

## § 74.1102

(2) FD&C Blue No. 1 Aluminum Lake shall be prepared in accordance with the requirements of § 82.51 of this chapter.

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

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

(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 FD&C Blue No. 1 shall be certified in accordance with regulations in part 80 of this chapter.

[47 FR 42565, Sept. 28, 1982, as amended at 59 FR 7638, Feb. 16, 1994]

## § 74.1102 FD&C Blue No. 2.

(a) *Identity.* (1) The color additive FD&C Blue No. 2 shall conform in identity to the requirements of § 74.102(a)(1).

(2) Color additive mixtures for use in ingested drugs made with FD&C Blue 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 drugs.

(b) The color additive FD&C Blue No. 2 for use in coloring ingested drugs shall conform to the specifications in § 74.102(b).

(c) The color additive FD&C Blue No. 2 may be safely used for coloring ingested drugs in amounts consistent with current 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 FD&C Blue No. 2 shall be certified in accord-

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ance with regulations in part 80 of this chapter.

[48 FR 5260, Feb. 4, 1983, as amended at 49 FR 10090, Mar. 19, 1984; 64 FR 48290, Sept. 3, 1999]

## § 74.1104 D&C Blue No. 4.

(a) *Identity.* (1) The color additive D&C Blue No. 4 is principally the diammonium salt of ethyl[4-[*p*-[ethyl(*m*-sulfobenzyl)amino]- $\alpha$ -(*o*-sulfophenyl)benzylidene]-2,5-cyclohexadien-1-ylidene] (*m*-sulfobenzyl) ammonium hydroxide inner salt with smaller amounts of the isomeric diammonium salts of ethyl [4-[*p*-[ethyl(*p*-sulfobenzyl) amino]- $\alpha$ -(*o*-sulfophenyl) benzylidene]-2,5-cyclohexadien - 1-ylidene](*p*-sulfobenzyl) ammonium hydroxide inner salt and ethyl[4-[*p*-[ethyl (*o*-sulfobenzyl)amino]- $\alpha$ -(*o*-sulfophenyl) benzylidene]-2,5-cyclohexadien-1-ylidene] (*o*-sulfobenzyl) ammonium hydroxide inner salt.

(2) Color additive mixtures for use in externally applied drugs made with D&C Blue No. 4 may contain only those diluents that are suitable and that are listed in part 73 of this chapter for use in color additive mixtures for coloring externally applied drugs.

(b) *Specifications.* D&C Blue No. 4 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:

Sum of volatile matter (at 135 °C) and chlorides and sulfates (calculated as sodium salts), not more than 15 percent.

Water-insoluble matter, not more than 0.2 percent.

Leuco base, not more than 5 percent.

Sum of *o*-, *m*-, and *p*-sulfobenzaldehydes, ammonium salt, not more than 1.5 percent.

*N*-ethyl, *N*-(*m*-sulfobenzyl) sulfanilic acid ammonium salt, not more than 0.3 percent.

Subsidiary colors, not more than 6 percent.

Chromium (as Cr), not more than 50 parts per million.

Lead (as Pb), not more than 20 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 85 percent.