4164-01-P

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: 5/7/2019 8:45 am; Publication Date: 5/8/2019]