CPSA and subpart G of part 1101 of title 16 of the CFR.

§ 1117.8 Effect of reports on liability.

A report by a manufacturer, distributor, retailer, or importer under this part shall not be interpreted, for any purpose, as an admission of liability or of the truth of the information contained in the report.

§ 1117.9 Prohibited acts and sanctions.

(a) Whoever knowingly and willfully falsifies or conceals a material fact in a report submitted under this part is subject to criminal penalties under 18 U.S.C. 1001.

(b) A failure to report to the Commission in a timely fashion as required by this part is a prohibited act under section 19(a)(3) of the CPSA, 15 U.S.C. 2068(a)(3).

(c) A subject firm that knowingly fails to report is subject to civil penalties under section 20 of the CPSA, 15 U.S.C. 2069. ''Knowing'' means the having of actual knowledge or the presumed having of knowledge deemed to be possessed by a reasonable person who acts in the circumstances, including knowledge obtainable upon the exercise of due care to ascertain the truth of representations. Section 20(d) of the CPSA, 15 U.S.C. 2069(d).

(d) Any person who knowingly and willfully violates section 19 of this Act after having received notice of noncompliance from the Commission may be subject to criminal penalties under section 21 of the CPSA, 15 U.S.C. 2070.

Dated: February 17, 1995.

Sadye E. Dunn,

Secretary, Consumer Product Safety Commission.

[FR Doc. 95–4483 Filed 2–24–95; 8:45 am]

BILLING CODE 6355–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 73

[Docket No. 93C–0380]

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 with 3-[tris(trimethylsiloxy)silyl]propyl vinyl carbamate (CAS Reg. No. 134072–99–4) and *N*-vinyl pyrrolidone to form contact lenses. This action is in response to a petition filed by Bausch & Lomb, Inc.

DATES: Effective on March 30, 1995, except as to any provisions that may be stayed by the filing of proper objections; written objections and requests for a hearing by March 29, 1995.

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, 202–418–3092.

SUPPLEMENTARY INFORMATION:

I. Introduction

In a notice published in the Federal Register of November 3, 1993 (58 FR 58699), FDA announced that a color additive petition (CAP 3C0242) had been filed by Bausch & Lomb, Inc., 1400 North Goodman St., Rochester, NY 14692–0450. The petition proposed that the color additive regulations be amended in § 73.3106 *1,4-Bis[4-(2-methacryloxyethyl) phenylamino]anthraquinone copolymers* (21 CFR 73.3106) to provide for the safe use of 1,4-bis[4-(2-methacryloxyethyl) phenylamino]anthraquinone copolymerized with *N*-vinyl pyrrolidone and 3[tris(trimethylsiloxy)silyl] propyl vinyl carbamate to form contact lenses. The filing notice erroneously indicated that the petition was filed under section 409(b)(5) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 348(b)(5)). The correct section of the act is 721(d)(1) (21 U.S.C. 379e(d)(1)).

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 in the device comes in direct contact with the body for a significant period of time (21 U.S.C. 379e(a)). The use of the reaction product of 1,4-bis[4-(2-methacryloxyethyl) phenylamino]anthraquinone copolymerized with 3-[tris(trimethylsiloxy)silyl]propyl vinyl carbamate 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 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. Identity

The color additive, when used to color contact lenses, is produced by copolymerizing the dye 1,4-bis[4-(2-methacryloxyethyl) phenylamino]anthraquinone (CAS Reg. No. 121888–69–5) with 3-[tris(trimethylsiloxy)silyl]propyl vinyl carbamate (CAS Reg. No. 134072–99–4) and *N*-vinyl pyrrolidone monomers. The dye 1,4-bis[4-(2-methacryloxyethyl) phenylamino]anthraquinone covalently bonds through two methacrylate groups to the polymer matrix during polymerization. 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 *N*-vinyl pyrrolidone/3-[tris(trimethylsiloxy)silyl]propyl vinyl carbamate/1,4-bis[4-(2-methacryloxyethyl) phenylamino]anthraquinone copolymer, it would be more readily absorbed into the body than the copolymeric color additive 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 maximum daily exposure to 1,4-bis[4-(2-methacryloxyethyl) phenylamino]anthraquinone from this petitioned use in contact lenses would be no greater than 0.08 micrograms per person per day (µg/p/d). The agency-calculated upper limit was based on two factors. First, the maximum use level anticipated by the petitioner is 300 parts per million (ppm) of the lens material or 15 µg of 1,4-bis[4-(2-methacryloxyethyl)

phenylamino]anthraquinone per lens (Ref. 1). Second, the agency made two worst-case assumptions: (1) The user will replace lenses tinted with 1,4-bis[4-(2-methacryloxyethyl) phenylamino]anthraquinone at the maximum use level once each year with a new pair of identical lenses; and (2) one hundred percent of 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 its use in coloring *N*-vinyl pyrrolidone/3-[tris(trimethylsiloxy)silyl]propyl vinyl carbamate contact lenses is likely to be far less than 0.08 µg/p/d (Ref. 1).

To establish the safety of 1,4-bis[4-(2-methacryloxyethyl) phenylamino]anthraquinone for coloring *N*-vinyl pyrrolidone/3-[tris(trimethylsiloxy)silyl]propyl vinyl carbamate contact lenses, the petitioner conducted toxicity studies with 1,4-bis[4-(2-methacryloxyethyl) phenylamino]anthraquinone, colored lenses, and colored lens extracts. The studies included five in vitro cytotoxicity studies, three by the agar overlay method (with 1,4-bis[4-(2-methacryloxyethyl) phenylamino]anthraquinone and lens) and two by the direct-contact method (with 1,4-bis[4-(2-methacryloxyethyl) phenylamino]anthraquinone and lens extract). The maximum noncytotoxic concentration for 1,4-bis[4-(2-methacryloxyethyl) phenylamino] anthraquinone was determined to be 1,810 µg/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 (Kligman) study 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 the dye, to the 0.08 µg/p/d exposure from wearing the colored lenses, the agency calculated the maximum concentration level of 1,4-bis[4-(2-methacryloxyethyl) phenylamino]anthraquinone in each eye that would result from the use of the contact lens. The agency estimated that the daily exposure to 1,4-bis[4-(2-methacryloxyethyl) phenylamino] anthraquinone in each eye would be 0.04 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 0.04 µg dye/mL. This concentration represents a more than a 45,000 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 *N*-vinyl pyrrolidone and 3-[tris(trimethylsiloxy)silyl]propyl vinyl carbamate 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 *N*-vinyl pyrrolidone and 3-[tris(trimethylsiloxy)silyl]propyl vinyl carbamate to form colored contact lenses, and that the color additive is safe and suitable for its intended use.

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 March 29, 1995, 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.

IX. 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 from the Chemistry Review Branch to the Indirect Additives Branch, ''CAP 3C0242 (MATS# 741)–Bausch & Lomb. Reactive Blue 246 for coloring contact lenses, copolymerized with *N*-vinyl pyrrolidinone and 3-[tris(trimethylsiloxy)silyl]propyl vinyl

carbamate. Submission dated 9–10–93,'' dated February 22, 1994.

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, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 342, 343, 348, 351, 352, 355, 361, 362, 371, 379e).

2. Section 73.3106 is amended by revising paragraph (a) 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, or a blend of 3-[tris(trimethylsiloxy)silyl]propyl vinyl carbamate (CAS Reg. No. 134072–99–4) and *N*-vinyl pyrrolidone monomers to form the contact lens material.

* * * * *

Dated: February 17, 1995.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 95–4767 Filed 2–24–95; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF STATE

Bureau of Consular Affairs

22 CFR Part 41

[Public Notice 2171]

Visas: Documentation of Nonimmigrants Under the Immigration and Nationality Act, as Amended

AGENCY: Bureau of Consular Affairs, DOS.

ACTION: Final rule.

SUMMARY: Legislation over the last several years has created several new nonimmigrant visa categories. This rule provides a new table of nonimmigrant visa symbols at § 41.12 which reflects these changes. Minor editorial changes have also been made throughout.

EFFECTIVE DATE: This rule takes effect on February 27, 1995.

ADDRESSES: Chief, Legislation and Regulation Division, Visa Office, Washington, D.C. 20522–1013.

FOR FURTHER INFORMATION CONTACT: Stephen K. Fischel, Chief, Legislation and Regulations Division, 202–663–1204.

SUPPLEMENTARY INFORMATION: The passage of the Violent Crime Control and Law Enforcement Act of 1994 and the enactment of the North American Free Trade Agreement Implementation Act, which implemented the North American Free Trade Agreement (NAFTA), resulted in the creation of new nonimmigrant visa categories. The visa symbols for these nonimmigrant categories, S–1 and S–2 and TN and TD, are added to the list of nonimmigrant visa symbols at § 41.12.

Aliens Supplying Critical Information Relating to a Criminal Organization or Enterprise

On September 13, 1994, the President signed into law the Violent Crime Control and Law Enforcement Act of 1994 (Pub. L. 103–322). Section 130001 of this Act amends the Immigration and Nationality Act (INA)(by adding a new subparagraph (S) at INA 101(a)(15), thus establishing a new nonimmigrant (S) classification (''S–1'' and ''S–2'') for these aliens and their dependents.

NAFTA Professionals

In December 1993, the United States concluded the North American Free Trade Agreement (NAFTA) with Canada and Mexico. The North American Free Trade Agreement Implementation Act (Pub. L. 103–182) implementing the NAFTA agreement was signed by the President on December 8, 1993 and took effect January 1, 1994. Section 341 of the Implementation Act provided for certain professionals entering the United States under this agreement to be treated as if classified as nonimmigrants under INA 101(a)(15). The symbols TN and TD have been designated for these professionals and their dependents.

Final Rule

This rule adds the S–1 and S–2 and TN and TD symbols to the list of nonimmigrant symbols at 22 CFR 41.12. This rule is not expected to have a significant impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. This rule imposes no reporting or record-keeping action from the public requiring the approval of the Office of Management and Budget under the Paperwork Reduction Act requirements. This rule has been reviewed as required by E.O. 12778 and certified to be in compliance therewith. This rule is exempted from E.O. 12866 but has been reviewed to ensure consistency therewith.

List of Subjects in 22 CFR Part 41

Classification of nonimmigrants, Classification symbols, Visas.

Accordingly, part 41 to 22 of the Code of Federal Regulations is amended to read as indicated below:

PART 41—[AMENDED]

1. The authority citation for Part 41 is revised to read as follows:

Authority: 8 U.S.C. 1101 and 1104; 19 U.S.C. 3401.

2. Section 41.12 is revised to read as follows:

§ 41.12 Classification symbols.

A visa issued to a nonimmigrant alien within one of the classes described in this section shall bear an appropriate visa symbol to show the classification of the alien. The symbol shall be inserted in the space provided in the visa stamp. The following visa symbols shall be used:

NONIMMIGRANTS

Symbol	Class	Section of law
A–1	Ambassador, Public Minister, Career Diplomat or Consular Officer, or Immediate Family	101(a)(15)(A)(i).
A–2	Other Foreign Government Official or Employee, or Immediate Family	101(a)(15)(A)(ii).
A–3	Attendant, Servant, or Personal Employee of A–1 or A–2, or Immediate Family	101(a)(15)(A)(iii).
B–1	Temporary Visitor for Business	101(a)(15)(B).