Document No.	Pages	Revision	Date
CF6–50 SB 78–3001 ..... Total Pages: 43.	1–43	2	December 18, 1997.
CF6–80A1/A3 SB 78–1002 ..... Total Pages: 31.	1–31	3	January 21, 1999.
CF6–80C2 ASB 78A1015 ..... Total Pages: 32.	1–32	5	January 21, 1999.

This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from Middle River Aircraft Systems, Mail Point 46, 103 Chesapeake Park Plaza, Baltimore, MD, 21220–4295, attn: Warranty Support, telephone: (410) 682–0094, fax: (410) 682–0100. Copies may be inspected at the FAA, New England Region, Office of the Regional Counsel, 12 New England Executive Park, Burlington, MA; or at the Office of the Federal Register, 800 North Capitol Street, NW, suite 700, Washington, DC.

(e) This amendment becomes effective on November 2, 1999.

Issued in Burlington, Massachusetts, on August 26, 1999.

Jorge A. Fernandez,

Acting Manager, Engine and Propeller Directorate, Aircraft Certification Service.

[FR Doc. 99–22967 Filed 9–2–99; 8:45 am]

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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

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 FD&C Blue No. 2–Aluminum Lake on alumina to color bone cement. This action responds to a petition filed by Biomet, Inc. The agency also is transferring the listing for FD&C Blue No. 2 in sutures to reflect the suture in which this color additive is used are devices not drugs.

DATES: This regulation is effective October 5, 1999; except as to any provisions that may be stayed by the filing of proper objections; written objections and requests for a hearing by October 4, 1999.

ADDRESSES: Submit written objections to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

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

SUPPLEMENTARY INFORMATION:

I. Introduction

In a notice published in the **Federal Register** of November 19, 1992 (57 FR 54598), FDA announced that a color additive petition (CAP 2C0239) had been filed by Biomet, Inc., P.O. Box 587, Warsaw, IN 46581–0587. The petition proposed to amend the color additive regulations to provide for the safe use of FD&C Blue No. 2–Aluminum Lake to color bone cement. The petition was filed under section 706(d)(1) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 376(d)(1)), presently designated as 721(d)(1) of the act (21 U.S.C. 379e(d)(1)).

The agency is changing the name of the color additive used in the filing notice to FD&C Blue No. 2–Aluminum Lake on alumina to make it conform to the nomenclature proposed for the permanent listing of color additive lakes (61 FR 8372, March 4, 1996). To reflect that sutures in which this color additive is used are devices, not drugs, the agency also is transferring 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 is making nonsubstantive amendments to § 74.1102. This transfer will provide for all medical device uses of FD&C Blue No. 2 and its lake to be listed uniformly and more correctly under subpart D—Medical Devices. Section 74.1102(c)(1)(iv) is being removed because it is no longer applicable.

The Medical Device Amendments (Public Law 94–295) (the amendments) were enacted into law on May 28, 1976, to provide a comprehensive system of regulation for devices. These amendments (21 U.S.C. 321, *et seq.*) expanded the definition of device, under section 201(h) of the act (21 U.S.C. 321(h)), to include many products that were previously regarded as drugs. These products are known as ''transitional'' devices and are subject to regulation under section 520(l) of the act (21 U.S. C. 360j(l)). In the **Federal Register** of December 16, 1977 (42 FR 63472), FDA published a notice listing those products that had previously been considered to be drugs that FDA now considered to be devices under the amendments. FDA listed nonabsorbable surgical sutures, and absorbable surgical sutures as transitional devices in the December 1977 notice (42 FR 63472 at 63474). Various types of surgical sutures are classified as devices in 21 CFR 878.4493, 878.4830, 878.5000, 878.5010, 878.5020, and 878.5030. Because all surgical sutures are regulated as devices, FDA is redesignating its listing of FD&C Blue No. 2 in sutures from § 74.1102 under subpart B—Drugs to new § 74.3102 under subpart D—Medical Devices.

II. Regulatory History and Current Listings

In a final rule published in the **Federal Register** on February 13, 1971 (36 FR 2967), FDA added 21 CFR 8.4022 (presently § 74.1102) to list FD&C Blue No. 2 for use to color nylon sutures for general surgery. In this final rule, FDA also added specifications for FD&C Blue No. 2 for use to color sutures.

In the **Federal Register** of February 4, 1983 (48 FR 5252), FDA issued a final rule adding § 74.102 and amending § 74.1102 to permanently list the color additive FD&C Blue No. 2 for use in food and ingested drugs, respectively. In the February 4, 1983, final rule, FDA also added new specifications for FD&C Blue No. 2 for use in food and ingested drugs that identified the color additive more precisely than those specifications that had previously been included in the provisional listing for FD&C Blue No. 2 in 21 CFR part 82. Further, to provide adequate assurance of safety, the agency specified in the February 4, 1983, final rule (48 FR 5252 at 5259–5260), through a general description, the manufacturing process for FD&C Blue No. 2.

III. Applicability of the Act

With the passage of the Medical Device Amendments of 1976 (Public

Law 94–295), Congress mandated the listing of color additives for use in medical devices when the color additive in the device comes into direct contact with the body for a significant period of time (section 721(a) of the act). The color additive FD&C Blue No. 2–Aluminum Lake on alumina is added to bone cement in such a way that at least some of the color additive will come into contact with the body for a significant period of time when the bone cement is in place. In addition, the bone cement may be used in permanent joint replacements. Thus, for both of these uses, the color additive FD&C Blue No. 2–Aluminum Lake on alumina will be in direct contact with the body for a significant period of time. Consequently, the petitioned use of the color additive is subject to the statutory listing requirement.

IV. The Color Additive

The color additive that is the subject of this rule, FD&C Blue No. 2–Aluminum Lake on alumina (CAS Reg. No. 16521–38–3), is the aluminum salt of the color additive FD&C Blue No. 2, extended on a substratum of alumina. The aluminum salt is formed when FD&C Blue No. 2 is mixed with aluminum sulfite, sodium carbonate, and water. The color additive FD&C Blue No. 2 is identified in § 74.102(a)(1).

V. Safety Evaluation

FDA estimates that the petitioned use of the additive, FD&C Blue No. 2–Aluminum Lake on alumina, at a level not to exceed 0.1 percent by weight of the bone cement, would result in exposure no greater than 90 micrograms per person over a 70-year lifetime or an ''estimated daily intake'' of 3 nanograms per person per day. Actual exposure to the subject color additive from the proposed use is expected to be significantly lower, because lakes are deliberately formulated to be insoluble and the petitioner submitted data to demonstrate that FD&C Blue No. 2–Aluminum Lake on alumina does not leach from cured bone cement in detectable quantities under simulated conditions of use.

To establish the safety of FD&C Blue No. 2–Aluminum Lake on alumina, the petitioner has submitted data from muscle implantation tests on the bone cement in rabbits, intraperitoneal toxicity studies of the cement in dogs, intracutaneous testing of cement extracts in rabbits, and cytotoxicity tests. No adverse effects attributable to FD&C Blue No. 2–Aluminum Lake on alumina were reported in these studies. Feeding studies available in agency files with the straight color, FD&C Blue No. 2, also demonstrated no adverse effects. The dietary route of exposure utilized in these studies with FD&C Blue No. 2 is not comparable to the route of exposure from the proposed use of FD&C Blue No. 2–Aluminum Lake on alumina in bone cement, but the absence of adverse effects associated with exposure to FD&C Blue No. 2 helps to mitigate concern for systemic toxicity from the use of FD&C Blue No. 2–Aluminum Lake on alumina in bone cement. Based on review of all available toxicological data on FD&C Blue No. 2 and FD&C Blue No. 2–Aluminum Lake on alumina, the agency concludes that the limited exposure resulting from the proposed use of FD&C Blue No. 2–Aluminum Lake on alumina in bone cement is safe.

VI. Conclusions

FDA has evaluated the data and information in the petition and other relevant material. Based on this information the agency concludes that: (1) The proposed use of FD&C Blue No. 2–Aluminum Lake on alumina, at a level not to exceed 0.1 percent by weight of the bone cement, to color bone cement is safe; and (2) the color additive will achieve its intended coloring effect, and thus, is suitable for this use. Further, the agency concludes that the color additive regulations in part 74 (21 CFR part 74) should be amended as set forth below.

To reflect that sutures in which this color additive is used are devices, not drugs, the agency is redesignating the current listing for the use of the color additive FD&C Blue No. 2 in sutures from § 74.1102, subpart B—Drugs to new § 74.3102, subpart D—Medical Devices and is making nonsubstantive amendments to § 74.1102.

VII. 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 are available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the information contact person listed above. 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.

VIII. Environmental Impact

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

IX. 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.

X. Objections

Any person who will be adversely affected by this regulation may at any time on or before October 4, 1999, file with the Dockets Management Branch (address above) written objections thereto. 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. Three copies of all documents shall be submitted and shall be identified 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 Dockets Management Branch 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**.

List of Subjects in 21 CFR Part 74

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, 21 CFR part 74 is amended as follows:

PART 74—LISTING OF COLOR ADDITIVES SUBJECT TO CERTIFICATION

1.The authority citation for 21 CFR part 74 continues to read as follows:

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

§ 74.1102 [Amended]

2. Section 74.1102 *FD&C Blue No. 2* is amended by removing paragraphs (b)(1) and (c)(1); and by redesignating paragraphs (b)(2) and (c)(2) as paragraphs (b) and (c) respectively.

3. Section 74.3102 is added to subpart D to read as follows:

§ 74.3102 FD&C Blue No. 2.

(a) *Identity.* The color additive FD&C Blue No. 2 shall conform in identity to the requirements of § 74.102(a)(1).

(b) *Specifications.* (1) The color additive FD&C Blue No. 2 for use in coloring surgical sutures shall conform to the following specifications and shall be free from impurities other than those named to the extent that such impurities may be avoided by current good manufacturing practice:

Sum of volatile matter at 135 °C (275 °F) and chlorides and sulfates (calculated as sodium salts), not more than 15 percent.

Water insoluble matter, not more than 0.4 percent.

Isatin-5-sulfonic acid, not more than 0.4 percent.

Isomeric colors, not more than 18 percent.

Lower sulfonated subsidiary colors, not more than 5 percent.

Lead (as Pb), not more than 10 parts per million.

Arsenic (as As), not more than 3 parts per million.

Total color, not less than 85 percent.

(2) The color additive FD&C Blue No. 2–Aluminum Lake on alumina for use in bone cement shall be prepared in accordance with the requirements of § 82.51 of this chapter.

(c) *Uses and restrictions.* (1) The color additive FD&C Blue No. 2 may be safely used for coloring nylon (the copolymer of adipic acid and hexamethylene diamine) surgical sutures for use in general surgery subject to the following restrictions:

(i) The quantity of color additive does not exceed 1 percent by weight of the suture;

(ii) The dyed suture shall conform in all respects to the requirements of the United States Pharmacopeia XX (1980); and

(iii) When the sutures are used for the purposes specified in their labeling, the color additive does not migrate to the surrounding tissues.

(2) The color additive FD&C Blue No. 2–Aluminum Lake on alumina may be safely used for coloring bone cement at a level not to exceed 0.1 percent by weight of the bone cement.

(3) Authorization and compliance with these uses 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 medical device in which the color additive FD&C Blue No. 2 and the color additive FD&C Blue No. 2–Aluminum Lake on alumina are used.

(d) *Labeling.* The labels of the color additive FD&C Blue No. 2 and the color additive FD&C Blue No. 2–Aluminum Lake on alumina shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification.* All batches of FD&C Blue No. 2 and its lake shall be certified in accordance with regulations in part 80 of this chapter.

Dated: August 25, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 99–22994 Filed 9–2–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 175

[Docket No. 99F–1420]

Indirect Food Additives: Adhesives and Components of Coatings

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of butylated reaction product of *p*-cresol and dicyclopentadiene as an antioxidant in pressure-sensitive adhesives intended for use in contact with food. This action responds to a petition filed by Goodyear Tire and Rubber Co.

DATES: This regulation is effective September 3, 1999. Submit written objections and requests for a hearing by October 4, 1999.

ADDRESSES: Submit written objections to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Vir D. Anand, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3081.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** May 26, 1999 (64 FR 28500), FDA announced that a food additive petition (FAP 9B4663) had been filed by Goodyear Tire and Rubber Co., c/o Keller and Heckman LLP, 1001 G St. NW., suite 500 West, Washington, DC 20001. The petition proposed to amend the food additive regulations in § 175.125 *Pressure-sensitive adhesives* (21 CFR 175.125) to provide for the safe use of butylated reaction product of *p*-cresol and dicyclopentadiene as an antioxidant in pressure-sensitive adhesives intended for use in contact with food.

FDA has evaluated data in the petition and other relevant material. Based on this information, the agency concludes that: (1) The proposed use of the additive is safe, (2) the additive will achieve its intended technical effect, and therefore, (3) the regulations in § 175.125 should be amended as set forth below.

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the information contact person listed above. As provided in § 171.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

The agency has previously considered the environmental effects of this final rule as announced in the Notice of Filing for FAP 9B4663 (64 FR 28500). 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.

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.

Any person who will be adversely affected by this regulation may at any time on or before October 4, 1999, file with the Dockets Management Branch (address above) written objections thereto. 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