4-bis[4-(2-methacryloxyethyl) phenylamino]anthraquinone with hydroxyethyl methacrylate and *N*-vinyl pyrrolidone to form colored contact lenses, and that the color additive is safe and suitable for its intended use. FDA also agrees with the petitioner's request to amend § 73.3106 to list the color additive as the reaction product of 1,4-bis[4-(2-methacryloxyethyl) phenylamino]anthraquinone copolymerized with other monomers, either hydroxyethyl methacrylate or a blend of hydroxyethyl methacrylate and *N*-vinyl pyrrolidone, to form a contact lens material.

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 (address above) by appointment with the information contact person listed above. 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.

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.

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 dated April 8, 1991, from the Food and Color Additives Review Section to the Indirect Additives Branch, "CAP 1C0229: Bausch & Lomb, submission of 10-2-90. 1,4-Bis[4-(2-methacryloxyethyl)-phenylamino]- anthraquinone (Reactive Blue 246) as a colorant in contact lenses."

IX. Objections

Any person who will be adversely affected by this regulation may at any time on or before May 5, 1993, 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. FDA will publish notice of the objections that the agency has received or lack thereof in the **Federal Register**.

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: Secs. 201, 401, 402, 403, 409, 501, 502, 505, 601, 602, 701, 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 342, 343, 348, 351, 352, 355, 361, 362, 371, 376).

2. Section 73.3106 is revised to read as follows:

§ 73.3106 1,4-Bis[4-(2-methacryloxyethyl) phenylamino]anthraquinone copolymers.

(a) *Identity.* The color additive is 1,4-bis[4-(2-methacryloxyethyl) phenylamino]anthraquinone (CAS Reg. No. 121888–69–5), copolymerized with hydroxyethyl methacrylate monomer or a blend of hydroxyethyl methacrylate

and *N*-vinyl pyrrolidone monomers to form the contact lens material.

(b) *Uses and restrictions.* (1) The substances listed in paragraph (a) of this section may be used in amounts not to exceed the minimum reasonably required to accomplish the intended coloring effect.

(2) Authorization and compliance with these uses 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 contact lenses made from the color additives.

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

(d) *Exemption from certification.* Certification of these color additives is not necessary for the protection of the public health and, therefore, the color additives are exempt from the certification requirements of section 706(c) of the act.

Dated: March 18, 1993.

Michael R. Taylor,

Deputy Commissioner for Policy.

[FR Doc. 93–7769 Filed 4–2–93; 8:45 am]

BILLING CODE 4160–01–F

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21 CFR Part 73

[Docket No. 89C–0480]

Listing of Color Additives for Coloring Contact Lenses; Vinyl Alcohol/Methyl Methacrylate-Dye Reaction Products

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 in coloring contact lenses of the reaction products formed by chemically bonding the following reactive dyes, alone or in combination, to the vinyl alcohol/methyl methacrylate copolymeric lens material:

(1) C.I. Reactive Black 5 [2,7-naphthalenedisulfonic acid, 4-amino-5-hydroxy-3,6-bis((4-((2-(sulfooxy)ethyl)sulfonyl)phenyl)azo)-, tetrasodium salt] (CAS Reg. No. 17095–24–8);

(2) C.I. Reactive Orange 78 [2-naphthalenesulfonic acid, 7-(acetylamino)-4-hydroxy-3-((4-((2-(sulfooxy)ethyl)sulfonyl)phenyl)azo)-] (CAS Reg. No. 68189–39–9);

(3) C.I. Reactive Yellow 15 [benzenesulfonic acid, 4-(4,5-dihydro-4-((2-methoxy-5-methyl-4-((2-(sulfooxy)ethyl)sulfonyl)phenyl)azo)-3-methyl-5-oxo-1*H*-pyrazol-1-yl)-] (CAS Reg. No. 60958–41–0);

(4) C.I. Reactive Blue No. 19 [2-anthracenesulfonic acid, 1-amino-9,10-dihydro-9,10-dioxo-4-((3-((2-(sulfooxy)ethyl)sulfonyl)phenyl)amino)-, disodium salt] (CAS Reg. No. 2580–78–1); and

(5) C.I. Reactive Blue 21 [copper, (29*H*,31*H*-phthalocyaninato(2-)-N^{29}, N^{30}, N^{31}, N^{32})-, sulfo((4-((2-(sulfooxy) ethyl)sulfonyl)phenyl)amino)sulfonyl derivatives] (CAS Reg. No. 73049–92–0).

This action is in response to a petition filed by CIBA Vision Corp.

DATES: Effective May 6, 1993, except as to any provisions that may be stayed by the filing of proper objections; written objections and requests for a hearing by May 5, 1993.

ADDRESSES: Submit written objections to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Mitchell Cheeseman, Center for Food Safety and Applied Nutrition (HFS–216), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–254–9511.

SUPPLEMENTARY INFORMATION:

I. Introduction

In a notice published in the **Federal Register** of December 19, 1989 (54 FR 51945), FDA announced that a color additive petition (CAP 9C0217) had been filed by CIBA Vision Corp., P.O. Box 105069, Atlanta, GA 30348. The petition proposed that the color additive regulations be amended to provide for the safe use of six vinyl sulfone reactive dyes to color contact lenses prepared from a copolymer that is the reaction product of the dye and a polyvinyl alcohol/methyl methacrylate copolymer. The dyes are as follows:

(1) C.I. Reactive Black 5 (2,7-naphthalenedisulfonic acid, 4-amino-5-hydroxy-3,6-bis((4-((2-(sulfooxy)ethyl)sulfonyl)phenyl)azo)-, tetrasodium salt, CAS Reg. No. 17095–24–8);

(2) C.I. Reactive Blue 21 (copper, (29*H*,31*H*-phthalocyaninato(2-)-N^{29}, N^{30}, N^{31}, N^{32})-, sulfo((4-((2-(sulfooxy) ethyl)sulfonyl)phenyl)amino)sulfonyl derivatives, CAS Reg. No. 73049–92–0);

(3) C.I. Reactive Orange 78 (2-naphthalenesulfonic acid, 7-(acetylamino)-4-hydroxy-3-((4-((2-(sulfooxy)ethyl)sulfonyl)phenyl)azo)-, CAS Reg. No. 68189–39–9);

(4) C.I. Reactive Yellow 15 (benzenesulfonic acid, 4-(4,5-dihydro-4-((2-methoxy-5-methyl-4-((2-(sulfooxy)ethyl)sulfonyl)azo)-3-methyl-5-oxo-1*H*-pyrazol-1-yl)-, CAS Reg. No. 60958–41–0);

(5) C.I. Reactive Blue No. 19 (2-anthracenesulfonic acid, 1-amino-9,10-dihydro-9,10-dioxo-4-((3-((2-(sulfooxy)ethyl)sulfonyl)phenyl)amino)-, disodium salt, CAS Reg. No. 2580–78–1); and

(6) C.I. Reactive Red 180 (5-(benzoylamino)-4-hydroxy-3-((1-sulfo-6-((2-(sulfooxy)ethyl)sulfonyl)-2-naphthalenyl)azo)-2,7-naphthalenedisulfonic acid, tetrasodium salt, CAS Reg. No. 98114–32–0).

Since publication of the filing notice, Ciba Vision Corp. has changed its address to 11460 Johns Creek Pkwy., Duluth, GA 30136–1518. Additionally, the color additive regulation providing for the safe use in coloring contact lenses of the reaction of C.I. Reactive Red 180 with vinyl alcohol/methyl methacrylate copolymer has been addressed in a previous final rule (January 8, 1993, 58 FR 3225). In the filing notice of December 19, 1989, the chemical nomenclature of C.I. Reactive Yellow 15 was incorrectly cited. This final rule corrects that error.

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 (Pub. L. 94–295), Congress mandated the listing of color additives for use in medical devices when the color additive comes into direct contact with the body for a significant period of time (21 U.S.C. 376(a)). The use of the vinyl alcohol/methyl methacrylate-dye reaction products as color additives in contact lenses is subject to this listing requirement. The color additives are added to contact lenses in such a way that at least some of the color additives will come into 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 additives will be in direct contact with the body for a significant period of time. Consequently, the use of the color additives currently before the agency is subject to the statutory listing requirement.

III. Identity

The color additives are the reaction products formed when the reactive dyes are chemically bonded, either alone or in combination, with the vinyl alcohol/methyl methacrylate copolymer. Specifically, the dyes are reacted with contact lenses fabricated from the vinyl alcohol/methyl methacrylate copolymer. During the reaction, the sulfate groups of the dyes are replaced by ether

linkages to the copolymeric lens material. As a result, a thin layer of colored copolymeric material forms on the surface of the lenses. As part of the manufacturing process, the lenses are thoroughly washed to remove unbound dye.

IV. Safety Evaluation

The agency believes that because the five reactive dyes have significantly lower molecular weights than the vinyl alcohol/methyl methacrylate-dye copolymers, they would be more readily absorbed into the body than the copolymeric color additives and would thus be expected to show a greater toxic effect. Therefore, the safety evaluation of the subject color additives focused primarily on the reactive dyes.

FDA concludes from the data submitted in the petition and from other relevant information that the exposure to each of the dyes from its use to produce the color additives in the contact lenses is no greater than 3 nanograms (ng) per person per day. The exposures calculated by the agency were based on extraction studies conducted by the petitioner on previously regulated contact lenses colored with the vinyl alcohol/methyl methacrylate-C.I. Reactive Red 180 reaction product, from which the agency has determined that the amount of C.I. Reactive Red 180 that could migrate from the colored contact lenses is no more than 0.6 micrograms (µg) per lens.

Because the chemical bonding of the five subject dyes to the vinyl alcohol/methyl methacrylate copolymeric lens material is expected to be similar to that observed in the vinyl alcohol/methyl methacrylate-C.I. Reactive Red 180 reaction product, the exposure to the five reactive dyes is likely to be no greater than that determined for C.I. Reactive Red 180.

The agency has also made the worst-case assumptions that: (1) A user will replace lenses colored with the vinyl alcohol/methyl methacrylate-dye copolymers once each year with a new pair of lenses tinted with the same color additive; and (2) 100 percent of the 0.6 µg of extractable dye will migrate from the lenses into the eyes over the 1-year period. Because these assumptions include numerous conservatisms, actual exposure to the reactive dyes from their use to produce color additives in contact lenses is likely to be far less than 3 ng per person per day (Ref. 1).

In evaluating the safety of the five reactive dyes, the agency considered two in vitro cytotoxicity studies on the reactive dyes by the direct-contact method that were contained in its files. From these studies, the maximum noncytotoxic concentrations for the reactive dyes using mouse fibroblast cells were determined to be 500 µg per milliliter (mL) for C.I. Reactive Black 5; 1,000 µg/mL for C.I. Reactive Orange 78; 750 µg/mL for C.I. Reactive Yellow 15; 250 µg/mL for C.I. Reactive Blue No. 19; and 100 µg/mL for C.I. Reactive Blue 21.

In addition, the petitioner conducted toxicity tests to establish that the vinyl alcohol/methyl methacrylate-dye reaction products are safe for use in coloring contact lenses. These tests included in vitro cytotoxicity studies on the lenses and on lens extracts using mouse fibroblast cells and the agar-overlay method. The petitioner also conducted acute systemic toxicity tests on mice using lens extracts and 21-day ocular irritation studies on rabbits using the colored lenses. The above-referenced studies demonstrated no evidence of cytotoxicity, acute systemic toxicity, or ocular irritation.

To relate the no-effect levels established in the direct-contact cytotoxicity studies on the reactive dyes to the 3 ng per person per day exposure from wearing the colored lenses, the agency calculated the maximum concentration level of reactive dye in each eye that would result from the use of the contact lens. The agency estimated the daily exposure to reactive dye in each eye would be no greater than 1.5 ng, and this daily exposure would be diluted by the average daily tear film of 1.2 mL produced in each eye. This concentration is equal to a maximum daily concentration in the tear flow of the eye of 1.25 ng per mL for each of the five reactive dyes. When this concentration is compared with the no-effect levels from the in vitro cytotoxicity tests, this represents safety factors of: At least 400,000-fold for C.I. Reactive Black 5, at least 800,000-fold for C.I. Reactive Orange 78, at least 600,000-fold for C.I. Reactive Yellow 15, at least 200,000-fold for C.I. Reactive Blue No. 19, and at least 80,000-fold for Reactive Blue 21 for this use in contact lenses.

Based upon the available toxicity data, the small amount of vinyl alcohol/methyl methacrylate-dye reaction products in the contact lenses, and the agency's exposure calculation, FDA finds that the reaction products formed by chemically bonding the five reactive dyes, either alone or in combination, to vinyl alcohol/methyl methacrylate copolymer are safe for coloring contact lenses. FDA further concludes that the use of the color additive shall be limited to the amount necessary to accomplish the intended coloring effect. Batch certification is not required to ensure safety.

V. Conclusions

Based on data contained in the petition and other relevant information, FDA concludes that there is a reasonable certainty that no harm will result from the petitioned use of vinyl alcohol/methyl methacrylate-dye reaction products as color additives in contact lenses, and that the additive is safe and suitable for the intended use. Therefore, the agency is amending § 73.3127 (21 CFR 73.3127) of the color additive regulations by revising paragraphs (a), (b)(1), and (b)(2) to provide for the use of the subject color additives.

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 (address above) by appointment with the information contact person listed above. 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.

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.

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 dated July 7, 1992, from the Food and Color Additives Review Section, to the Direct Additives Branch, CAP 9C0217 Ciba Vision, exposure estimates for reactive dyes, submission dated June 12, 1992.

IX. Objections

Any person who will be adversely affected by this regulation may at any time on or before May 5, 1993, 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. FDA will publish notice of the objections that the agency has received or lack thereof in the Federal Register.

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: Secs. 201, 401, 402, 403, 409, 501, 502, 505, 601, 602, 701, 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 342, 343, 348, 351, 352, 355, 361, 362, 371, 376).

2. Section 73.3127 is amended by revising paragraphs (a), (b)(1), and (b)(2) to read as follows:

§ 73.3127 Vinyl alcohol/methyl methacrylate-dye reaction products.

(a) *Identity.* The color additives are formed by reacting the dyes, either alone or in combination, with a vinyl alcohol/methyl methacrylate copolymer, so that the sulfate groups of the dyes are replaced by ether linkages to the vinyl alcohol/methyl methacrylate copolymer. The dyes are:

(1) C.I. Reactive Red 180 [5-(benzoylamino)-4-hydroxy-3-((1-sulfo-6-((2-(sulfooxy)ethyl)sulfonyl)-2-naphthalenyl)azo)-2,7-naphthalenedisulfonic acid, tetrasodium salt] (CAS Reg. No. 98114-32-0).

(2) C.I. Reactive Black 5 [2,7-naphthalenedisulfonic acid, 4-amino-5-hydroxy-3,6-bis[(4-((2-(sulfooxy)ethyl)sulfonyl)phenyl)azo)-, tetrasodium salt] (CAS Reg. No. 17095-24-8).

(3) C.I. Reactive Orange 78 [2-naphthalenesulfonic acid, 7-(acetylamino)-4-hydroxy-3-((4-((2-(sulfooxy)ethyl)sulfonyl)phenyl)azo)-] (CAS Reg. No. 68189-39-9).

(4) C.I. Reactive Yellow 15 [benzenesulfonic acid, 4-(4,5-dihydro-4-((2-methoxy-5-methyl-4-((2-(sulfooxy)ethyl)sulfonyl)phenyl)azo)-3-methyl-5-oxo-1*H*-pyrazol-1-yl)-] (CAS Reg. No. 60958-41-0).

(5) C.I. Reactive Blue No. 19 [2-anthracenesulfonic acid, 1-amino-9,10-dihydro-9,10-dioxo-4-((3-((2-(sulfooxy)ethyl)sulfonyl)phenyl)amino)-, disodium salt] (CAS Reg. No. 2580-78-1).

(6) C.I. Reactive Blue 21 [copper, (29*H*,31*H*-phthalocyaninato(2-)-N^{29}, N^{30}, N^{31}, N^{32})-, sulfo((4-((2-(sulfooxy) ethyl)sulfonyl)phenyl)amino)sulfonyl derivatives] (CAS Reg. No. 73049-92-0).

(b) *Uses and restrictions.* (1) The substances listed in paragraph (a) of this section may be used to color contact lenses in amounts not to exceed the minimum reasonably required to accomplish the intended coloring effect.

(2) As part of the manufacturing process, the lenses containing the color additives are thoroughly washed to remove unbound reactive dye.

* * * * *

Dated: March 22, 1993.

Michael R. Taylor,

Deputy Commissioner for Policy.

[FR Doc. 93-7843 Filed 4-2-93; 8:45 am]

BILLING CODE 4160-01-F

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21 CFR Part 74

[Docket No. 91C-0033]

Listing of Color Additives Subject to Certification; FD&C Blue No. 1

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 manganese dioxide as an oxidizing agent in the manufacture of FD&C Blue No. 1. This action is in response to a petition filed by the Hilton Davis Co.

DATES: Effective May 6, 1993, except as to any provisions that may be stayed by the filing of proper objections; written objections by May 5, 1993.

ADDRESSES: Submit written objections to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Wes Long, Center for Food Safety and Applied Nutrition (HFS-217), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-254-9519.

SUPPLEMENTARY INFORMATION:

I. Introduction

In a notice published in the Federal Register of March 1, 1991 (56 FR 8781), FDA announced that a color additive petition (CAP 0C0227) had been filed by the Hilton Davis Co., 2235 Landon Farm Rd., Cincinnati, OH 45237, proposing that the color additive regulations for FD&C Blue No. 1 be amended to provide for the safe use of manganese dioxide to manufacture the color additive. The petition was filed under section 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 376).

II. Identity

Although the identity of the color additive FD&C Blue No. 1 in part 74 (21 CFR part 74) remains the same, the manufacturing process that is specified in § 74.2101(a) will be modified to include the option of using manganese dioxide as an oxidant. The manufacturing process for FD&C Blue No. 1 in § 74.1101(a)(2) for externally applied drugs conforms to the requirements in § 74.2101(a). Currently, no manufacturing process is specified for FD&C Blue No. 1 in the identity section for foods (§ 74.101(a)(1)) or ingested drugs (§ 74.1101(a)(1)).

In the final rule issued in the Federal Register of September 28, 1982 (47 FR 42563), FD&C Blue No. 1 was permanently listed for use in externally applied drugs and in cosmetics. The agency concluded that a brief description of the manufacturing process was necessary to provide adequate assurance of safety until suitable specifications could be developed. The manufacturing process for FD&C Blue No. 1 in cosmetics was specified in § 74.2101(a) and cross-referenced in § 74.1101(a)(2) for externally applied drugs. At that time, the agency also stated its intention to amend the identity requirements for FD&C Blue No. 1 for foods in § 74.101(a) and, by cross-reference, for ingested drugs in § 74.1101(a)(1), to include a description of the manufacturing

process. This action is still planned by the agency.

III. Specifications

This document modifies the specifications for FD&C Blue No. 1 in § 74.101(b) to include a specification for manganese impurity. This specification is included in § 74.1101(b) for externally applied and ingested drugs, and this specification is included in § 74.2101(b) for cosmetics by cross-reference to § 74.101(b).

IV. Uses

The manufacturing process is specified in § 74.2101(a) for cosmetics, and it is specified by cross-reference in § 74.1101(a)(2) for externally applied drugs, but it is not specified in § 74.101(a)(1) for foods or in § 74.1101(a)(1) for ingested drugs. Inclusion of the description of the manufacturing process in the regulation for use of FD&C Blue No. 1 in ingested drugs and foods will be the subject of a separate action to be initiated by the agency. However, the intended uses of FD&C Blue No. 1 manufactured using manganese dioxide as the oxidizing agent will include food, drug, and cosmetic uses. FDA has evaluated the safety of FD&C Blue No. 1 manufactured using manganese dioxide for use in foods, drugs, and cosmetics.

V. Conclusions

Based on data contained in the petition and other relevant information, FDA concludes that there is a reasonable certainty that no harm will result from the petitioned use of manganese dioxide as an oxidant in the manufacture of FD&C Blue No. 1. The agency also concludes on the basis of that data and material that the use of manganese dioxide as an alternative oxidant will not affect the identity of the color additive and that the color additive will continue to perform its intended coloring effect in foods, drugs, and cosmetics. Thus, FD&C Blue No. 1 manufactured using manganese dioxide as the oxidizing agent is suitable for this use. The agency, therefore, is amending the color additive regulations in §§ 74.101 and 74.2101 to provide for use of manganese dioxide in the manufacture of FD&C Blue No. 1.

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 (address above) by appointment with the information contact person listed above. 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.

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.

VIII. Objections

Any person who will be adversely affected by this regulation may at any time on or before May 5, 1993, 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. FDA will publish notice of the objections that the agency has received or lack thereof in the **Federal Register**.

List of Subjects in 21 CFR Part 74

Color additives, Cosmetics, Drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 74 is amended as follows:

PART 74—LISTING OF COLOR ADDITIVES SUBJECT TO CERTIFICATION

1. The authority citation for 21 CFR part 74 continues to read as follows:

Authority: Secs. 201, 401, 402, 403, 409, 501, 502, 505, 601, 602, 701, 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 342, 343, 348, 351, 352, 355, 361, 362, 371, 376).

2. Section 74.101 is amended by revising paragraph (b) to read as follows:

§ 74.101 FD&C Blue No. 1.

* * * * *

(b) *Specifications.* FD&C Blue No. 1 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 current good manufacturing practice:

Sum of volatile matter (at 135 °C) and chlorides and sulfates (calculated as sodium salts), not more than 15.0 percent.

Water-insoluble matter, not more than 0.2 percent.

Leuco base, not more than 5 percent.

Sum of *o*-, *m*-, and *p*-sulfobenzaldehydes, not more than 1.5 percent.

N-Ethyl,*N*-(*m*-sulfobenzyl)sulfanilic acid, not more than 0.3 percent.

Subsidiary colors, not more than 6.0 percent.

Chromium (as Cr), not more than 50 parts per million.

Manganese (as Mn), not more than 100 parts per million.

Arsenic (as As), not more than 3 parts per million.

Lead (as Pb), not more than 10 parts per million.

Total color, not less than 85.0 percent.

* * * * *

3. Section 74.2101 is amended by revising paragraph (a) to read as follows:

§ 74.2101 FD&C Blue No. 1.

(a) *Identity.* The color additive FD&C Blue No. 1 is principally the disodium salt of ethyl[4-[*p*-[ethyl(*m*-sulfobenzyl)amino]-α-(*o*-sulfophenyl)benzylidene]-2,5-cyclohexadien-1-ylidene](*m*-sulfobenzyl)ammonium hydroxide inner salt with smaller amounts of the isomeric disodium salts of ethyl[4-[*p*-[ethyl(*p*-sulfobenzyl)amino]-α-(*o*-sulfophenyl)benzylidene]-2,5-cyclohexadien-1-ylidene](*p*-sulfobenzyl)ammonium hydroxide inner salt and ethyl[4-[*p*-[ethyl(*o*-sulfobenzyl)amino]-α-(*o*-sulfophenyl)benzylidene]-2,5-cyclohexadien-1-ylidene](*o*-

sulfobenzyl)ammonium hydroxide inner salt. Additionally, FD&C Blue No. 1 is manufactured by the acid catalyzed condensation of one mole of sodium 2-formylbenzenesulfonate with two moles from a mixture consisting principally of 3-[(ethylphenylamino)methyl] benzenesulfonic acid, and smaller amounts of 4-[(ethylphenylamino)methyl] benzenesulfonic acid and 2-[(ethylphenylamino)methyl] benzenesulfonic acid to form the leuco base. The leuco base is then oxidized with lead dioxide and acid, or with dichromate and acid, or with manganese dioxide and acid to form the dye. The intermediate sodium 2-formylbenzenesulfonate is prepared from 2-chlorobenzaldehyde and sodium sulfite.

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Dated: March 18, 1993.

Michael R. Taylor,

Deputy Commissioner for Policy.

[FR Doc. 93–7841 Filed 4–2–93; 8:45 am]

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21 CFR Part 178

[Docket No. 92N–0388]

Indirect Food Additives: Adjuvants, Production Aids, and Sanitizers; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the titles of material incorporated by reference in the regulation that provides for the use of polyhydric alcohol esters of oxidatively refined (Gersthofen process) montan wax acids (§ 178.3770 (21 CFR 178.3770)). The titles of the material included in § 178.3770(a)(2), (a)(3), (b)(2), (b)(3), (d)(2), and (d)(3) were inadvertently transposed. Therefore the agency is inserting the correct titles for the incorporated material.

EFFECTIVE DATE: April 5, 1993.

FOR FURTHER INFORMATION CONTACT: Vir D. Anand, Center for Food Safety and Applied Nutrition (HFF–335), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–254–9500.

SUPPLEMENTARY INFORMATION: In reviewing its regulations on food additives, FDA has determined that the titles of certain material incorporated by reference in § 178.3770 are incorrect. In each of the paragraphs listed below the titles of the methods ("Standard Test Method for Saponification Number (Empirical) of Synthetic and Natural Waxes" (Revised 1978) and "Standard Test Method for Acid Number (Empirical) of Synthetic Natural Waxes" (Revised 1978)) are transposed.

Upon review, the agency determined that these errors occurred when it amended the incorporating regulatory text in 21 CFR parts 170 through 189 to make clear that an incorporation by reference was intended as required by 1 CFR part 51 (47 FR 11835, March 19, 1982). These errors appeared in § 178.3770(a)(2), (a)(3), (b)(2), and (b)(3). This error was later extended to § 178.3770(d)(2) and (d)(3), which were added in the **Federal Register** of July 9, 1990 (55 FR 28020).

FDA concludes that notice and comment rulemaking to correct these errors is impracticable, contrary to the public interest, and unnecessary because these corrections rectify mistakes that are clear on their face, and which do not involve any controversial or substantive matters (5 U.S.C. 553(b)(B)).

List of Subjects in 21 CFR Part 178

Food additives, Food packaging, Incorporation by reference.

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 of the Center for Food Safety and Applied Nutrition, 21 CFR part 178 is amended as follows:

PART 178—INDIRECT FOOD ADDITIVES: ADJUVANTS, PRODUCTION AIDS, AND SANITIZERS

1. The authority citation for 21 CFR part 178 continues to read as follows:

Authority: Secs. 201, 402, 409, 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 348, 376).

2. Section 178.3770 *Polyhydric alcohol esters of oxidatively refined (Gersthofen process) montan wax acids* is amended in paragraphs (a)(2), (b)(2), and (d)(2) by removing the words "ASTM method D1386–78 ("Standard Test Method for Saponification" and adding in their place the words "ASTM method D 1386–78 ("Standard Test Method for Acid"; and in paragraphs (a)(3), (b)(3), and (d)(3) by removing the words "ASTM method D1387–78 ("Standard Test Method for Acid" and adding in their place the words "ASTM method D 1387–78 ("Standard Test Method for Saponification"; and in paragraph (d)(2) by removing "20 to 30" and replacing it with "20–30".

Dated: February 12, 1993.

Jerry Burke,

Acting Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 93–7766 Filed 4–2–93; 8:45 am]

BILLING CODE 4160–01–F

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21 CFR Part 178

[Docket No. 91F–0020]

Indirect Food Additives: Adjuvants, Production Aids, and Sanitizers

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of phosphoric acid, mono- and dihexyl esters, compounds with tetramethylnonylamines and C_{11-14}-alkylamines as components of surface lubricants that may contact food. This action is in response to a petition filed by the Ciba-Geigy Corp.

DATES: Effective April 5, 1993; written objections and requests for a hearing by May 5, 1993.

ADDRESSES: Submit written objections to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Richard H. White, Center for Food Safety and Applied Nutrition (HFS–216), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–254–9511.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of February 5, 1991 (56 FR 4632), FDA announced that a food additive petition (FAP 0B4232) had been filed by the Ciba-Geigy Corp., Seven Skyline Dr., Hawthorne, NY 10532–2188, proposing that § 178.3910 *Surface lubricants used in the manufacture of metallic articles* (21 CFR 178.3910) be amended to provide for the safe use of phosphoric acid, mono- and dihexyl esters reacted with tetramethylnonylamines and C_{11-14}-alkylamines as components of surface lubricants that may contact food. Upon further review, however, the agency has noted that the same additive is currently regulated in 21 CFR 178.3570 as phosphoric acid, mono- and dihexyl esters, compounds with tetramethylnonylamines and C_{11-14}-alkylamines. FDA is therefore adopting the name that is currently used in 21 CFR 178.3570, to avoid confusion over the identity of the additive.