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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 74

[Docket No. 92C-0348]

**Listing of Color Additives for Coloring Bone Cement; FD&C Blue No. 2-Aluminum Lake on Alumina; Confirmation of Effective Date**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule; confirmation of effective date.

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**SUMMARY:** The Food and Drug Administration (FDA) is confirming the effective date of October 5, 1999 (64 FR 48288), for the final rule that appeared in the **Federal Register** of September 3, 1999, and that amended the color additive regulations to provide for the safe use of FD&C Blue No. 2-Aluminum Lake on alumina to color bone cement. The agency also transferred the listing for the use of FD&C Blue No. 2 in sutures to reflect that sutures in which this color additive is used are devices, not drugs.

**DATES:** Effective date confirmed: October 5, 1999.

**FOR FURTHER INFORMATION CONTACT:** Ellen M. Waldron, Center for Food Safety and Applied Nutrition (HFS-215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3089.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of September 3, 1999 (64 FR 48288), FDA amended the color additive regulations to provide for the safe use of FD&C Blue No. 2-Aluminum Lake on alumina to color bone cement. To reflect that sutures in which this color additive is used are devices, not drugs, the agency also transferred the listing for the use of FD&C Blue No. 2 in sutures from § 74.1102 *FD&C Blue No. 2* (21 CFR 74.1102) under subpart B—

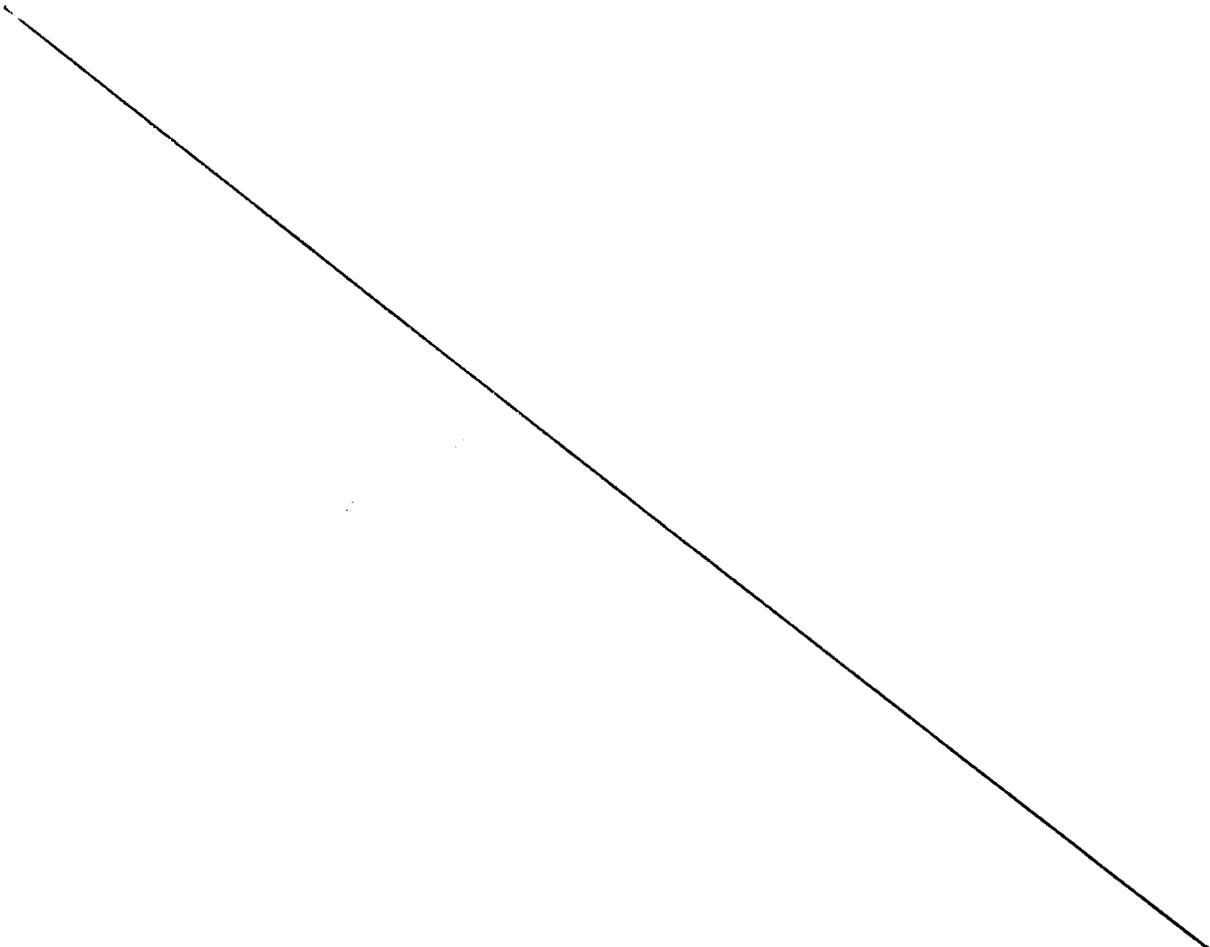
Drugs to new § 74.3102 *FD&C Blue No. 2* (21 CFR 74.3102) under subpart D—Medical Devices and made nonsubstantive amendments to § 74.1102.

FDA gave interested persons until October 4, 1999, to file objections or requests for a hearing. The agency received no objections or requests for a hearing on the final rule. Therefore, FDA finds that the effective date of the final rule that published in the **Federal Register** of September 3, 1999, should be confirmed.

**List of Subjects in 21 CFR Part 74**

Color additives, Cosmetics, Drugs, Foods, Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 342, 343, 348, 351, 352, 355, 361, 362, 371, 379e) and under authority delegated to the Commissioner of



Food and Drugs (21 CFR 5.10), notice is given that no objections or requests for a hearing were filed in response to the September 3, 1999, final rule. Accordingly, the amendments issued thereby became effective October 5, 1999.

Dated: November 9, 1999



William K. Hubbard  
Senior Associate Commissioner for Policy, Planning, and Legislation

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