

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

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Center R. LEDSMAN
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[Docket Nos. 2005C-0302, 2005C-0303, and 2005C-0304]

CIBA Vision Corp.; Filing of Color Additive Petitions

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that CIBA Vision Corp. has filed three petitions proposing that the color additive regulations be amended to provide for the safe use of Color Index (C.I.) Pigment Violet 19, C.I. Pigment Yellow 154, and C.I. Pigment Red 122 as color additives in contact lenses.

FOR FURTHER INFORMATION CONTACT:

Regarding CAPs 5C0278 and 5C0280: Celeste Johnston,
Center for Food Safety and Applied Nutrition (HFS-265),
Food and Drug Administration,
5100 Paint Branch Pkwy.,
College Park, MD 20740-3835,
301-436-1282.

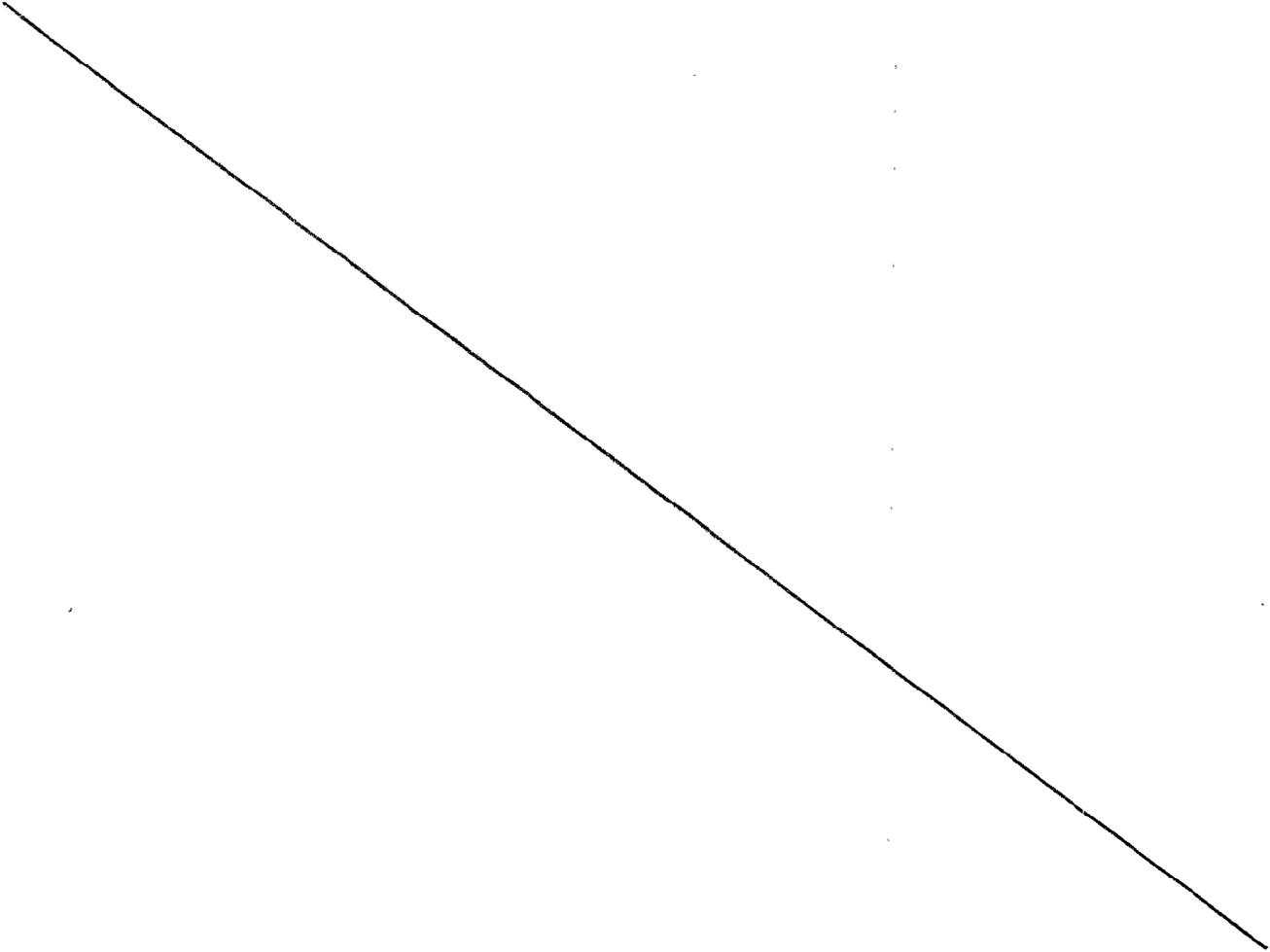
Regarding CAP 5C0279: Harold Woodall,
Center for Food Safety and Applied Nutrition (HFS-206),
Food and Drug Administration,
5100 Paint Branch Pkwy.,
College Park, MD 20740-3835
301-436-1259.

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SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 721(d)(1) (21 U.S.C. 379e(d)(1))), notice is given that three color additive petitions (CAP 5C0278, Docket No. 2005C-0302; CAP 5C0279, Docket No. 2005C-0303; CAP 5C0280, Docket No. 2005C-0304) have been filed by CIBA Vision Corp., 11460 Johns Creek Pkwy., Duluth, GA 30097-1556. The petitions propose to amend the color additive regulations in 21 CFR part 73 to provide for the safe use of C.I. Pigment Violet 19 (CAP 5C0278), C.I. Pigment Yellow 154 (CAP 5C0279), and C.I. Pigment Red 122 (CAP 5C0280), as color additives in contact lenses.

The agency has determined under 21 CFR 25.32(1) 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: July 22, 2005.
July 22, 2005.

Laura M. Tarantino

Laura M. Tarantino,
Director,
Office of Food Additive Safety,
Center for Food Safety and Applied Nutrition.

