Food and Drug Administration, HHS

```
74.2333
       D&C Red No. 33.
74.2334
        D&C Red No. 34.
74.2336
        D&C Red No. 36.
74.2340
       FD&C Red No. 40.
74.2602 D&C Violet No. 2.
74.2602a Ext. D&C Violet No. 2.
74.2705
       FD&C Yellow No. 5.
74.2706
       FD&C Yellow No. 6.
74.2707 D&C Yellow No. 7.
74.2707a Ext. D&C Yellow No. 7.
74.2708 D&C Yellow No. 8.
       D&C Yellow No. 10.
74.2710
       D&C Yellow No. 11.
74.2711
```

Subpart D—Medical Devices

```
74.3045 [Phthalocyaninato(2-)] copper.
74.3102 FD&C Blue No. 2.
74.3106 D&C Blue No. 6.
74.3206 D&C Green No. 6.
74.3230 D&C Red No. 17.
74.3602 D&C Violet No. 2.
74.3710 D&C Yellow No. 10.
```

APPENDIX A TO PART 74—THE PROCEDURE FOR DETERMINING ETHER SOLUBLE MATERIAL IN D&C RED NOS. 6 AND 7

AUTHORITY: 21 U.S.C. 321, 341, 342, 343, 348, 351, 352, 355, 361, 362, 371, 379e.

SOURCE: 42 FR 15654, Mar. 22, 1977, unless otherwise noted.

Subpart A—Foods

§74.101 FD&C Blue No. 1.

- (a) Identity. (1) The color additive FD&C Blue No. 1 is principally the disodium salt of ethyl [4-[p-[ethyl (msulfobenzyl) amino]- α -(o-sulfophenyl) benzylidene] - 2,5 -cyclohexadien - 1 ylidene] (m-sulfobenzyl) ammonium hydroxide inner salt with smaller amounts of the isomeric disodium salts [4-[p-[ethyl(p-sulfobenzyl) ethvl of amino]- α -(o-sulfophenyl) benzylidene]-2,5-cyclohexadien-1-ylidene] hvdroxide sulfobenzyl) ammonium inner salt and ethyl [4-[p-[ethyl (osulfobenzyl) amino] α (0 benzylidene]-2,5--sulfophenyl) cyclohexadien-1-ylidene] hydroxide sulfobenzyl) ammonium inner salt.
- (2) Color additive mixtures for food use (including dietary supplements) 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 foods.
- (b) Specifications. FD&C Blue No. 1 shall conform to the following specifications and shall be free from impuri-

ties other than those named to the extent that such 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 15.0 percent. Water-insoluble matter, not more than 0.2

Water-insoluble matter, not more than percent.

Leuco base, not more than 5 percent.

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

 $N ext{-Ethyl}, N ext{-}(m ext{-sulfobenzyl})$ sulfanilic acid, not more than 0.3 percent.

Subsidiary colors, not more than 6.0 percent. Chromium (as Cr), not more than 50 parts per million.

Manganese (as Mn), not more than 100 parts per million.

Arsenic (as As), not more than 3 parts per million.

Lead (as Pb), not more than 10 parts per million.

Total color, not less than 85.0 percent.

- (c) Uses and restrictions. FD&C Blue No. 1 may be safely used for coloring foods (including dietary supplements) generally in amounts consistent with 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. 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.

 $[42\ {\rm FR}\ 15654,\ {\rm Mar.}\ 22,\ 1977,\ {\rm as}\ {\rm amended}\ {\rm at}\ 58\ {\rm FR}\ 17511,\ {\rm Apr.}\ 5,\ 1993]$

§ 74.102 FD&C Blue No. 2.

(a) *Identity*. (1) The color additive FD&C Blue No. 2 is principally the disodium salt of 2-(1,3-dihydro-3-oxo-5-sulfo-2*H*-indol-2-ylidene)-2,3-dihydro-3-oxo-1*H*-indole-5-sulfonic acid (CAS Reg. No. 860-22-0) with smaller amounts of the disodium salt of 2-(1,3-dihydro-3-oxo-7-sulfo-2*H*-indol-2-ylidene)-2,3-dihydro-3-oxo-1*H*-indole-5-sulfonic acid (CAS Reg. No. 54947-75-0) and the sodium salt of 2-(1,3-dihydro-3-oxo-2*H*-indol-2-ylidene)-2,3-dihydro-3-oxo-1*H*-indole-5-sulfonic acid (CAS Reg. No.