

Norridgewock, ME, Central Maine Arpt of Norridgewock, Takeoff Minimums and Obstacle DP, Amdt 3

Cadillac, MI, Wexford County, NDB RWY 7, Amdt 2B, CANCELLED

Cadillac, MI, Wexford County, NDB RWY 25, Amdt 2, CANCELLED

Drummond Island, MI, Drummond Island, NDB RWY 26, Amdt 1, CANCELLED

Harrisonville, MO, Lawrence Smith Memorial, VOR/DME RWY 35, Orig-A, CANCELLED

Lincoln Park, NJ, Lincoln Park, NDB RWY 1, Amdt 3, CANCELLED

Clovis, NM, Clovis Muni, Takeoff Minimums and Obstacle DP, Orig

Lima, OH, Lima Allen County, VOR RWY 28, Amdt 16A, CANCELLED

Chickasha, OK, Chickasha Muni, Takeoff Minimums and Obstacle DP, Orig

Seven Springs Borough, PA, Seven Springs, Takeoff Minimums and Obstacle DP, Orig, CANCELLED

Seven Springs Borough, PA, Seven Springs, VOR OR GPS-A, Amdt 2A, CANCELLED

Wilkes-Barre/Scranton, PA, Wilkes-Barre/Scranton Intl, NDB-A, Amdt 17A

Panhandle, TX, Panhandle-Carson County, GPS RWY 35, Orig-A, CANCELLED

Panhandle, TX, Panhandle-Carson County, RNAV (GPS) RWY 17, Orig

Panhandle, TX, Panhandle-Carson County, RNAV (GPS) RWY 35, Orig

Panhandle, TX, Panhandle-Carson County, Takeoff Minimums and Obstacle DP, Orig

Panhandle, TX, Panhandle-Carson County, VOR RWY 17, Orig, CANCELLED

Panhandle, TX, Panhandle-Carson County, VOR-A, Orig

Blacksburg, VA, Virginia Tech/Montgomery Executive, Takeoff Minimums and Obstacle DP, Amdt 5

Dublin, VA, New River Valley, ILS OR LOC Y RWY 6, Orig

Dublin, VA, New River Valley, ILS OR LOC Z RWY 6, Amdt 5

Dublin, VA, New River Valley, RNAV (GPS) RWY 6, Orig

Dublin, VA, New River Valley, RNAV (GPS) RWY 24, Amdt 1

Dublin, VA, New River Valley, VOR-A, Amdt 9

Dublin, VA, New River Valley, VOR/DME RWY 6, Amdt 8

Yakima, WA, Yakima Air Terminal/Mcallister Field, COPTER NDB RWY 27, Amdt 2

Saratoga, WY, Shively Field, RNAV (GPS) RWY 5, Orig

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 73

[Docket No. FDA-2009-C-0543]

Listing of Color Additives Exempt From Certification; Reactive Blue 69

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the color additive regulations to provide for the safe use of disodium 1-amino-4-[[4-[(2-bromo-1-oxoallyl)amino]-2-sulphonatophenyl]amino]-9,10-dihydro-9,10-dioxoanthracene-2-sulphonate (CAS Reg. No. 70209-99-3), also known as Reactive Blue 69, as a color additive in contact lenses. This action is in response to a petition filed by Sauflon Pharmaceuticals Ltd.

DATES: This rule is effective June 6, 2011. Submit either electronic or written objections and requests for a hearing by June 3, 2011. See section VII of this document for information on the filing of objections.

ADDRESSES: You may submit either electronic or written objections and requests for a hearing, identified by Docket No. FDA-2009-C-0543, by any of the following methods:

Electronic Submissions

Submit electronic objections in the following ways:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.

Written Submissions

Submit written objections in the following ways:

- FAX: 301-827-6870.
- Mail/Hand delivery/Courier (for paper, disk, or CD-ROM submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Agency name and Docket No. FDA-2009-C-0543 for this rulemaking. All objections received will be posted without change to <http://www.regulations.gov>, including any personal information provided. For detailed instructions on submitting objections, see the "Objections" heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or

objections received, go to <http://www.regulations.gov> and insert the docket numbers, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Raphael A. Davy, Center for Food Safety and Applied Nutrition (HFS-265), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740-3835, 240-402-1272.

SUPPLEMENTARY INFORMATION:

I. Introduction

In a notice published in the **Federal Register** of November 18, 2009 (74 FR 59560), FDA announced that a color additive petition (CAP 8C0287) had been filed by Sauflon Pharmaceuticals Ltd., 49-53 York St., Twickenham, Middlesex, TW1 3LP, United Kingdom. The petition proposed to amend the color additive regulations in part 73 (21 CFR part 73), subpart D, *Medical Devices*, to provide for the safe use of disodium 1-amino-4-[[4-[(2-bromo-1-oxoallyl)amino]-2-sulphonatophenyl]amino]-9,10-dihydro-9,10-dioxoanthracene-2-sulphonate (Reactive Blue 69) (CAS Reg. No. 70209-99-3, Colour Index No. 612037) as a color additive in contact lenses. The petition was filed under section 721 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 379e).

II. Safety Evaluation

Under section 721(b)(4) of the FD&C Act, a color additive may not be listed for a particular use unless a fair evaluation of the data and information available to FDA establishes that the color additive is safe for that use. FDA's color additive regulations at 21 CFR 70.3(i) define safe to mean that there is "convincing evidence that establishes with reasonable certainty that no harm will result from the intended use of the color additive."

During its review of the safety of the use of Reactive Blue 69 pigment in contact lenses, the Agency considered the exposure to the color additive from the petitioned use. Based on information submitted in the petition, the Agency notes that it is highly unlikely that Reactive Blue 69 will migrate out of the contact lens into the aqueous environment of the eye because the color additive is covalently incorporated (copolymerized) into the polymeric lens matrix. Therefore, the Agency concludes that the exposure to the color additive, including any impurities that may be present in it,

from the petitioned use would be negligible (Ref. 1).

To establish that Reactive Blue 69 is safe for use in contact lenses, the petitioner submitted toxicity data from various studies. In a primary ocular irritation study in rabbits, there was no evidence of ocular irritation from saline and cottonseed oil extracts of the tinted lens material. The petitioner also conducted tests on lens extracts systemically injected into mice and cytotoxicity studies of lens extracts using L-959 mouse fibroblast cells. Neither study produced any evidence of toxicity (Ref. 2).

III. Conclusion

Based on the data contained in the petition and other available relevant material, FDA concludes that the petitioned use of the color additive in contact lenses is safe and that the color additive will achieve its intended technical effect. FDA also concludes that there is no need for imposing a limitation on the amount of the color additive that may be present in the lens, beyond the limitation that only the amount necessary to accomplish the intended technical effect may be used. Therefore, the regulations in part 73 should be amended as set forth in this document. In addition, based upon the factors listed in 21 CFR 71.20(b), the Agency concludes that certification of Reactive Blue 69 is not necessary for the protection of the public health.

IV. Inspection of Documents

In accordance with § 71.15 (21 CFR 71.15), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition will be made available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the information contact person (see **FOR FURTHER INFORMATION CONTACT**). As provided in § 71.15, the Agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

V. Environmental Impact

The Agency has previously considered the environmental effect of this rule as announced in the notice of filing for CAP 8C0287 (74 FR 59560, November 18, 2009). No new information or comments have been received that would affect the Agency's previous determination that there is no significant impact on the human environment and that an environmental impact statement is not required.

VI. Paperwork Reduction Act of 1995

This final rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

VII. Objections

This rule is effective as shown in the **DATES** section of this document; except as to any provisions that may be stayed by the filing of proper objections. Any person who will be adversely affected by this regulation may file with the Division of Dockets Management (see **ADDRESSES**) either electronic or written objections. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. It is only necessary to send one set of documents. It is no longer necessary to send three copies of all documents. Identify documents with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday. FDA will publish notice of the objections that the Agency has received or lack thereof in the **Federal Register**.

VIII. References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Memorandum from H. Lee, Division of Petition Review, Chemistry Review Team, FDA, to R. Davy, Division of Petition Review, Regulatory Group II, FDA, October 8, 2010.

2. Memorandum from T. Thurmond, Division of Petition Review, Toxicology Review Group, FDA, to R. Davy, Division of Petition Review, Regulatory Group II, FDA, October 25, 2010.

List of Subjects in 21 CFR Part 73

Color additives, Cosmetics, Drugs, Medical devices.

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, Center for Food Safety and Applied Nutrition, 21 CFR part 73 is amended as follows:

PART 73—LISTING OF COLOR ADDITIVES EXEMPT FROM CERTIFICATION

■ 1. The authority citation for 21 CFR part 73 continues to read as follows:

Authority: 21 U.S.C. 321, 341, 342, 343, 348, 351, 352, 355, 361, 362, 371, 379e.

■ 2. Add § 73.3129 to subpart D to read as follows:

§ 73.3129 Disodium 1-amino-4-[[4-[(2-bromo-1-oxoallyl)amino]-2-sulphonatophenyl]amino]-9,10-dihydro-9,10-dioxoanthracene-2-sulphonate.

(a) *Identity.* The color additive is disodium 1-amino-4-[[4-[(2-bromo-1-oxoallyl)amino]-2-sulphonatophenyl]amino]-9,10-dihydro-9,10-dioxoanthracene-2-sulphonate (Reactive Blue 69) (CAS Reg. No. 70209-99-3, Colour Index No. 612037).

(b) *Uses and restrictions.* (1) The substance listed in paragraph (a) of this section may be used as a color additive in contact lenses in amounts not to exceed the minimum reasonably required to accomplish the intended coloring effect.

(2) Authorization and compliance with this use shall not be construed as waiving any of the requirements of sections 510(k), 515, and 520(g) of the Federal Food, Drug, and Cosmetic Act with respect to the contact lenses in which the additive is used.

(c) *Labeling.* The label of the color additive shall conform to the requirements in § 70.25 of this chapter.

(d) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 721(c) of the Federal Food, Drug, and Cosmetic Act.

Dated: April 21, 2011.

Susan M. Bernard,

Acting Director, Office of Regulations, Policy and Social Sciences, Center for Food Safety and Applied Nutrition.

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