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DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration

21 CFR Part 74

[Docket No. 98C-0041]

Listing of Color Additives for Coloring Sutures; [Phthalocyaninato(2-)] Copper

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 [phthalocyaninato(2-)] copper in coloring nonabsorbable sutures for general and ophthalmic surgery made from a blend of poly(vinylidene fluoride) and poly(vinylidene fluoride-co-hexafluoropropylene). This action responds to a petition filed by Ethicon, Inc.

DATES: This regulation is effective (*insert date 30 days plus 1 business day after date of publication in the Federal Register*); except as to any provisions that may be stayed by the filing of proper objections; written objections and requests for a hearing by (*insert date 30 days after date of publication in the Federal Register*).

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 February 2, 1998 (63 FR 5387), FDA announced that a color additive petition (CAP 8C0253) had been filed by Ethicon, Inc., P.O. Box

NFR 1

151, Somerville, NJ 08876–0151. The petition proposed to amend the color additive regulations in § 74.3045 [*Phthalocyaninato(2-)*] copper (21 CFR 74.3045) to provide for the safe use of [*phthalocyaninato(2-)*] copper in coloring nonabsorbable sutures for general and ophthalmic surgery made from a blend of poly(vinylidene fluoride) and poly(vinylidene fluoride-co-hexafluoropropylene). The petition was filed under section 721(d)(1) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 379e(d)(1)).

II. Applicability of the Act

With the passage of the Medical Device Amendments of 1976 (Pub. L. 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(d)(1) of the act). [*Phthalocyaninato(2-)*] copper is added to nonabsorbable sutures made from a blend of poly(vinylidene fluoride) and poly(vinylidene fluoride-co-hexafluoropropylene) in such a way that at least some of the color additive will come into contact with the body when the sutures are in place. In addition, the sutures are intended to remain in the body at least until healing is complete. Thus, the color additive 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.

III. Safety of the Petitioned Use of the Additive

Based on data submitted in the petition and from other relevant information, FDA concludes that the petitioned use of the additive, [*phthalocyaninato(2-)*] copper, will result in exposure to no greater than 7.5 milligrams (mg) per person over a 70-year lifetime or 0.31 microgram per person per day (Ref. 1).

To establish that the color additive [*phthalocyaninato(2-)*] copper is safe for use in coloring sutures made from a blend of poly(vinylidene fluoride) and poly(vinylidene fluoride-co-hexafluoropropylene), the petitioner conducted eight biocompatibility tests on the colored sutures

or their extracts to evaluate the toxicity of the subject color additive. Based on an evaluation of these tests, the agency concludes that the colored sutures or their extracts are noncytotoxic, nonpyrogenic, and nonirritating.

Based on the available toxicity data, the small amount of [phthalocyaninato(2-)] copper used to the color sutures, and the agency's exposure calculation for the proposed use of the subject additive, FDA finds that [phthalocyaninato(2-)] copper is safe for use in coloring sutures made from a blend of poly(vinylidene fluoride) and poly(vinylidene fluoride-co-hexafluoropropylene).

IV. Specifications and Certification

[Phthalocyaninato(2-)] copper is currently produced as a certified color additive for use in coloring contact lenses and certain sutures for general and ophthalmic surgery in accordance with 21 CFR part 80. The agency concludes that the specifications listed in § 74.3045 for these uses are adequate to ensure the safe use of this color additive in sutures for general and ophthalmic surgery that are made from a blend of poly(vinylidene fluoride) and poly(vinylidene fluoride-co-hexafluoropropylene).

V. Conclusions on Safety

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 [phthalocyaninato(2-)] copper, at a level not to exceed 0.5 percent by weight of the suture material, for coloring sutures made from a blend of poly(vinylidene fluoride) and poly(vinylidene fluoride-co-hexafluoropropylene) is safe; and (2) the color additive will achieve its intended coloring effect, and thus, is suitable for this use. Further, the agency concluded that the color additive regulations in § 74.3045 should be amended as set forth below.

VI. 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 (address above) 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.

VII. 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.

VIII. Paperwork Reduction Act of 1995

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

IX. Objections

Any person who will be adversely affected by this regulation may at any time on or before (*insert date 30 days after date of publication in the **Federal Register***), 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**.

X. Reference

The following reference has been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Memorandum from the Division of Product Manufacture and Use, Chemistry Review Team, FDA, to the Division of Petition Control, FDA, concerning “CAP 8C0253 (MATS M2.0 & 2.1): Ethicon, Inc. (Submission of November 26, 1997). Petition for the safe use of use of [sic] phthalocyaninato(2-) copper as a colorant for nonabsorbable sutures,” dated January 26, 1998.

List of Subjects in 21 CFR Part 74

Color additives, Cosmetics, Drugs.

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:

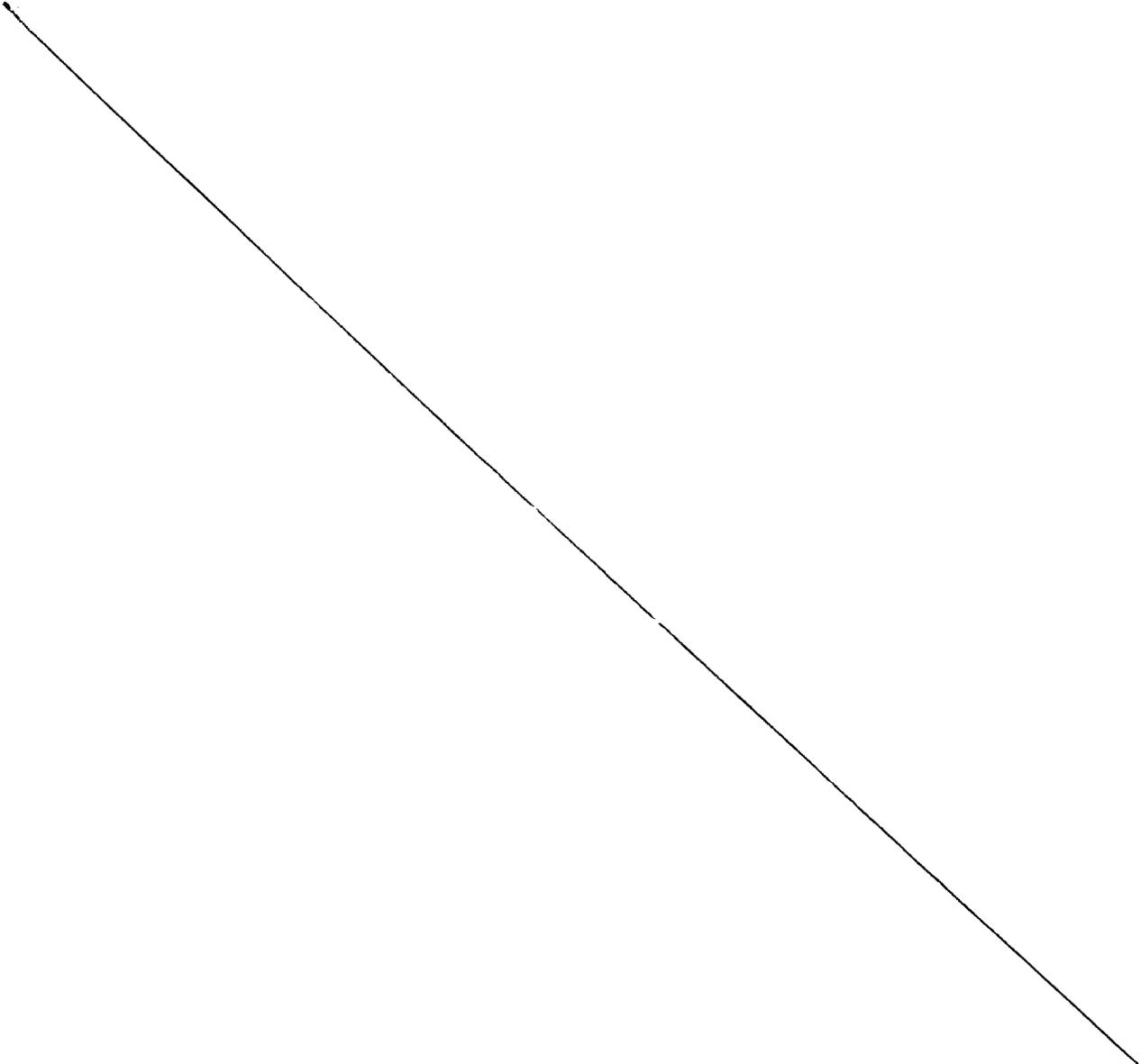
Authority: 21 U.S.C. 321, 341, 342, 343, 348, 351, 352, 355, 361, 362, 371, 379e.

2. Section 74.3045 is amended by revising the introductory text of paragraph (c)(1) to read as follows:

§ 74.3045 [Phthalocyaninato(2-)] copper.

* * * * *

(c) *Uses and restrictions.* (1) The color additive [phthalocyaninato(2-)] copper may be safely used to color polypropylene sutures, polybutester (the generic designation for the suture fabricated from 1,4-benzenedicarboxylic acid, polymer with 1,4-butanediol and *alpha*-hydro-*omega*-hydroxypoly(oxy-1,4-butanediyl), CAS Reg. No. 37282-12-5) nonabsorbable sutures for use in general and ophthalmic surgery, polybutylene terephthalate nonabsorbable monofilament sutures for general and ophthalmic surgery, nonabsorbable sutures made from poly(vinylidene fluoride)



and poly(vinylidene fluoride-co-hexafluoropropylene) for general and ophthalmic surgery, and polymethylmethacrylate monofilament used as supporting haptics for intraocular lenses, subject to the following restrictions:

* * * * *

Dated: April 23 1999
April 23, 1999



William K. Hubbard
Associate Commissioner
for Policy Coordination

[FR Doc. 98-???? Filed ??-??-98; 8:45 am]

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