



4160-01-P

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]

Listing of Color Additives Exempt From Certification; Reactive Blue 246 and Reactive Blue 247 Copolymers; Confirmation of Effective Date

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; confirmation of effective date.

SUMMARY: The Food and Drug Administration (FDA or we) is confirming the effective date of May 2, 2013, for the final rule that published in the Federal Register of April 1, 2013 (78 FR 19413), and that amended the color additive regulations to provide for the safe use of additional copolymers of 1,4-bis[4-(2-methacryloxyethyl)phenylamino]anthraquinone (C.I. Reactive Blue 246) and copolymers of 1,4-bis[(2-hydroxyethyl)amino]-9,10-anthracenedione bis(2-methyl-2-propenoic)ester (C.I. Reactive Blue 247) as color additives in contact lenses.

DATES: Effective date confirmed: May 2, 2013.

FOR FURTHER INFORMATION CONTACT: Regarding CAP 1C0291 (C.I. Reactive Blue 246): 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 (C.I. Reactive Blue 247): 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: In the Federal Register of April 1, 2013, we amended the color additive regulations in §§ 73.3100 and 73.3106 (21 CFR 73.3100 and 73.3106), respectively, to provide for the safe use of additional copolymers of 1,4-bis[(2-hydroxyethyl)amino]-9,10-anthracenedione bis(2-methyl-2-propenoic)ester (C.I. Reactive Blue 247) and additional copolymers of 1,4-bis[4-(2-methacryloxyethyl)phenylamino]anthraquinone (C.I. Reactive Blue 246), as color additives in contact lenses. We also corrected the nomenclature for Reactive Blue 247 by inserting “2-methyl” before “2-propenoic.”

We gave interested persons until May 1, 2013, to file objections or requests for a hearing. We received no objections or requests for a hearing on the final rule. Therefore, we find that the effective date of the final rule that published in the Federal Register of April 1, 2013, should be confirmed.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, and redelegated to the Director, Office of Food Additive Safety, we are giving notice that no objections or requests for a hearing were filed in response to the April 1, 2013, final rule. Accordingly, the amendments issued thereby became effective May 2, 2013.

Dated: June 18, 2013.

Susan M. Bernard,

Director,

Office of Regulations, Policy and Social Sciences,

Center for Food Safety and Applied Nutrition.

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