

conform in identity and specifications to the requirements of § 74.1707(a)(1) and (b).

(b) *Uses and restrictions.* D&C Yellow No. 7 may be safely used for coloring externally applied cosmetics in amounts consistent with good manufacturing practice.

(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 Yellow No. 7 shall be certified in accordance with regulations in part 80 of this chapter.

§ 74.2707a Ext. D&C Yellow No. 7.

(a) *Identity and specifications.* The color additive Ext. D&C Yellow No. 7 shall conform in identity and specifications to the requirements of § 74.1707a (a)(1) and (b).

(b) *Uses and restrictions.* Ext. D&C Yellow No. 7 may be safely used for coloring externally applied cosmetics in amounts consistent with good manufacturing practice.

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

(d) *Certification.* All batches of Ext. D&C Yellow No. 7 shall be certified in accordance with regulations in part 80 of this chapter.

§ 74.2708 D&C Yellow No. 8.

(a) *Identity and specifications.* The color additive D&C Yellow No. 8 shall conform in identity and specifications to the requirements of § 74.1708(a)(1) and (b).

(b) *Uses and restrictions.* D&C Yellow No. 8 may be safely used for coloring externally applied cosmetics in amounts consistent with good manufacturing practice.

(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 Yellow No. 8 shall be certified in accordance with regulations in part 80 of this chapter.

§ 74.2710 D&C Yellow No. 10.

(a) *Identity and specifications.* The color additive D&C Yellow No. 10 shall conform in identity and specifications

to the requirements of § 74.1710(a)(1) and (b).

(b) *Uses and restrictions.* The color additive D&C Yellow No. 10 may be safely used for coloring cosmetics generally in amounts consistent with current good manufacturing practice.

(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 Yellow No. 10 shall be certified in accordance with regulations in part 80 of this chapter.

[48 FR 39220, Aug. 30, 1983, as amended at 49 FR 8432, Mar. 7, 1984]

§ 74.2711 D&C Yellow No. 11.

(a) *Identity and specifications.* The color additive D&C Yellow No. 11 shall conform in identity and specifications to the requirements of § 74.1711(a)(1) and (b).

(b) *Uses and restrictions.* D&C Yellow No. 11 may be safely used for coloring externally applied cosmetics in amounts consistent with good manufacturing practice.

(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 Yellow No. 11 shall be certified in accordance with regulations in part 80 of this chapter.

Subpart D—Medical Devices

§ 74.3045 [Phthalocyaninato(2-)] copper.

(a) *Identity.* The color additive is [phthalocyaninato(2-)] copper (CAS Reg. No. 147-14-8) having the structure shown in Colour Index No. 74160.

(b) *Specifications.* The color additive [phthalocyaninato(2-)] copper shall conform to the following specifications and shall be free from impurities other than those named to the extent that such impurities may be avoided by current good manufacturing practice:

Volatile matter 135 °C (275 °F), not more than 0.3 percent.

Salt content (as NaCl), not more than 0.3 percent.

Alcohol soluble matter, not more than 0.5 percent.

Organic chlorine, not more than 0.5 percent.

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Aromatic amines, not more than 0.05 percent.
Lead (as Pb), not more than 40 parts per million.
Arsenic (as As), not more than 3 parts per million.
Mercury (as Hg), not more than 1 part per million.
Total color, not less than 98.5 percent.

(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, 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 or haptic material.

(ii) The dyed suture shall conform in all respects to the requirements of the U.S. Pharmacopeia.

(2) The color additive [phthalocyaninato(2-)] copper may be safely used for coloring contact lenses in amounts not to exceed the minimum reasonably required to accomplish the intended coloring effect.

(3) Authorization for these uses shall not be construed as waiving any of the requirements of section 510(k), 515, or 520(g) the Federal Food, Drug, and Cosmetic Act with respect to the medical device in which [phthalocyaninato(2-)] copper 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 [phthalocyaninato (2-)] copper shall be certified in accordance with regulations in part 80 of this chapter.

[48 FR 34947, Aug. 2, 1983, as amended at 50 FR 16228, Apr. 25, 1985; 51 FR 22929, June 24, 1986; 51 FR 28930, Aug. 13, 1986; 51 FR 39371, Oct. 28, 1986; 52 FR 15945, May 1, 1987; 55 FR 19620, May 10, 1990]

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§ 74.3106 D&C Blue No. 6.

(a) *Identity.* The color additive D&C Blue No. 6 is principally [^Δ2,2'-biindoline]-3,3' dione (CAS Reg. No. 482-89-3).

(b) *Specifications.* D&C Blue No. 6 shall conform to the following specifications and shall be free from impurities other than those named to the extent that such impurities may be avoided by good manufacturing practice:

Volatile matter at 135 °C (275 °F), not more than 3 percent.

Matter insoluble in *N,N*-dimethylformamide, not more than 1 percent.

Isatin, not more than 0.3 percent.

Anthranilic acid, not more than 0.3 percent.

Indirubin, not more than 1 percent.

Lead (as Pb), not more than 10 parts per million.

Arsenic (as As), not more than 3 parts per million.

Mercury (as Hg), not more than 1 part per million.

Total color, not less than 95 percent.

(c) *Uses and restrictions.* (1) D&C Blue No. 6 may be safely used at a level—

(i) Not to exceed 0.2 percent by weight of the suture material for coloring polyethylene terephthalate surgical sutures for general surgical use;

(ii) Not to exceed 0.25 percent by weight of the suture material for coloring plain or chromic collagen absorbable sutures for general surgical use;

(iii) Not to exceed 0.5 percent by weight of the suture material for coloring plain or chromic collagen absorbable sutures for ophthalmic surgical use;

(iv) Not to exceed 0.5 percent by weight of the suture material for coloring polypropylene surgical sutures for general surgical use; and

(v) Not to exceed 0.5 percent by weight of the suture material for coloring polydioxanone synthetic absorbable sutures for ophthalmic and general surgical use.

(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 the color additive is used.