DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Airspace Docket No. 97–AWA–4]

RIN 2120–AA66

Establishment of Class C Airspace and Revocation of Class D Airspace, Austin-Bergstrom International Airport, TX; and Revocation of Robert Mueller Municipal Airport Class C Airspace; TX

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; delay of effective date.

SUMMARY: On February 11, 1999, the FAA published a final rule establishing a Class C airspace area and revoking the Class D airspace area for the Austin-Bergstrom International Airport, TX. The rule also revoked the Class C airspace area for the Robert Mueller Municipal Airport, TX. In view of the delay in the opening date of the new Austin-Bergstrom International Airport, TX, this action delays the rule's effective date until May 23, 1999.

EFFECTIVE DATE: Effective April 30, 1999, the effective date of the Final Rule at 64 FR 6793 is delayed until 0601 UTC, May 23, 1999.

FOR FURTHER INFORMATION CONTACT: Sheri Edgett Baron, Airspace and Rules Division, ATA–400, Office of Air Traffic Airspace Management, FAA, 800 Independence Avenue, SW., Washington, DC 20591; telephone: (202) 267–8783.

SUPPLEMENTARY INFORMATION: On February 11, 1999, the FAA published a final rule establishing a Class C airspace area and revoking the Class D airspace area for Austin-Bergstrom International Airport, TX (64 FR 6793). The rule also revoked the Class C airspace area for Robert Mueller Municipal Airport, TX. Due to construction delays, the official opening of the Austin-Bergstrom International Airport has been delayed until May 23, 1999. Accordingly, the effective date of the establishment and revocation of the related Class C and Class D airspace areas is postponed until the opening of the new airport.

Because the public needs to be made aware of this postponement immediately, notice and public procedure are impracticable and good cause exists for making the postponement effective in less than 30 days.

In consideration of the foregoing, effective April 30, 1999, the effective date of the final rule establishing the Class C airspace area and revoking the Class D airspace area for Austin-Bergstrom International Airport; and revoking the Class C airspace area for Robert Mueller Municipal Airport (64 FR 6793; February 11, 1999) is delayed from May 2, 1999, to May 23, 1999.

Issued in Washington, DC, on April 20, 1999.

Reginald C. Matthews,

Acting Program Director for Air Traffic Airspace Management.

[FR Doc. 99–10964 Filed 4–29–99; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 5

Delegation of Authority and Organization; Center for Veterinary Medicine; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending the regulation to reflect a redelegation of authority with respect to approval of supplemental new animal drug applications to the Director, Division of Manufacturing Technology, Office of New Animal Drug Evaluation, Center for Veterinary Medicine (CVM). This action is necessary to ensure the continued accuracy of the regulation.

EFFECTIVE DATE: December 22, 1998.

FOR FURTHER INFORMATION CONTACT:

Carol Haley, Center for Veterinary Medicine (HFV–6), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1682;

Donna G. Page, Division of Management Systems and Policy (HFA–340), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4816.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of December 22, 1998 (63 FR 70650), FDA amended the regulation for redelegations of authority to incorporate provisions for feed mill licensing and to update positions and component titles associated with the authorities under § 5.83 (21 CFR 5.83). The regulation in § 5.83(c)(1) reflected a redelegation with respect to approval of certain supplemental new animal drug applications to the position title ''Director, Division of Human Food Safety, Office of New Animal Drug Evaluation, CVM.'' The correct position title to which these functions should have been redelegated is the ''Director, Division of Manufacturing Technologies, Office of New Animal Drug Evaluation, CVM,'' because that office is responsible for supplemental applications for manufacturing. Therefore, the redelegation to the ''Director, Division of Human Safety Office of New Animal Drug Evaluation, CVM'' has been amended and a new redelegation made to the ''Director, Division of Manufacturing Technologies, Office of New Animal Drug Evaluation, CVM.'' The regulation in § 5.83(c)(1) has been revised to reflect this redelegation. Further redelegation of authorities is not authorized at this time. Authority delegated to a position may be exercised by a person officially designated to serve in such position in an acting capacity or on a temporary basis.

List of Subjects in 21 CFR Part 5

Authority delegations (Government agencies), Imports, Organization and functions (Government agencies).

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 5 is amended to read as follows:

PART 5—DELEGATIONS OF AUTHORITY AND ORGANIZATION

1. The authority citation for 21 CFR part 5 continues to read as follows:

Authority: 5 U.S.C. 504, 552, App. 2; 7 U.S.C. 138a, 2271; 15 U.S.C. 638, 1261–1282, 3701–3711a; 15 U.S.C. 1451–1461; 21 U.S.C. 41–50, 61–63, 141–149, 321–394, 467f, 679(b), 801–886, 1031–1309; 35 U.S.C. 156; 42 U.S.C. 241, 242, 242a, 242l, 242n, 243, 262, 263, 264, 265, 300u–300u–5, 300aa–1; 1395y, 3246b, 4332, 4831(a), 10007–10008; E.O. 11921, 41 FR 24294, 3 CFR 1977 Comp., p. 124–131; E.O. 12591, 52 FR 13414, 3 CFR, 1988 Comp., p. 220–223.

2. Section 5.83 is amended by revising paragraph (c)(1) to read as follows:

§ 5.83 Approval of new animal drug applications, medicated feed mill license applications, and their supplements.

* * * * *

(c) * * *

(1) The Director, Division of Manufacturing Technologies, Office of New Animal Drug Evaluation, CVM.

* * * * *

Dated: April 23, 1999.

William K. Hubbard,

Acting Deputy Commissioner for Policy.

[FR Doc. 99–10847 Filed 4–29–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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 June 2, 1999; except as to any provisions that may be stayed by the filing of proper objections; written objections and requests for a hearing by June 1, 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 February 2, 1998 (63 FR 5387), FDA announced that a color additive petition (CAP 8C0253) had been filed by Ethicon, Inc., P.O. Box 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