Food and Drug Administration, HHS

§ 74.1317

(a) **Identity.** (1) The color additive D&C Red No. 7 is principally 1-[(4-phenylazo)phenylazo]-2-naphthalenol.

(2) Color additive mixtures for drug use made with D&C Red No. 7 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.** The color additive D&C Red No. 7 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 current good manufacturing practice:

Sum of volatile matter (at 135 °C) and chlorides and sulfates (calculated as sodium salts), not more than 10 percent.

Ether-soluble matter, passes test entitled “The Procedure for Determining Ether-Soluble Material in D&C Red Nos. 6 and 7,” which is an appendix A to part 74.

2-Amino-5-methylbenzenesulfonic acid, calcium salt, not more than 0.2 percent.

3-Hydroxy-2-naphthaleneacarboxylic acid, calcium salt, not more than 0.4 percent.

3-Hydroxy-4-{[(4-methyl-2-sulfophenyl)azo]-2-naphthaleneacarboxylic acid, calcium salt, not more than 0.5 percent.

p-Toluidine, not more than 15 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 90 percent.

(c) **Uses and restrictions.** The color additive D&C Red No. 7 may be safely used for coloring drugs such that the combined total of D&C Red No. 6 and D&C Red No. 7 does not exceed 5 milligrams per daily dose of the drug.

(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 Red No. 7 shall be certified in accordance with regulations in part 80 of this chapter.

[47 FR 57687, Dec. 26, 1982]

§ 74.1307 D&C Red No. 7.

(a) **Identity.** (1) The color additive D&C Red No. 7 is principally the calcium salt of 3-hydroxy-4-[(4-methyl-2-sulfophenyl)azo]-2-naphthaleneacarboxylic acid (CAS Reg. No. 5281-04-9). To manufacture the additive, 2-amino-5-methylbenzenesulfonic acid is diazotized with hydrochloric acid and sodium nitrite. The diazo compound is coupled in alkaline medium with 3-hydroxy-2-naphthaleneacarboxylic acid and the resulting dye converted to the calcium salt with calcium chloride.

(2) Color additive mixtures for drug use made with D&C Red No. 7 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.** The color additive D&C Red No. 7 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 current good manufacturing practice:

Sum of volatile matter (at 135 °C) and chlorides and sulfates (calculated as sodium salts), not more than 10 percent.

ether-soluble matter, passes test entitled “The Procedure for Determining Ether-Soluble Material in D&C Red Nos. 6 and 7,” which is an appendix A to part 74.

2-Amino-5-methylbenzenesulfonic acid, sodium salt, not more than 0.2 percent.

3-Hydroxy-2-naphthaleneacarboxylic acid, sodium salt, not more than 0.4 percent.

3-Hydroxy-4-[(4-methylphenyl)azo]-2-naphthaleneacarboxylic acid, sodium salt, not more than 0.5 percent.

p-Toluidine, not more than 15 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 90 percent.

(c) **Uses and restrictions.** The color additive D&C Red No. 7 may be safely used for coloring drugs such that the combined total of D&C Red No. 6 and D&C Red No. 7 does not exceed 5 milligrams per daily dose of the drug.

(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 Red No. 7 shall be certified in accordance with regulations in part 80 of this chapter.

[47 FR 57687, Dec. 26, 1982]