

§ 74.1340

N,N-(β,β' -Dihydroxy-diethyl) aniline, not more than 0.2 percent.

Subsidiary colors, not more than 3.0 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 95.0 percent.

(c) *Uses and restrictions.* The color additive D&C Red No. 39 may be safely used for the coloring of quaternary ammonium type germicidal solutions intended for external application only, and subject to the further restriction that the quantity of the color additive does not exceed 0.1 percent by weight of the finished drug product.

(d) *Labeling.* The label of the color additive and any mixtures prepared therefrom and 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 Red No. 39 shall be certified in accordance with regulations promulgated under part 80 of this chapter.

§ 74.1340 FD&C Red No. 40.

(a) *Identity and specifications.* (1) The color additive FD&C Red No. 40 shall conform in identity and specifications to the requirements of § 74.340(a)(1) and (b).

(2) Color additive mixtures for drug use made with FD&C Red No. 40 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 drugs.

(3) The listing of this color additive includes lakes prepared as described in §§ 82.51 and 82.1051 of this chapter, except that the color additive used is FD&C Red No. 40 and the resultant lakes meet the specification and labeling requirements prescribed by §§ 82.51 or 82.1051 of this chapter.)

(b) *Uses and restrictions.* (1) FD&C Red No. 40 and FD&C Red No. 40 Aluminum Lake may be safely used in coloring drugs, including those intended for use in the area of the eye, subject to the restrictions on the use of color additives in § 70.5(b) and (c) of this chapter, in amounts consistent with current good manufacturing practice.

(2) Other lakes of FD&C Red No. 40 may be safely used in coloring drugs, subject to the restrictions on the use of

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color additives in § 70.5 of this chapter, in amounts consistent with current good manufacturing practice.

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

(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 (tartrazine) as a 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 they comply with the requirements of § 701.3 of this chapter.

(3) For prescription drugs for human use containing FD&C Yellow No. 5 that are administered orally, nasally, vaginally, or rectally, or for use in the area of the eye, the labeling required by § 201.100(d) of this chapter shall, in addition to the label statement required under paragraph (c)(2) of this section, bear the warning statement "This product contains FD&C Yellow No. 5 (tartrazine) which may cause allergic-type reactions (including bronchial asthma) in certain susceptible persons. Although the overall incidence of FD&C Yellow No. 5 (tartrazine) sensitivity in the general population is low, it is frequently seen in patients who also have aspirin hypersensitivity." This warning statement shall appear in the "Precautions" section of the labeling.

(d) *Certification.* All batches of FD&C Yellow No. 5 shall be certified in accordance with regulations in part 80 of this chapter.

[42 FR 15654, Mar. 22, 1977, as amended at 44 FR 37220, June 26, 1979; 50 FR 35782, Sept. 4, 1985; 51 FR 24519, July 7, 1986; 59 FR 60897, Nov. 29, 1994]

§ 74.1706 FD&C Yellow No. 6.

(a) *Identity and specifications.* (1) The color additive FD&C Yellow No. 6 shall conform in identity and specifications to the requirements of § 74.706(a)(1) and (b).

(2) Color additive mixtures for drug use made with FD&C Yellow No. 6 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 drugs.

(b) *Uses and restrictions.* FD&C Yellow No. 6 may be safely used for coloring drugs generally in amounts consistent with current good manufacturing practice.

(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) [Reserved]