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Issued in Des Moines, Washington, on May 1, 2019.

Michael Kaszycki,

Acting Director, System Oversight Division, Aircraft Certification Service.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 73

[Docket No. FDA-2019-C-1782]

CooperVision, Inc.; Filing of Color Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of petition.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing that we have filed a petition, submitted by CooperVision, Inc., proposing that the color additive regulations be amended to provide for the safe use of disperse orange 3 methacrylamide to color contact lenses. The color additive is intended to be copolymerized with various monomers to produce colored contact lens materials.

DATES: The color additive petition was filed on March 28, 2019.

ADDRESSES: For access to the docket to read background documents or comments received, go to <https://www.regulations.gov> and insert the docket number found in brackets in the heading of this document into the "Search" box and follow the prompts, and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Molly A. Harry, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-1075.

SUPPLEMENTARY INFORMATION: Under section 721(d)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379e(d)(1)), we are giving notice that we have filed a color additive petition (CAP 9C0315), submitted by CooperVision, Inc., 5870 Stoneridge Dr., Suite 1, Pleasanton, CA 94588. The petition proposes to amend the color additive regulations in 21 CFR part 73, *Listing of*

Color Additives Exempt from Certification, to provide for the safe use of disperse orange 3 methacrylamide (CAS Reg. No. 58142-15-7; CAS name 2-propenamide, 2-methyl-N-[4-[2-(4-nitrophenyl)diazenyl]phenyl]-) to color contact lenses. The color additive is intended to be copolymerized with various monomers to produce colored contact lens materials.

The petitioner has claimed that this action is categorically excluded under 21 CFR 25.32(l) because disperse orange 3 methacrylamide is intended for use in contact lenses. In addition, the petitioner has stated that, to their knowledge, no extraordinary circumstances exist. If FDA determines a categorical exclusion applies, neither an environmental assessment nor an environmental impact statement is required. If FDA determines a categorical exclusion does not apply, we will request an environmental assessment and make it available for public inspection.

Dated: May 2, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019-09411 Filed 5-7-19; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket Number USCG-2019-0300]

RIN 1625-AA08

Special Local Regulations; Festival of Sail Duluth 2019 Parade of Sail, Lake Superior, Duluth, MN

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard is proposing to establish a temporary special local regulation for a designated area of the Duluth Harbor entrance to Superior Bay on Lake Superior during the Festival of Sail 2019 event in Duluth, MN. This action is necessary to provide for the safety of life on these navigable waters around the port of Duluth, MN during a parade of sail event on August 11, 2019. This proposed rulemaking would prohibit persons and vessels from being in the designated region unless authorized by the Captain of the Port Duluth or a designated representative. We invite your comments on this proposed rulemaking.

DATES: Comments and related material must be received by the Coast Guard on or before June 7, 2019.

ADDRESSES: You may submit comments identified by docket number USCG-2019-0300 using the Federal eRulemaking Portal at <https://www.regulations.gov>. See the "Public Participation and Request for Comments" portion of the **SUPPLEMENTARY INFORMATION** section for further instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: If you have questions about this proposed rulemaking, call or email Lieutenant Abbie Lyons, Waterways Management, MSU Duluth, U.S. Coast Guard; telephone 218-725-3818, email Abbie.E.Lyons@uscg.mil.

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
DHS Department of Homeland Security
FR Federal Register
NPRM Notice of Proposed Rulemaking
§ Section
U.S.C. United States Code

II. Background, Purpose, and Legal Basis

On December 11, 2018, Draw Events LLC notified the Coast Guard that it will be conducting a Parade of Sail from 7 a.m. through 1 p.m. on August 11, 2019, as part of the 2019 Festival of Sail event in Duluth, MN from August 11 through August 13, 2019. Hazards from spectator vessels and the limited maneuverability of the sailing vessels exist. The Captain of the Port Duluth (COTP) has determined that potential hazards associated with the parade of sail would be a safety concern for anyone within the route of the parade.

The purpose of this rulemaking is to ensure the safety of vessels and the navigable waters within the parade route before, during, and immediately after the scheduled event. The legal basis for this proposed rule is the Coast Guard's authority under 46 U.S.C. 70041; 33 CFR 1.05-1.

III. Discussion of Proposed Rule

The COTP is proposing to establish a special local regulation from 7 a.m. through 1 p.m. on August 11, 2019. The special local regulation would cover all navigable waters encompassed within the following boundaries: Beginning at position 46°46'48.36" N, 092°05'16.44" W, across Duluth Harbor to 46°47'02.76" N, 092°05'17.88" W, turning north toward the Duluth Lift Bridge at to 46°47'19.32" N, 092°04'04.80" W, to 46°46'50.88" N, 092°05'17.88" W, out