

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 73

[Docket Nos. FDA-2011-C-0344 and FDA-2011-C-0463]

CooperVision, Inc.; Filing of Color Additive Petitions

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of petitions.

SUMMARY: The Food and Drug Administration (FDA) is announcing that CooperVision, Inc., has filed two petitions proposing that the color additive regulations be amended to provide for the safe use of 1,4-bis[4-(2-methacryloxyethyl)phenylamino]anthraquinone (C.I. Reactive Blue 246) and 1,4-bis[(2-hydroxyethyl)amino]-9,10-anthracenedione bis(2-methyl-2-propenoic)ester (C.I. Reactive Blue 247). The color additives are intended to be copolymerized with various monomers for use as colored contact lens materials.

FOR FURTHER INFORMATION CONTACT:

Regarding CAP 1C0291: Judith Kidwell, Center for Food Safety and Applied Nutrition (HFS-265), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740-3835, 240-402-1071.

Regarding CAP 1C0292: Teresa Croce, Center for Food Safety and Applied Nutrition (HFS-265), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740-3835, 240-402-1281.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (section 721(d)(1) (21 U.S.C. 379e(d)(1))), notice is given that two color additive petitions (CAP 1C0291, Docket No. FDA-2011-C-0344 and CAP 1C0292, Docket No. FDA-2011-C-0463) have been filed by CooperVision, Inc., 6150 Stoneridge Mall Rd., Suite 370, Pleasanton, CA 94588. The petitions propose to amend the color additive regulations in 21 CFR part 73, subpart D, *Medical Devices*, to provide for the safe use of 1,4-bis[4-(2-methacryloxyethyl)phenylamino]anthraquinone (C.I. Reactive Blue 246; CAS Reg. No. 121888-69-5) (CAP 1C0291) and 1,4-bis[(2-hydroxyethyl)amino]-9,10-anthracenedione bis(2-methyl-2-propenoic)ester (C.I. Reactive Blue 247; CAS Reg. No. 109561-07-1) (CAP 1C0292). The color additives are intended to be copolymerized with various monomers for use as colored contact lens materials.

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

Dated: June 20, 2011.

Mitchell A. Cheeseman,

Acting Director, Office of Food Additive Safety, Center for Food Safety and Applied Nutrition.

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Parts 100 and 165

[Docket No. USCG-2011-0109]

RIN 1625-AA08; AA00

Special Local Regulations and Safety Zones; Recurring Events in Captain of the Port Boston Zone

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to amend special local regulations (SLR) and to establish permanent safety zones in the Coast Guard Sector Boston Captain of the Port (COTP) Zone for annual recurring marine events. When these SLRs or safety zones are activated, and thus subject to enforcement, this rule would restrict persons and vessels from portions of waterway during annual events listed in TABLES 1 and 2 that pose a hazard to public safety. The revised SLRs and safety zones are proposed to reduce administrative overhead, expedite public notification of events, and to ensure the protection of the maritime public and event participants from the hazards associated with firework displays, boat races, and other marine events.

DATES: Comments and related material must be received by the Coast Guard on or before July 28, 2011.

Requests for public meetings must be received by the Coast Guard on or before July 5, 2011.

ADDRESSES: You may submit comments identified by docket number USCG-2011-0109 using any one of the following methods:

- (1) *Federal e-Rulemaking Portal:* <http://www.regulations.gov>.
- (2) *Fax:* 202-493-2251.
- (3) *Mail:* Docket Management Facility (M-30), U.S. Department of

Transportation, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue, SE., Washington, DC 20590-0001.

(4) *Hand delivery:* Same as mail address above, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is 202-366-9329.

To avoid duplication, please use only one of these four methods. See the "Public Participation and Request for Comments" portion of the **SUPPLEMENTARY INFORMATION** section below for instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: If you have questions on this proposed rule, call or e-mail Petty Officer (PO) David Labadie of the Waterways Management Division, U.S. Coast Guard Sector Boston; telephone 617-223-3010, e-mail David.J.Labadie@uscg.mil. If you have questions on viewing or submitting material to the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202-366-9826.

SUPPLEMENTARY INFORMATION:

Public Participation and Request for Comments

We encourage you to participate in this rulemaking by submitting comments and related materials. All comments received will be posted without change to <http://www.regulations.gov> and will include any personal information you have provided.

Submitting Comments

If you submit a comment, please include the docket number for this rulemaking (USCG-2011-0109), indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation. You may submit your comments and material online (via <http://www.regulations.gov>) or by fax, mail, or hand delivery, but please use only one of these means. If you submit a comment online via <http://www.regulations.gov>, it will be considered received by the Coast Guard when you successfully transmit the comment. If you fax, hand deliver, or mail your comment, it will be considered as having been received by the Coast Guard when it is received at the Docket Management Facility. We recommend that you include your name and a mailing address, an e-mail address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.