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]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 73

[Docket No. 93C-0380]

BILLING CODE 6355-01-M

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-(2methacryloxyethyl) phenylamino]anthraquinone copolymers (21 CFR 73.3106) to provide for the safe use of 1,4-bis[4-(2methacryloxyethyl) 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 eve 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-(2methacryloxyethyl) 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) phenylaminolanthraquinone 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 1,4bis[4-(2-methacryloxyethyl) phenylaminolanthraquinone has a significantly lower molecular weight than the N-vinyl pyrrolidone/3-[tris(trimethylsiloxy)silyl]propyl vinyl carbamate/1,4-bis[4-(2methacryloxyethyl) 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) phenylaminolanthraquinone.

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 (μ g/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 μ g of 1,4-bis[4-(2-methacryloxyethyl)