other impurities may be avoided by current good manufacturing practice:

Sum of volatile matter (at 135 °C) and chlorides and sulfates (calculated as sodium salts), not more than 13 percent.
Water insoluble matter, not more than 0.2 percent.
Sodium salt of 4-aminobenzenesulfonic acid, not more than 0.2 percent.
Sodium salt of 6-hydroxy-2-naphthalenesulfonic acid, not more than 0.3 percent.
Disodium salt of 6,6′-oxybis[2-naphthalenesulfonic acid], not more than 1 percent.
Disodium salt of 4,4′-(1-triazene-1,3-diyl)bis[benzenesulfonic acid], not more than 0.1 percent.
Sum of the sodium salt of 6-hydroxy-5-(phenylazo)-2-naphthalenesulfonic acid and the sodium salt of 4-[(2-hydroxy-1-naphthalenyl)azo]benzenesulfonic acid, not more than 1 percent.
Sum of the trisodium salt of 3-hydroxy-4-[(4-sulfophenyl)azo]-2,7-naphthalenedisulfonic acid and other higher sulfonated subsidiaries, not more than 5 percent.
4-Aminoazobenzene, not more than 50 parts per billion.
4-Aminobiphenyl, not more than 15 parts per billion.
Aniline, not more than 250 parts per billion.
Azobenzene, not more than 200 parts per billion.
Benzidine, not more than 1 part per billion.
1,3-Diphenyltriazene, not more than 40 parts per billion.
1-(Phenylazo)-2-naphthalenol, not more than 10 parts per million.
Lead (as Pb), not more than 10 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 87 percent.

(c) *Uses and restrictions.* The color additive FD&C Yellow No. 6 may be safely used for coloring foods (including dietary supplements) generally in amounts consistent with current good manufacturing practice, except that it may not be used to color foods for which standards of identity have been promulgated under section 401 of the act unless added color is authorized by such standards.

(d) *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]

(e) *Certification.* All batches of FD&C Yellow No. 6 shall be certified in accordance with regulations in part 80 of this chapter.

[51 FR 41782, Nov. 19, 1986, as amended at 52 FR 21508, June 8, 1987; 53 FR 49138, Dec. 6, 1988]

Subpart B—Drugs

§ 74.1101 FD&C Blue No. 1

(a) *Identity.* (1) For ingested drugs, the color additive FD&C Blue No. 1 shall conform in identity to the requirements of § 74.101(a)(1).

(2) For externally applied drugs, the color additive FD&C Blue No. 1 shall conform in identity to the requirements of § 74.2101(a).

(3) Color additive mixtures for drug use made with FD&C Blue No. 1 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) *Specifications.* (1) The color additive FD&C Blue No. 1 for use in coloring drugs generally shall conform in specifications to the requirements of § 74.101(b).

(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 accordance 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)ami-no]-α-(*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]-α-(*o*-sulfophenyl) benzylidene]-2,5-cyclohexadien - 1-ylidene](*p*-sulfobenzyl) ammonium hydroxide inner salt and ethyl[4-[*p*-[ethyl (*o*-sulfobenzyl)amino]-α-(*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.

(c) *Uses and restrictions.* D&C Blue No. 4 may be safely used in 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 Blue No. 4 shall be certified in accordance with regulations in part 80 of this chapter.

§ 74.1109 D&C Blue No. 9.

(a) *Identity.* The color additive D&C Blue No. 9 is principally 7,16-dichloro-6,15 - dihydro - 5,9,14,18 - anthrazinetetrone.

(b) *Specifications.* D&C Blue No. 9 shall conform to the following specifications and shall be free from impurities other than those named to the extent that such impurities may be