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(d) *Certification.* All batches of FD&C Red No. 40 and lakes thereof shall be certified in accordance with regulations, in part 80 of this chapter.

[42 FR 15654, Mar. 22, 1977, as amended at 59 FR 7636, Feb. 16, 1994]

§ 74.1602 D&C Violet No. 2.

(a) *Identity.* (1) The color additive D&C Violet No. 2 is principally 1-hydroxy -4-[(4-methylphenyl)amino]-9,10-anthracenedione.

(2) Color additive mixtures for use in externally applied drugs made with D&C Violet No. 2 may contain only those diluents that are suitable and that are listed in part 73 of this chapter as safe for use in color additive mixtures for coloring externally applied drugs.

(b) *Specifications.* D&C Violet No. 2 shall conform to the following specifications and shall be free from impurities, other than those named, to the extent that such other impurities can be avoided by good manufacturing practice:

Volatile matter (at 135 °C.), not more than 2.0 percent.

Matter insoluble in both carbon tetrachloride and water, not more than 0.5 percent.

p- Toluidine, not more than 0.2 percent.

1-Hydroxy-9,10-anthracenedione, not more than 0.5 percent.

1,4-Dihydroxy-9,10-anthracenedione, not more than 0.5 percent.

Subsidiary colors, not more than 1.0 percent.

Lead (as Pb), not more than 20 parts per million.

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

Total color, not less than 96.0 percent.

(c) *Uses and restrictions.* The color additive D&C Violet No. 2 may be safely used for coloring externally applied drugs in amounts consistent with good manufacturing practice.

(d) *Labeling.* The label of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

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

[42 FR 15654, Mar. 22, 1977, as amended at 45 FR 62978, Sept. 23, 1980; 55 FR 18868, May 7, 1990]

§ 74.1705 FD&C Yellow No. 5.

(a) *Identity and specifications.* (1) The color additive FD&C Yellow No. 5 shall conform in identity and specifications to the requirements of § 74.705 (a)(1) and (b).

(2) FD&C Yellow No. 5 Aluminum Lake shall be prepared in accordance with the requirements of § 82.51 of this chapter.

(3) Color additive mixtures for drug use made with FD&C Yellow No. 5 may contain only those diluents that are suitable and are listed in part 73 of this chapter as safe for use in color additive mixtures for coloring drugs.

(b) *Uses and restrictions.* (1) FD&C Yellow No. 5 may be safely used for coloring drugs generally, including drugs intended for use in the area of the eye, in amounts consistent with current good manufacturing practice.

(2) FD&C Yellow No. 5 Aluminum Lake may be safely used for coloring drugs intended for use in the area of the eye, when prepared in accordance with § 82.51 of this chapter.

(c) *Labeling requirements.* (1) The label of the color additive and any mixtures intended solely or in part for coloring purposes prepared therefrom shall conform to the requirements of § 70.25 of this chapter.

(2) The label of OTC and prescription drug products intended for human use administered orally, nasally, rectally, or vaginally, or for use in the area of the eye, containing FD&C Yellow No. 5 shall specifically declare the presence of FD&C Yellow No. 5 by listing the color additive using the names FD&C Yellow No. 5 and tartrazine. The label shall bear a statement such as ''Contains FD&C Yellow No. 5 (tartrazine) as a color additive'' or ''Contains color additives including FD&C Yellow No. 5 (tartrazine).'' The labels of certain drug products subject to this labeling requirement that are also cosmetics, such as: antibacterial mouthwashes and fluoride toothpastes, need not comply with this requirement provided