for coloring poliglecaprone 25 (e-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(e-caprolactone) absorbable sutures for use in general surgery.

(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.

(vi) At a level not to exceed 0.2 percent by weight of the suture material for coloring absorbable sutures prepared from homopolymers of glycolide 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) The color additive, D&C Violet No. 2, may be safely used for coloring absorbable meniscal tacks made from poly(L-lactic acid) at a level not to exceed 0.15 percent by weight of the tack material.

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

[52 FR 28690, Aug. 3, 1987]

PART 80—COLOR ADDITIVE CERTIFICATION

Subpart A—General Provisions

§ 80.10 Fees for certification services.

Subpart B—Certification Procedures

80.21 Request for certification.

80.22 Samples to accompany requests for certification.

80.31 Certification.

80.32 Limitations of certificates.

80.34 Authority to refuse certification service.

80.35 Color additive mixtures; certification and exemption from certification.

80.37 Treatment of batch pending certification.

80.38 Treatment of batch after certification.

80.39 Records of distribution.


SOURCE: 42 FR 15662, Mar. 22, 1977, unless otherwise noted.

Subpart A—General Provisions

§ 80.10 Fees for certification services.

(a) Fees for straight colors including lakes. The fee for the services provided by the regulations in this part in the case of each request for certification submitted in accordance with §80.21(j)(1) and (j)(2) shall be $0.35 per