

Rabbit Software Corporation  
\$.01 par common

Reisterstown Federal Savings Bank  
(Maryland)  
\$1.00 par common

Rhone-Poulenc, S.A.  
American Depository Receipts

Riverside National Bank (California)  
\$1.25 par common

Roosevelt Federal Savings & Loan  
Association (Missouri)  
\$.01 par common

Royalpar Industries, Inc.  
\$.01 par common

SBT Corporation  
No par common

Scherer, R.P. Corporation  
\$1.00 par convertible preferred

Seacoast Savings Bank (New Hampshire)  
\$1.00 par common

Sonora Gold Corporation  
No par common

Spear Financial Services, Inc.  
\$.05 par common

Stadynamics, Inc.  
\$.01 par common

Strober Organization, Inc., The  
\$.01 par common

Sunrise Federal Savings and Loan  
Association (Kentucky)  
\$1.00 par common

Systems Software Associates, Inc.  
\$.0033 par common

Telematics International, Inc.  
\$.01 par common

Thermo Process Systems, Inc.  
\$.10 par common

Todd-Ao Corporation, The  
\$.25 par common

Total Health Systems, Inc.  
\$.01 par common

Unico American Corporation  
No par common

United Companies Financial Corporation  
\$2.00 par common

Universal Medical Buildings, Inc.  
Depository Receipts for units of shares of  
beneficial interest

Village Super Market, Inc.  
Class A, No par common

Vivigen, Inc.  
\$.01 par common

Washington Bancorporation (Washington,  
DC)  
\$2.50 par common

Waterford Glass Group, Plc.  
American Depository Receipts representing  
10 Units, each unit consists of ordinary  
shares and income shares

Webb, Del E., Corporation  
Warrants (expire 02-01-90)

West Newton Savings Bank (Massachusetts)  
\$.10 par common

Western Auto Supply Company  
\$.01 par common

Weston, Roy F., Inc.  
Class A, \$.10 par common

WTD Industries, Inc.  
No par common

Xylogics, Inc.  
\$.10 par common

Yorkridge-Calvert Savings and Loan  
Association (Maryland)  
\$1.00 par common

ZZZZ Best Company, Inc.  
Warrants (expire 12-15-89)

By order of the Board of Governors of  
the Federal Reserve System acting by its  
Director of the Division of Banking  
Supervision and Regulation pursuant to  
delegated authority (12 CFR 265.2(c)(18),  
April 24, 1987.

Barbara R. Lowrey,

Associate Secretary of the Board.

[FR Doc. 87-9725 Filed 4-30-87; 8:45 am]

BILLING CODE 6210-01-M

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 74

[Docket No. 86C-0301]

#### Listing of Color Additives Subject to Certification; [Phthalocyaninato (2-)] Copper

AGENCY: Food and Drug Administration.

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 to color polymethylmethacrylate monofilament used as supporting haptics for intraocular lenses. This action responds to a petition filed by Surgidev Corp.

**DATES:** Effective June 2, 1987, except as to any provisions that may be stayed by the filing of proper objections: Objections by June 1, 1987.

**ADDRESS:** Written objections to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Marvin D. Mack, Center for Food Safety and Applied Nutrition (HFF-335), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-472-5690.

#### SUPPLEMENTARY INFORMATION:

##### I. Introduction

In a notice published in the Federal Register of August 19, 1986 (51 FR 29612), FDA announced that a color additive petition (CAP 6C0200) had been filed by Surgidev Corp., 5743 Thornwood Dr., Goleta, CA 93117, proposing that § 74.3045 [Phthalocyaninato (2-)] copper (21 CFR 74.3045) be amended to provide for the safe use of [phthalocyaninato (2-)] copper to color polymethylmethacrylate monofilament used as supporting haptics for intraocular lenses. The petition was filed under section 706 of the Federal

Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 376).

Haptics are suture-like loops used to hold intraocular lenses in place within the eye. Color additives are added to sutures and to haptics to increase their visibility for the physician. Small size sutures and haptics are difficult to see. Thus, they require intense color and a high percentage of color additive.

##### 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 comes in contact with the body for a significant period of time (21 U.S.C. 376(a)). [Phthalocyaninato(2-)] copper is used in supporting haptics for intraocular lenses in such a way that at least some of the color additive will come in contact with the eye when the lens is worn. In addition, the lens fixed with the support haptic monofilament is permanently placed in the eye by the surgeon. Consequently, the use of the color additive currently before the agency is subject to the statutory listing requirement.

##### III. Analysis of Data

[Phthalocyaninato(2-)] copper is currently regulated as a color additive, subject to certification, for use in coloring contact lenses in amounts not to exceed the minimum amount reasonably required to accomplish the intended coloring effect and for use in coloring certain nonabsorbable sutures in general and ophthalmic surgery at a level not to exceed 0.5 percent by weight of the suture.

To establish that the color additive [phthalocyaninato(2-)] copper is safe for use in coloring polymethylmethacrylate monofilament used as supporting haptics for intraocular lenses, the petitioner submitted various toxicity studies on the colored monofilament or its extracts. The studies include an acute systemic toxicity study on extracts of the colored monofilament in mice, acute intracutaneous exposure of rabbits to colored monofilament extracts, a maximization test in guinea pigs using an extract of the monofilaments, a 7-day muscle implantation study in rabbits using colored monofilament strands, and cytotoxicity and acute hemolysis studies with the colored monofilament and its extracts. There were no treatment related or other adverse effects observed in any of these studies.

To estimate the potential maximum exposure to [phthalocyaninato(2-)]

copper from its use in coloring polymethylmethacrylate haptics, FDA has applied the principles for estimating exposure that it has applied in evaluating the safety of the use of color additives in suture materials (Ref. 1). Based on its review of numerous petitions, FDA considers that the maximum length of suture used in any single ophthalmic surgery is not likely to exceed 30 centimeters, and that lifetime exposure will not exceed 60 centimeters of suture. The agency also estimates that polymethylmethacrylate haptics will have approximately the same density as silk sutures (size 8-0). Moreover, the use of the color additive to color polymethylmethacrylate haptics will not exceed 0.5 percent by weight.

Based upon these approximations, FDA has calculated the total acute exposure to the color additive to be 3.5 micrograms and a lifetime chronic exposure of 0.3 nanogram per day. No cytotoxic or other effects were observed in the safety studies submitted by the petitioner, or in other studies available to FDA, at concentrations many times greater than these approximate maximum levels of exposure.

#### IV. Conclusion

Based on data contained in the petition and other relevant material, FDA concludes that there is reasonable certainty that no harm will result from the petitioned use of [phthalocyaninato(2-)] copper for coloring supporting haptics for intraocular lenses when used at a maximum level of 0.5 percent by weight of the haptic. The agency also concludes on the basis of that data and material that the color additive will perform its intended coloring effect in the haptic material, polymethylmethacrylate, and thus is suitable for this use. The agency, therefore, is amending the color additive regulations to provide for the use of the color additive at a maximum level of 0.5 percent in polymethylmethacrylate haptics.

#### V. 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 use of the color additive in coloring polymethylmethacrylate monofilament used as supporting haptics 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.

#### VI. Environmental Impact

The agency has carefully considered the potential environmental effects of this action and 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. This action was considered under FDA's final rule implementing the National Environmental Policy Act (21 CFR Part 25).

#### VII. Reference

The following information has been placed on file at the Dockets Management Branch (address above) and is available for review in that office between 9 a.m. and 4 p.m., Monday through Friday.

1. Memorandum to the record dated October 10, 1985, from the Food Additive Chemistry Evaluation Branch, Re: "Exposure Estimates for Color Additives in Sutures."

#### VIII. Objections

Any person who will be adversely affected by this regulation may at any time on or before June 1, 1987 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 ground 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, 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: Secs. 701, 706, 52 Stat. 1055-1056 as amended, 74 Stat. 399-407 as amended (21 U.S.C. 371, 376); 21 CFR 5.10.

2. Section 74.3045 is amended by revising the introductory text of paragraph (c)(1) and paragraph (c)(1)(i) 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, and polymethylmethacrylate monofilament used as supporting haptics for intraocular lenses, subject to the following restrictions:

(i) The quantity of the color additive does not exceed 0.5 percent by weight of the suture of haptic material.

Dated: April 27, 1987.

John M. Taylor,  
Associated Commissioner for Regulatory Affairs.

[FR Doc. 87-9912 Filed 4-30-87; 8:45 am]  
BILLING CODE 4160-01-M

#### 21 CFR Part 81

[Docket No. 76N-0366]

Provisional Listing of D&C Red No. 33 and D&C Red No. 36; Postponement of Closing Date

AGENCY: Food and Drug Administration.

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is postponing the closing date for the provisional listing of D&C Red No. 33 and D&C No. 36 for use as color additives in drugs and cosmetics. The new closing date will be July 6, 1987. FDA has decided that this brief postponement is necessary to provide time for the preparation of documents that will explain the bases for the agency's decisions concerning the conditions under which these color additives may be safely used.

**EFFECTIVE DATE:** Effective May 4, 1987, the new closing date for D&C Red No. 33 and D&C Red No. 36 will be July 6, 1987.

**FOR FURTHER INFORMATION CONTACT:** Gerad L. McCowin, Center for Food Safety and Applied Nutrition (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-472-5676.

**SUPPLEMENTARY INFORMATION:** FDA established the current closing date of May 4, 1987, for the provisional listing of D&C Red No. 33 and D&C Red No. 36 by regulation published in the *Federal Register* of March 3, 1987 (52 FR 6323). FDA extended the closing date for these color additives until May 4, 1987, to provide time for submission of further information, for completion of the agency's review and evaluation of the data concerning the drug and cosmetic uses of these color additives, and for publication of a regulation in the *Federal Register* regarding the agency's final decision on the petitions for the permanent listing of these color additives. The regulation set forth below will postpone the May 4, 1987, closing date for the provisional listing of these color additives until July 6, 1987.

FDA has essentially completed its review and evaluation of available information relevant to the use of these color additives in drugs and cosmetics. The agency has concluded that the drug and cosmetic uses of D&C Red No. 33 and D&C Red No. 36 are safe. Thus, the agency has decided to permanently list the color additives for these uses. New certification specifications are also being developed for these color additives.

The agency has not yet completed documents fully describing the bases for each of these decisions and setting forth detailed conditions for use. Therefore, FDA believes that it is reasonable to postpone the closing date for these color additives until July 6, 1987, to provide time for the preparation and publication of appropriate *Federal Register* documents. The agency intends to publish these documents as soon as

possible. FDA concludes that this short extension is consistent with the public health and the standards set forth for continuation of provisional listing in *McIlwain v. Hayes*, 690 F.2d 1041 (D.C. Cir. 1982).

Because of the shortness of time until the May 4, 1987, closing date, FDA concludes that notice and public procedure on this regulation are impracticable and that good cause exists for issuing the postponement as a final rule and for an effective date of May 4, 1987. This regulation will permit the uninterrupted use of these color additives until further action is taken. In accordance with 5 U.S.C. 553 (b) and (d) (1) and (3), this postponement is issued as a final regulation, effective on May 4, 1987.

**List of Subjects in 21 CFR Part 81**

Color additives, Cosmetics, Drugs.

Therefore, under the Transitional Provisions of the Color Additive Amendments of 1960 to the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, Part 81 is amended as follows:

**PART 81—GENERAL SPECIFICATIONS AND GENERAL RESTRICTIONS FOR PROVISIONAL COLOR ADDITIVES FOR USE IN FOODS, DRUGS, AND COSMETICS**

1. The authority citation for 21 CFR Part 81 continues to read as follows:

**Authority:** Secs. 701, 706, 52 Stat. 1055-1056 as amended, 74 Stat. 399-407 as amended (21 U.S.C. 371, 376); Title II, Pub. L. 86-618; sec. 203, 74 Stat. 404-407 (21 U.S.C. 376, note); 21 CFR 5.10.

**§ 81.1 [Amended]**

2. In § 81.1 *Provisional lists of color additives* by revising the closing dates for "D&C Red No. 33" and "D&C Red No. 36" in paragraph (b) to read "July 6, 1987".

**§ 81.27 [Amended]**

3. In § 81.27 *Conditions of provisional listing* by revising the closing dates for "D&C Red No. 33" and "D&C Red No. 36" in paragraph (d) introductory text table, to read "July 6, 1987".

Dated: April 27, 1987.

John M. Taylor,  
Associate Commissioner for Regulatory Affairs.

[FR Doc. 87-9913 Filed 4-30-87; 8:45 am]

BILLING CODE 4160-01-M

**DEPARTMENT OF DEFENSE****Office of the Secretary****32 CFR Part 286**

[DoD Directive 5400.7 and DoD 5400.7-R]

**DoD Freedom of Information Act Program; Uniform Fee Schedules and Administrative Guidelines; Correction**

**AGENCY:** Office of the Secretary, DoD.

**ACTION:** Interim rule; Correction.

**SUMMARY:** This notice is to correct erroneous information printed in the *Federal Register* on April 24, 1987 on page 13641.

**EFFECTIVE DATE:** April 24, 1987.

**ADDRESS:** Office of the Assistant Secretary of Defense (Public Affairs), The Pentagon, Washington, DC 2031-1400.

**FOR FURTHER INFORMATION CONTACT:** Colonel Charlie Talbott, telephone (202) 697-1180.

**List of Subjects in 32 CFR Part 286**

Freedom of information.

**PART 286—[AMENDED]**

Accordingly, 32 CFR Part 286 is corrected as follows:

1. The authority citation for Part 286 continues to read as follows:

**Authority:** Pub. L. 99-570, sections 1801-04; Pub. L. 99-661, section 2328; 5 U.S.C. 552.

2. In the **DATE**, change "Subpart F" to read § 286.33 and § 286.35 which are effective . . ."

3. In the **SUMMARY**, page 13642, first paragraph, last sentence, change the word "Subpart F" to read "§ 286.33 and § 286.35."

4. Remove the last paragraph of the **SUMMARY** and replace with the following:

This notice also announces § 286.37 as a final rule (Pub. L. 99-661). Section 286.37 was published as § 286.62 in the *Federal Register* on January 9, 1987. Section 286.62 is now designated as § 286.37 and was effective February 14, 1987. No comments were received; however, the fee rates were revised to reflect both direct and indirect costs as required by Pub. L. 99-661.

April 28, 1987.

Linda M. Lawson,  
Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 87-9956 Filed 4-30-87; 8:45 am]

BILLING CODE 3810-01-M