

Food and Drug Administration, HHS

§ 80.10

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; 63 FR 20098, Apr. 23, 1998; 64 FR 32805, June 18, 1999; 65 FR 46344, July 28, 2000]

§ 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]

PART 80—COLOR ADDITIVE CERTIFICATION

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AUTHORITY: 21 U.S.C. 371, 379e.

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 pound of the batch covered by such requests, but no such fee shall be less than \$224.

(b) *Fees for repacks of certified color additives and color additive mixtures.* The fees for the services provided under the regulations in this part in the case of each request for certification submitted in accordance with § 80.21(j)(3) and (j)(4) shall be:

(1) 100 pounds or less—\$35.

(2) Over 100 pounds but not over 1,000 pounds—\$35 plus \$0.06 for each pound over 100 pounds.

(3) Over 1,000 pounds—\$89 plus \$0.02 for each pound over 1,000 pounds.

(c) *Advance deposits.* Any person regularly requesting certification services may deposit funds in advance of requests as prepayment of fees required by this section.

(d) *Method of payment.* All deposits and fees required by this section shall be paid by money order, bank draft, or certified check, drawn to the order of the Food and Drug Administration, collectible at par at Washington, DC. All such deposits and fees shall be forwarded to the Center for Food Safety and Applied Nutrition (HFS-100), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, whereupon after making appropriate records thereof, they will be transmitted to the Treasurer of the United