§ 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 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]

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

§ 74.1707  D&C Yellow No. 7.

(a) Identity. (1) The color additive D&C Yellow No. 7 is principally fluorescein.

(2) Color additive mixtures for use in externally applied drugs made with D&C Yellow No. 7 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 Yellow 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 good manufacturing practice:

- Sum of water and chlorides and sulfates (calculated as sodium salts), not more than 6 percent.
- Matter insoluble in alkaline water, not more than 0.5 percent.
- Resorcinol, not more than 0.5 percent.
- Phthalic acid, not more than 0.5 percent.
- 2-2,4-(Dihydroxybenzoyl) benzoic acid, not more than 0.5 percent.
- 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 94 percent.

(c) Uses and restrictions. D&C Yellow No. 7 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 Yellow No. 7 shall be certified in accordance with regulations in part 80 of this chapter.

§ 74.1707a  Ext. D&C Yellow No. 7.

(a) Identity. (1) The color additive Ext. D&C Yellow No. 7 is principally the disodium salt of 3-hydroxy-5,7-dinitro-2-naphthalenesulfonic acid.