

(2) The color additive FD&C Blue No. 2-Aluminum Lake on alumina may be safely used for coloring bone cement at a level not to exceed 0.1 percent by weight of the bone cement.

(3) Authorization and compliance with 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 FD&C Blue No. 2 and the color additive FD&C Blue No. 2-Aluminum Lake on alumina are used.

(d) *Labeling.* The labels of the color additive FD&C Blue No. 2 and the color additive FD&C Blue No. 2-Aluminum Lake on alumina shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification.* All batches of FD&C Blue No. 2 and its lake shall be certified in accordance with regulations in part 80 of this chapter.

[64 FR 48290, Sept. 3, 1999]

§ 74.3106 D&C Blue No. 6.

(a) *Identity.* The color additive D&C Blue No. 6 is principally [^{2,2'}-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.

(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