(vi) A pipeline must post notices of operational flow orders, critical periods, and other critical notices on its Internet web site and must notify affected parties of such notices in either of the following ways to be chosen by the affected party: Internet E-Mail or direct notification to the party's Internet URL address.

[FR Doc. 98–10685 Filed 4–22–98; 8:45 am]
BILLING CODE 6717–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 74

[Docket No. 95C–0399]

Listing of Color Additives for Coloring Sutures; D&C Violet No. 2

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 D&C Violet No. 2 as a color additive in glycolide/dioxanone/trimethylene carbonate tripolymer absorbable sutures for general surgery. This action responds to a petition filed by United States Surgical Corp.

DATES: This regulation is effective May 27, 1998; except as to any provisions that may be stayed by the filing of proper objections; written objections and requests for a hearing by May 26, 1998.

ADDRESSES: Submit written objections to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

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 October 23, 1995 (60 FR 54379), FDA announced that a color additive petition (CAP 5C0248) had been filed by United States Surgical Corp., 150 Glover Ave., Norwalk, CT 06856. The petition proposed to amend the color additive regulations in § 74.3602 *D&C Violet No. 2* (21 CFR 74.3602) to provide for the safe use of D&C Violet No. 2 as a color additive in glycolide/dioxanone/trimethylene carbonate tripolymer absorbable sutures for general surgery. 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. Regulatory History

The regulatory history of D&C Violet No. 2 was summarized in a final rule published in the **Federal Register** of May 7, 1990 (55 FR 18865). Since the publication of the May 7, 1990, final rule, other uses of D&C Violet No. 2 have been approved by the agency. For example, in a final rule published in the **Federal Register** on March 14, 1994 (59 FR 11718), FDA amended § 74.3602 to list D&C Violet No. 2 for use to color poly(ε-caprolactone) absorbable sutures for use in general surgery.

III. 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(a) of the act). D&C Violet No. 2 is added to glycolide/dioxanone/trimethylene carbonate tripolymer absorbable sutures 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 be absorbed by the body, and during the absorption, the color additive will be deposited in body tissue. 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.

IV. The Color Additive

D&C Violet No. 2 is principally 1-hydroxy-4-[(4-methylphenyl)amino]-9,10-anthracenedione (CAS Reg. No. 81–48–1). It is manufactured by either condensation of quinizarin with *p*-toluidine or by condensation of 1-hydroxy-halogenoanthroquinone with *p*-toluidine. Because no chemical reaction consumes all the starting materials and yields only the desired product, both the resulting reaction mixture and commercial product will contain residual amounts of the starting materials, including *p*-toluidine. This fact is significant because Weisburger et al., have demonstrated that *p*-toluidine is a carcinogen in the mouse (Ref. 1).

Residual amounts of reactants, such as *p*-toluidine, and manufacturing aids are commonly found as impurities in chemical products, including color additives.

V. Determination of Safety

Under the general safety clause of the act (section 721(b)(4) of the act) for color additives, a color additive cannot be listed for a particular use unless a fair evaluation of the data available to FDA establishes that the color additive is safe for that use. FDA's color additive regulations (21 CFR 70.3(i)) define ''safe'' as ''reasonable certainty that no harm will result from the intended use of the color additive.''

The color additives anticancer, or Delaney, clause of the color additive amendments (section 721(b)(5)(B) of the act) provides that no noningested color additive shall be deemed safe and shall be listed if, after tests that are appropriate for evaluating the safety of the additive for such use, it is found to induce cancer in man or animal. Importantly, however, the Delaney clause applies to the additive itself and not to impurities in the additive. That is, where an additive itself has not been shown to cause cancer, but contains a carcinogenic impurity, the additive is properly evaluated under the general safety standard using risk assessment procedures to determine whether there is reasonable certainty that no harm will result from the proposed use of the additive (*Scott* v. *FDA*, 728 F.2d 322 (6th Cir. 1984)).

VI. Safety of the Petitioned Use of the Additive

FDA estimates that the petitioned use of the additive, D&C Violet No. 2, will result in exposure to no greater than 3.8 milligrams per person over a 70-year lifetime or an estimated daily intake (EDI) of 0.15 microgram per person per day (/p/d) (Ref. 2).

FDA does not ordinarily consider chronic toxicological studies to be necessary to determine the safety of an additive whose use will result in such low exposure levels (Ref. 3), and the agency has not required such testing here. However, the agency has reviewed the available toxicological data on the additive and concludes that the estimated small daily intake resulting from the proposed use of this additive is safe.

FDA has evaluated the safety of this additive under the general safety standard, considering all available data and using risk assessment procedures to estimate the upper-bound limit of lifetime human risk presented by *p*-toluidine, the carcinogenic chemical that may be present as an impurity in the additive. The risk evaluation of *p*-toluidine has two aspects: (1) Assessment of exposure to the impurity from the proposed use of the additive,

and (2) extrapolation of the risk observed in the animal bioassay to the conditions of exposure to humans.

A. p-Toluidine

FDA has estimated the lifetime exposure to *p*-toluidine from the petitioned use of D&C Violet No. 2 in glycolide/dioxanone/trimethylene carbonate tripolymer absorbable sutures to be no more than is 0.3 nanogram (ng)/p/d (Ref. 2). The agency used data from a long-term rodent bioassay on *p*-toluidine conducted by Weisburger et al. (Ref. 1), to estimate the upper-bound limit of lifetime human risk from exposure to this chemical resulting from the proposed use of the additive. The authors reported that the rodent bioassay showed that the test material caused an increased incidence of hepatomas (liver tumors).

Based on the agency's estimate that exposure to *p*-toluidine will not exceed 0.3 ng/p/d. FDA estimates that the upper-bound limit of lifetime human risk from the proposed use of the subject additive is 2×10^{-11} or 2 in 100 billion (Ref. 4). Because of the numerous conservative assumptions used in calculating the exposure estimate, the actual lifetime-averaged individual exposure to *p*-toluidine is likely to be substantially less than the estimated exposure, and therefore, the probable lifetime human risk would be less than the upper-bound limit of lifetime human risk. Thus, the agency concludes that there is reasonable certainty that no harm from exposure to *p*-toluidine would result from the proposed use of the additive.

B. Specifications

The agency has also considered whether specifications are necessary to control the amount of *p*-toluidine present as an impurity in D&C Violet No. 2. The additive is currently produced as a certified color additive for use in externally applied drugs and cosmetics, in sutures, and in contact lenses in accordance with 21 CFR part 80. Based upon the low level of exposure to *p*-toluidine that results under the current specifications for D&C Violet No. 2 in § 74.1602 (21 CFR 74.1602), the agency concludes that the specifications listed in § 74.1602 are adequate to ensure the safe use of this color additive and to control the amount of *p*-toluidine that may exist as an impurity in the color additive when used in glycolide/dioxanone/trimethylene carbonate tripolymer absorbable sutures for general surgery.

VII. 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 D&C Violet No. 2, at a level not to exceed 0.2 percent by weight of the suture material, for coloring glycolide/dioxanone/trimethylene carbonate tripolymer absorbable sutures is safe; and (2) the color additive will achieve its intended coloring effect, and thus, is suitable for this use. The agency therefore, is amending the color additive regulations in § 74.3602 as set forth below.

VIII. 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.

IX. 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.

X. Objections

Any person who will be adversely affected by this regulation may at any time on or before May 26, 1998, 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.

XI. References

The following references have 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. Weisburger, E. K. et al., ''Testing of Twenty-One Environmental Aromatic Amines or Derivatives for Long-Term Toxicology or Carcinogenicity,'' *Journal of Environmental Pathology and Toxicology*, 2:325–356, 1978.

2. Memorandum from the Chemistry Review Team, FDA, to the Indirect Additives Team, FDA, concerning ''CAP 5C0248: United States Surgical Corporation. Use of D&C Violet No. 2 as a colorant in synthetic absorbable surgical suture. Correction of Exposure Estimate.,'' dated March 6, 1997.

3. Kokoski, C. J., ''Regulatory Food Additive Toxicology'' in *Chemical Safety Regulation and Compliance*, edited by F. Homburger and J. K. Marquis, published by S. Karger, New York, NY, pp. 24–33, 1985.

4. Report of the Quantitative Risk Assessment Committee, FDA, concerning ''Upper Bound Lifetime Risk for *p*-Toluidine in D&C Violet No. 2 Used as a Color Additive for glycolide/dioxanone/trimethylene carbonate tripolymer absorbable sutures designated as USSC Monofilament polysorb sutures (UMPS),'' dated September 4, 1997.

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 74.3602 is amended by adding paragraph (b)(2)(v) to read as follows:

§ 74.3602 D&C Violet No. 2.

* * * * *

(b) * * *

(2) * * *

(v) At a level not to exceed 0.2 percent by weight of the suture material for coloring glycolide/dioxanone/trimethylene carbonate tripolymer absorbable sutures for use in general surgery.

* * * * *

Dated: April 16, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–10779 Filed 4–22–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

29 CFR Parts 1910 and 1926

[Docket No. H–049]

RIN 1218–AA05

Respiratory Protection; Correction

AGENCY: Occupational Safety and Health Administration (OSHA), Department of Labor.

ACTION: Final rule; correction.

SUMMARY: OSHA is correcting errors in the regulatory text of the Respiratory Protection final rule that appeared in the **Federal Register** on January 8, 1998 (63 FR 1152).

DATES: These corrections become effective on April 23, 1998.

FOR FURTHER INFORMATION CONTACT: Bonnie Friedman, Director, OSHA Office of Public Affairs, Room N–3647, U.S. Department of Labor, 200 Constitution Avenue, N.W., Washington, D.C. 20210; Telephone: (202) 219–8148.

SUPPLEMENTARY INFORMATION: On January 8, 1998 (63 FR 1152), OSHA promulgated revised regulations for respiratory protection in general industry (part 1910), shipyards (part 1915), marine terminals (part 1917), longshoring (part 1918), and construction (part 1926).

Subsequently, technical and typographic errors were discovered in the regulatory text. This notice is being published to correct these errors. With the exception of the explanations discussed below, these corrections are self-explanatory.

In paragraph (i)(1)(ii), *Breathing air quality and use*, the reference to ''Type 1—Grade D breathing air'' has been corrected to read ''Grade D breathing air'' to conform to the ANSI/Compressed Gas Association Commodity Specification for Air, G–7.1–1989.

Paragraph (n)(3) is corrected to state that the respiratory protection provisions of the previous standard, 29 CFR 1910.134 as contained in the 29 CFR parts 1900 to 1910.999 edition of the Code of Federal Regulations published July 1, 1997, will continue in effect until October 5, 1998, the date for full compliance with the revised standard, rather than April 8, 1998, the effective date of the revised standard.

In Appendix A, in the protocol for the Bitrex qualitative fit test, the part numbers for the fit test hood assembly now match the part numbers given in the saccharin qualitative fit test protocol. Also, in the generated aerosol quantitative fit testing protocol, a reference for using P100 filters as one of the methods to filter exhaust air flow from the fit test chamber is incorrect and is deleted. In the condensation nuclei counter quantitative fit test protocol, the requirement in paragraph (a)(1) that a high-efficiency filter be fitted has been revised to allow for the fit testing of additional types of filters as appropriate. For the controlled negative fit test protocol, the pressure setting for the default test pressure has been changed from −1.5 mm to the correct value of −15 mm.

In Appendix C a typographic error in Part A, Section 2, question 11(e) has been corrected to read ''d. Any other eye or vision problem: Yes/No''.

Appendix D has been entitled ''mandatory'' since the employer is required by paragraph (k)(6) of the standard to provide the basic advisory information on respirators presented in Appendix D to any employees who voluntarily use respirators.

Since some of the 13 carcinogens are vapors, language has been added to paragraph (c)(4)(iv) of § 1910.1013 permitting the use of air-purifying canisters or cartridges, in addition to particulate filters. This provision requires appropriate respirator filters for these carcinogens.

This correction removes the provision in the revised Lead standard (§ 1910.1025(f)(1)(i)) that limits respirator use to a maximum of 4.4 hours per day. The 4.4 hour requirement had been removed earlier by OSHA (see 60 FR 52859).

Typographic errors in provisions in the Benzene standard (§ 1910.1028 (g)(2)(i)), Acrylonitrile standard (§ 1910.1045 (h)(2)(i)), and the Formaldehyde standard (§ 1910.1048 (g)(2)(i)) that referenced § 1910.134 (d)(3)(iii)(b)(1) have been corrected to read (d)(3)(iii)(B)(1).

Appendix E of the Methylenedianiline standard (§ 1910.1050), which specifies fit testing protocols, has been removed to match changes made to other substance specific standards. These changes require the use of the fit testing protocols in Appendix A of the revised respiratory protection standard.

The Methylene chloride standard limits respiratory protection to supplied-air respirators except for emergency escape. Paragraphs (d)(3)(iii)(B) (1) and (2) of the revised respiratory protection standard address the use of end-of-service-life indicators or change schedules for cartridges and canisters, and do not apply to supplied-air or emergency escape respirators. Accordingly, these paragraphs have been removed from the respiratory protection program required by the Methylene chloride standard to be in compliance with the revised § 1910.134 respiratory protection standard.

The correction to paragraph (h)(2)(iv) of the Asbestos standard for the construction industry reinstates an earlier revision made by OSHA to this standard. This revision permitted the use of PAPRs with HEPA filters or supplied-air respirators with HEPA egress cartridges under the conditions specified in this paragraph (see 60 FR 33985).

All these corrections to the standard are deemed to be ''minor'' amendments within the meaning of 29 CFR 1911.5. OSHA finds good cause, pursuant to 29 CFR 1911.5 and the Administrative Procedure Act, for promulgating the corrections without notice and opportunity for public comment.

Correction of Publication

The following corrections are made in the final rule for Respiratory Protection published in the **Federal Register** on January 8, 1998 (63 FR 1152).

Respiratory Protection [Correction]

§ 1910.134 [Correction]

1. On page 1275, first column, paragraph (i)(1)(ii), lines 2 and 3, are corrected to read ''meet at least the requirements for Grade D breathing air described in''.

2. On page 1275, first column, paragraph (i)(4)(ii), line 4, is corrected to read ''requirements for Grade D''.

3. On page 1276, second column, paragraph (n)(3), line 2, the date ''April 8, 1998'' is corrected to read ''October 5, 1998''.

4. On page 1278, third column, paragraph (a)(1), line 10, the reference ''parts #14 and #15'' is corrected to read ''parts # FT 14 and # FT 15''.