

(d) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification.* All batches of D&C Blue No. 6 shall be certified in accordance with regulations in part 80 of this chapter.

[49 FR 29956, July 25, 1984; 49 FR 34447, Aug. 31, 1984, as amended at 50 FR 30698, July 29, 1985]

**§ 74.3206 D&C Green No. 6.**

(a) *Identity.* The color additive D&C Green No. 6 shall conform in identity to the requirements of § 74.1206(a).

(b) *Specifications.* The color additive D&C Green No. 6 for use in medical devices shall conform to the specifications of § 74.1206(b).

(c) *Uses and restrictions.* (1) The color additive D&C Green No. 6 may be safely used at a level

(i) Not to exceed 0.03 percent by weight of the lens material for coloring contact lenses;

(ii) Not to exceed 0.75 percent by weight of the suture material for coloring polyethylene terephthalate surgical sutures, including sutures for ophthalmic use;

(iii) Not to exceed 0.1 percent by weight of the suture material for coloring polyglycolic acid surgical sutures with diameter greater than U.S.P. size 8-0, including sutures for ophthalmic use;

(iv) Not to exceed 0.5 percent by weight of the suture material for coloring polyglycolic acid surgical sutures with diameter not greater than U.S.P. size 8-0, including sutures for ophthalmic use;

(v) Not to exceed 0.21 percent by weight of the suture material for coloring poly(glycolic acid-co-trimethylene carbonate) sutures (also referred to as 1,4-dioxan-2,5-dione polymer with 1,3-dioxan-2-one) for general surgical use; and

(vi) Not to exceed 0.10 percent by weight of the haptic material for coloring polymethylmethacrylate support haptics of intraocular lenses.

(2) Authorization for 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 D&C Green No. 6 is used.

(d) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification.* All batches of D&C Green No. 6 shall be certified in accordance with regulations in part 80 of this chapter.

[48 FR 13022, Mar. 29, 1983, as amended at 51 FR 9784, Mar. 21, 1986; 51 FR 37909, Oct. 27, 1986; 58 FR 21542, Apr. 22, 1993]

**§ 74.3230 D&C Red No. 17.**

(a) *Identity and specifications.* The color additive D&C Red No. 17 shall conform in identity and specifications to the requirements of § 74.1317(a)(1) and (b).

(b) *Uses and restrictions.* (1) The substance listed in paragraph (a) of this section may be used as a color additive in contact lens in amounts not to exceed the minimum reasonably required to accomplish the intended coloring effect.

(2) Authorization for this use shall not be construed as waiving any of the requirements of section 510(k), 515, and 520(g) of the Federal Food, Drug, and Cosmetic Act with respect to the contact lens in which the color additive is used.

(c) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Certification.* All batches of D&C Red No. 17 shall be certified in accordance with regulations in part 80 of this chapter.

[55 FR 22898, June 5, 1990]

**§ 74.3602 D&C Violet No. 2.**

(a) *Identity and specifications.* The color additive D&C Violet No. 2 shall conform in identity and specifications to the requirements of § 74.1602(a)(1) and (b).

(b) *Uses and restrictions.* (1) The color additive, D&C Violet No. 2, may be safely used for coloring contact lenses in amounts not to exceed the minimum reasonably required to accomplish the intended coloring effect.

(2) D&C Violet No. 2 may be safely used for coloring sutures for use in surgery subject to the following conditions:

(i) At a level not to exceed 0.2 percent by weight of the suture material for coloring polyglactin 910 (glycolic-lactic acid polyester) synthetic absorbable sutures for use in general and ophthalmic surgery; and

(ii) At a level not to exceed 0.3 percent by weight of the suture material for coloring polydioxanone synthetic absorbable sutures for use in general and ophthalmic surgery.

(iii) At a level not to exceed 0.25 percent by weight of the suture material for coloring poliglecaprone 25 ( $\epsilon$ -caprolactone/glycolide copolymer) synthetic absorbable sutures for use in general surgery.

(iv) At a level not to exceed 0.1 percent by weight of the suture material for coloring poly( $\epsilon$ -caprolactone) absorbable sutures for use in general surgery.

(3) The color additive, D&C Violet No. 2, may be safely used for coloring polymethylmethacrylate intraocular lens haptics at a level not to exceed 0.2 percent by weight of the haptic material.

(4) Authorization for 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 devices in which the color additive is used.

(c) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Certification.* All batches of D&C Violet No. 2 shall be certified in accordance with regulations in part 80 of this chapter.

[52 FR 19722, May 27, 1987, as amended at 55 FR 18868, May 7, 1990; 58 FR 60109, Nov. 15, 1993; 59 FR 11720, Mar. 14, 1994]

#### § 74.3710 D&C Yellow No. 10.

(a) *Identity.* The color additive D&C Yellow No. 10 shall conform to the identity requirements of § 74.1710(a).

(b) *Specifications.* The color additive D&C Yellow No. 10 for use in contact lenses shall conform to the specifications of § 74.1710(b).

(c) *Uses and restrictions.* (1) The color additive D&C Yellow No. 10 may be used for coloring contact lenses in amounts not to exceed the minimum

reasonably required to accomplish the intended coloring effect.

(2) Authorization for this use 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 contact lens in which the color additive is used.

(d) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification.* All batches of D&C Yellow No. 10 shall be certified in accordance with regulations in part 80 of this chapter.

[52 FR 28690, Aug. 3, 1987]

#### APPENDIX A TO PART 74—THE PROCEDURE FOR DETERMINING ETHER SOLUBLE MATERIAL IN D&C RED NOS. 6 AND 7

The dye is dissolved in glacial acetic and 8 N hydrochloric acids (1.33:1) and extracted with diethyl ether. Sulfonated moieties, including the color additive, are discarded in subsequent aqueous extractions of the ether. Carboxylated moieties are removed from the ether by extraction with 2% (w/w) NaOH. The ether is evaporated to near dryness, ethanol (95%) is added, and the solution is analyzed spectrophotometrically in the visible range. The absorbance at each wavelength must not exceed 150% of the absorbance similarly obtained for D&C Red No. 6 Lot AA5169.

##### APPARATUS

(A) Spectrophotometer (Cary 118 or equivalent).

(B) Separatory funnels—one 1000 mL and one 500 mL.

##### REAGENTS

NOTE: Use *distilled* water when water is required.

(A) Glacial Acetic Acid (ACS grade).

(B) Diethyl ether (Anhydrous)—Note and follow safety precautions on container.

(C) 8 N HCl—Pour 165 mL H<sub>2</sub>O into a 500 mL graduate. Place the graduate in hood, then add HCl conc. to bring to volume. Carefully pour this solution into a 500 mL Erlenmeyer flask, Stopper and shake. Label the flask.

(D) 2% (w/w) NaOH—Pour ca 190 mL H<sub>2</sub>O into a 250 mL mixing graduate. Add 8 g. (5.23 mL) of 50% (w/w) NaOH, bring to 200 mL volume with water, stopper and mix. Pour this solution into a glass bottle, label and stopper with a polytetrafluoroethylene top.

(E) Ethanol (95%).