



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 73

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

CooperVision, Inc.; Withdrawal of Color Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification; withdrawal of petition.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the withdrawal, without prejudice to a future filing, of a color additive petition (CAP 9C0315) proposing that the color additive regulations be amended to provide for the safe use of disperse orange 3 methacrylamide as a color additive in contact lenses.

DATES: The color additive petition was withdrawn on June 15, 2020.

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: In the *Federal Register* of May 8, 2019 (84 FR 20060), we announced that we had filed a color additive petition (CAP 9C0315), submitted by CooperVision, 5870 Stoneridge Dr., Suite 1, Pleasanton, CA 94588. The petition proposed 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. 58142-15-7; CAS name 2-propenamamide, 2-methyl-N-[4-[2-(4-nitrophenyl)diazenyl]phenyl]-) as a color additive in silicone-based hydrogel contact lenses. The color additive was intended to copolymerize with various monomers in the contact lens formulation to produce colored contact lenses. Through this notice, we are announcing that CooperVision has withdrawn the petition without prejudice to a future filing (21 CFR 71.6(c)(2)).

Dated: July 31, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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