

minimum reasonably required to accomplish the intended coloring effect.

(2) Authorization and compliance with this use shall not be construed as waiving any of the requirements of sections 510(k), 515, and 520(g) of the Federal Food, Drug, and Cosmetic Act (the act) with respect to the contact lenses in which the additive is used.

(c) *Labeling.* The label of the color additive shall conform to the requirements in § 70.25 of this chapter.

(d) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 721(c) of the act.

[67 FR 65312, Oct. 24, 2002]

§ 73.3129 Disodium 1-amino-4-[[4-(2-bromo-1-oxoallyl)amino]-2-sulfonatophenyl]amino]-9,10-dihydro-9,10-dioxoanthracene-2-sulfonate.

(a) *Identity.* The color additive is disodium 1-amino-4-[[4-(2-bromo-1-oxoallyl)amino]-2-sulfonatophenyl]amino]-9,10-dihydro-9,10-dioxoanthracene-2-sulfonate (Reactive Blue 69) (CAS Reg. No. 70209-99-3, Colour Index No. 612037).

(b) *Uses and restrictions.* (1) The substance listed in paragraph (a) of this section may be used as a color additive in contact lenses in amounts not to exceed the minimum reasonably required to accomplish the intended coloring effect.

(2) Authorization and compliance with this use shall not be construed as waiving any of the requirements of sections 510(k), 515, and 520(g) of the Federal Food, Drug, and Cosmetic Act with respect to the contact lenses in which the additive is used.

(c) *Labeling.* The label of the color additive shall conform to the requirements in § 70.25 of this chapter.

(d) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 721(c) of the Federal Food, Drug, and Cosmetic Act.

[76 FR 25235, May 4, 2011, as amended at 78 FR 14664, Mar. 7, 2013]

PART 74—LISTING OF COLOR ADDITIVES SUBJECT TO CERTIFICATION

Subpart A—Foods

| Sec. | |
|--------|--------------------|
| 74.101 | FD&C Blue No. 1. |
| 74.102 | FD&C Blue No. 2. |
| 74.203 | FD&C Green No. 3. |
| 74.250 | Orange B. |
| 74.302 | Citrus Red No. 2. |
| 74.303 | FD&C Red No. 3. |
| 74.340 | FD&C Red No. 40. |
| 74.705 | FD&C Yellow No. 5. |
| 74.706 | FD&C Yellow No. 6. |

Subpart B—Drugs

| | |
|----------|------------------------|
| 74.1101 | FD&C Blue No. 1. |
| 74.1102 | FD&C Blue No. 2. |
| 74.1104 | D&C Blue No. 4. |
| 74.1109 | D&C Blue No. 9. |
| 74.1203 | FD&C Green No. 3. |
| 74.1205 | D&C Green No. 5. |
| 74.1206 | D&C Green No. 6. |
| 74.1208 | D&C Green No. 8. |
| 74.1254 | D&C Orange No. 4. |
| 74.1255 | D&C Orange No. 5. |
| 74.1260 | D&C Orange No. 10. |
| 74.1261 | D&C Orange No. 11. |
| 74.1303 | FD&C Red No. 3. |
| 74.1304 | FD&C Red No. 4. |
| 74.1306 | D&C Red No. 6. |
| 74.1307 | D&C Red No. 7. |
| 74.1317 | D&C Red No. 17. |
| 74.1321 | D&C Red No. 21. |
| 74.1322 | D&C Red No. 22. |
| 74.1327 | D&C Red No. 27. |
| 74.1328 | D&C Red No. 28. |
| 74.1330 | D&C Red No. 30. |
| 74.1331 | D&C Red No. 31. |
| 74.1333 | D&C Red No. 33. |
| 74.1334 | D&C Red No. 34. |
| 74.1336 | D&C Red No. 36. |
| 74.1339 | D&C Red No. 39. |
| 74.1340 | FD&C Red No. 40. |
| 74.1602 | D&C Violet No. 2. |
| 74.1705 | FD&C Yellow No. 5. |
| 74.1706 | FD&C Yellow No. 6. |
| 74.1707 | D&C Yellow No. 7. |
| 74.1707a | Ext. D&C Yellow No. 7. |
| 74.1708 | D&C Yellow No. 8. |
| 74.1710 | D&C Yellow No. 10. |
| 74.1711 | D&C Yellow No. 11. |

Subpart C—Cosmetics

| | |
|---------|-------------------|
| 74.2052 | D&C Black No. 2. |
| 74.2053 | D&C Black No. 3. |
| 74.2101 | FD&C Blue No. 1. |
| 74.2104 | D&C Blue No. 4. |
| 74.2151 | D&C Brown No. 1. |
| 74.2203 | FD&C Green No. 3. |
| 74.2205 | D&C Green No. 5. |
| 74.2206 | D&C Green No. 6. |

§ 74.101

21 CFR Ch. I (4-1-25 Edition)

| | |
|----------|------------------------|
| 74.2208 | D&C Green No. 8. |
| 74.2254 | D&C Orange No. 4. |
| 74.2255 | D&C Orange No. 5. |
| 74.2260 | D&C Orange No. 10. |
| 74.2261 | D&C Orange No. 11. |
| 74.2304 | FD&C Red No. 4. |
| 74.2306 | D&C Red No. 6. |
| 74.2307 | D&C Red No. 7. |
| 74.2317 | D&C Red No. 17. |
| 74.2321 | D&C Red No. 21. |
| 74.2322 | D&C Red No. 22. |
| 74.2327 | D&C Red No. 27. |
| 74.2328 | D&C Red No. 28. |
| 74.2330 | D&C Red No. 30. |
| 74.2331 | D&C Red No. 31. |
| 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. |
| 74.2710 | D&C Yellow No. 10. |
| 74.2711 | D&C Yellow No. 11. |

Subpart D—Medical Devices

| | |
|---------|--------------------------------|
| 74.3045 | [Phthalocyaninato(2-)] copper. |
| 74.3054 | D&C Black No. 4. |
| 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. |
| 74.3708 | D&C Yellow No. 8. |
| 74.3710 | D&C Yellow No. 10. |

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 (*m*-sulfobenzyl) amino]- α -(*o*-sulfophenyl) benzylidene] - 2,5 -cyclohexadien - 1 - ylidene] (*m*-sulfobenzyl) ammonium hydroxide inner salt with smaller amounts of the isomeric disodium 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 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 impurities 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 percent.

Leuco base, not more than 5 percent.

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

N-Ethyl,*N*-(*m*-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 FR 15654, Mar. 22, 1977, as amended at 58 FR 17511, 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. 605-18-5). Additionally, FD&C Blue No. 2 is obtained by heating indigo (or indigo paste) in the presence of sulfuric acid. The color additive is isolated and subjected to purification procedures. The indigo (or indigo paste) used above is manufactured by the fusion of *N*-phenylglycine (prepared from aniline and formaldehyde) in a molten mixture of sodamide and sodium and potassium hydroxides under ammonia pressure. The indigo is isolated and subjected to purification procedures prior to sulfonation.

(2) Color additive mixtures for food use (including dietary supplements) 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 foods.

(b) *Specifications.* The color additive FD&C Blue No. 2 shall conform to the following specifications and shall be free from impurities 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 (275 °F) and chlorides and sulfates (calculated as sodium salts), not more than 15 percent.

Water insoluble matter, not more than 0.4 percent.

Isatin-5-sulfonic acid, not more than 0.4 percent.

5-Sulfoanthranilic acid, not more than 0.2 percent.

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, not more than 18 percent.

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, not more than 2 percent.

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 85 percent.

(c) *Uses and restrictions.* The color additive FD&C Blue No. 2 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 Federal Food, Drug, and Cosmetic 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. 2 shall be certified in accordance with regulations in part 80 of this chapter.

[48 FR 5260, Feb. 4, 1983]

§ 74.203 FD&C Green No. 3.

(a) *Identity.* (1) The color additive FD&C Green No. 3 is principally the inner salt disodium salt of *N*-ethyl-*N*-[4-[[4-[ethyl[(3-sulfophenyl)methyl]amino]phenyl](4-hydroxy-2-sulfophenyl)methylene]-2,5-cyclohexadien-1-ylidene]-3-sulfobenzene-methanaminium hydroxide (CAS Reg. No. 2353-45-9); with smaller amounts of the isomeric inner salt disodium salt of *N*-ethyl-*N*-[4-[[4-[ethyl[(3-sulfophenyl)methyl]amino]phenyl](4-hydroxy-2-sulfophenyl)methylene]-2,5-cyclohexadien-1-ylidene]-4-sulfobenzene-methanaminium hydroxide; of *N*-ethyl-*N*-[4-[[4-[ethyl[(4-sulfophenyl)methyl]amino]phenyl](4-hydroxy-2-sulfophenyl)methylene]-2,5-cyclohexadien-1-ylidene]-4-sulfobenzene-methanaminium hydroxide and of *N*-ethyl-*N*-[4-[[4-[ethyl[(2-sulfophenyl)methyl]amino]phenyl](4-hydroxy-2-sulfophenyl)methylene]-2,5-cyclohexadien-1-ylidene]-3-sulfobenzene-methanaminium hydroxide. Additionally, FD&C Green No. 3 is manufactured by the acid catalyzed condensation of one molecule of 2-formyl-5-hydroxybenzenesulfonic acid

§ 74.250

21 CFR Ch. I (4-1-25 Edition)

with two molecules from a mixture consisting principally of 3-[(ethylphenylamino)methyl]benzenesulfonic acid, and smaller amounts of 4-[(ethylphenylamino)methyl]benzenesulfonic acid and 2-[(ethylphenylamino)methyl]benzenesulfonic acid to form the leuco base. The leuco base is then oxidized with lead dioxide and acid or with dichromate and acid to form the dye. The intermediate 2-formyl-5-hydroxybenzenesulfonic acid is prepared by the potassium permanganate oxidation of 2,2'-(1,2-ethenediyl)-bis(5-aminobenzenesulfonic acid) to sodium 5-amino-2-formylbenzenesulfonate. This amine is diazotized and the resulting diazonium salt is hydrolyzed to the desired 2-formyl-5-hydroxybenzenesulfonic acid.

(2) Color additive mixtures for food use (including dietary supplements) made with FD&C Green No. 3 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 food.

(b) *Specifications.* The color additive FD&C Green No. 3 shall conform to the following specifications and shall be free from impurities 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 (275 °F) 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 2-,3-,4-formylbenzenesulfonic acids, sodium salts, not more than 0.5 percent.
- Sum of 3- and 4-[[ethyl(4-sulfophenyl)amino]methyl]benzenesulfonic acid, disodium salts, not more than 0.3 percent.
- 2-Formyl-5-hydroxybenzenesulfonic acid, sodium salt, not more than 0.5 percent.
- Subsidiary colors, not more than 6 percent.
- Chromium (as Cr), not more than 50 parts per million.
- Arsenic (as As), not more than 3 parts per million.
- Lead (as Pb), not more than 10 parts per million.
- Mercury (as Hg), not more than 1 part per million.
- Total color, not less than 85 percent.

(c) *Uses and restrictions.* The color additive FD&C Green No. 3 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.* 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 Green No. 3 shall be certified in accordance with regulations in part 80 of this chapter.

[47 FR 52143, Nov. 19, 1982; 47 FR 56489, Dec. 17, 1982]

§ 74.250 Orange B.

(a) *Identity.* (1) The color additive Orange B is principally the disodium salt of 1-(4-sulfophenyl)-3-ethylcarboxy-4-(4-sulfonaphthylazo)-5-hydroxy-pyrazole.

(2) The diluents in color additive mixtures for food use containing Orange B are limited to those listed in part 73 of this chapter as safe and suitable in color additive mixtures for coloring foods.

(b) *Specifications.* Orange B shall conform to the following specifications:

- Volatile matter (at 135 °C.), not more than 6.0 percent.
- Chlorides and sulfates (calculated as the sodium salts), not more than 7.0 percent.
- Water insoluble matter, not more than 0.2 percent.
- 1-(4-Sulfophenyl)-3-ethylcarboxy-5-hydroxypyrazolone and 1-(4-sulfophenyl)-3-carboxy-5-hydroxypyrazolone, not more than 0.7 percent.
- Naphthionic acid, not more than 0.2 percent.
- Phenylhydrazine-*p*-sulfonic acid, not more than 0.2 percent.
- The trisodium salt of 1-(4-sulfophenyl)-3-carboxy-4-(4-sulfonaphthylazo)-5-hydroxypyrazole, not more than 6.0 percent.
- Other subsidiary dyes, not more than 1.0 percent.
- Lead (as Pb), not more than 10 parts per million.
- Arsenic (as As), not more than 1 part per million.
- Total color, not less than 87.0 percent.

(c) *Uses and restrictions.* Orange B may be safely used for coloring the casings or surfaces of frankfurters and sausages subject to the restriction that the quantity of the color additive does not exceed 150 parts per million by weight of the finished food.

(d) *Labeling requirements.* 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.

(e) *Certification.* All batches of Orange B shall be certified in accordance with regulations promulgated under part 80 of this chapter.

§ 74.302 Citrus Red No. 2.

(a) *Identity.* (1) The color additive Citrus Red No. 2 is principally 1-(2,5-dimethoxyphenylazo)-2-naphthol.

(2) The following diluents may be used in aqueous suspension, in the percentages specified, to facilitate application to oranges in accordance with paragraph (c)(1) of this section:

(i) Suitable diluents used in accordance with § 73.1(a) of this chapter.

(ii) Volatile solvents that leave no residue after application to the orange.

(iii) Salts of fatty acids meeting the requirements of § 172.863 of this chapter.

(iv) Sodium tripolyphosphate, not more than 0.05 percent.

(b) *Specifications.* Citrus Red No. 2 shall conform to the following specifications and shall be free from impurities, other than those named, to the extent that such other impurities may be avoided by good manufacturing practice:

Volatile matter (at 100 °C.), not more than 0.5 percent.

Water-soluble matter, not more than 0.3 percent.

Matter insoluble in carbon tetrachloride, not more than 0.5 percent.

Uncombined intermediates, not more than 0.05 percent.

Subsidiary dyes, not more than 2.0 percent.

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

Arsenic (as As), not more than 1 part per million.

Total color, not less than 98 percent.

(c) *Uses and restrictions.* (1) Citrus Red No. 2 shall be used only for coloring the skins of oranges that are not intended

or used for processing (or if so used are designated in the trade as *Packinghouse elimination*) and that meet minimum maturity standards established by or under the laws of the States in which the oranges are grown.

(2) Oranges colored with Citrus Red No. 2 shall bear not more than 2.0 parts per million of such color additive, calculated on the basis of the weight of the whole fruit.

(d) *Labeling.* The label of the color additive and any mixtures prepared therefrom and intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter. To meet the requirements of § 70.25 (b) and (c) of this chapter the label shall bear:

(1) The statement (or its equivalent) "To be used only for coloring skins of oranges."

(2) Directions for use to limit the amount of the color additive to not more than 2.0 parts per million, calculated on the basis of the weight of the whole fruit.

(e) *Certification.* All batches of Citrus Red No. 2 shall be certified in accordance with regulations in part 80 of this chapter.

§ 74.303 FD&C Red No. 3.

(a) *Identity.* (1) The color additive FD&C Red No. 3 is principally the monohydrate of 9 (*o*-carboxyphenyl)-6-hydroxy - 2,4,5,7-tetraiodo-3H-xanthen-3-one, disodium salt, with smaller amounts of lower imidinated fluoresceins.

(2) Color additive mixtures for food use made with FD&C Red No. 3 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 Red No. 3 shall conform to the following specifications and shall be free from impurities other than those named to the extent that such other impurities may be avoided by good manufacturing practice:

Volatile matter (at 135 °C.) and chlorides and sulfates (calculated as the sodium salts), total not more than 13 percent.

Water-insoluble matter, not more than 0.2 percent.

§ 74.340

Unhalogenated intermediates, total not more than 0.1 percent.
Sodium iodide, not more than 0.4 percent.
Triiodoresorcinol, not more than 0.2 percent.
2(2',4'-Dihydroxy-3', 5'-diiodobenzoyl) benzoic acid, not more than 0.2 percent.
Monoiodofluoresceins not more than 1.0 percent.
Other lower iodinated fluoresceins, not more than 9.0 percent.
Lead (as Pb), not more than 10 parts per million.
Arsenic (as As), not more than 3 parts per million.
Total color, not less than 87.0 percent.

(c) *Uses and restrictions.* FD&C Red No. 3 may be safely used for coloring foods generally (including dietary supplements) 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 Red No. 3 shall be certified in accordance with regulations in part 80 of this chapter.

EFFECTIVE DATE NOTE: Amendments to § 74.303 were published at 90 FR 4636, Jan. 16, 2025, effective Jan. 15, 2027.

§ 74.340 FD&C Red No. 40.

(a) *Identity.* (1) The color additive FD&C Red No. 40 is principally the disodium salt of 6-hydroxy-5-[(2-methoxy-5-methyl-4-sulfophenyl)azo]-2-naphthalenesulfonic acid.

(2) Color additive mixtures for food use (including dietary supplements) made with FD&C Red No. 40 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.

(3) The listing of this color additive includes lakes prepared as described in § 82.51 of this chapter, except that the color additive used is FD&C Red No. 40 and the resultant lakes meet the specification and labeling requirements prescribed by § 82.51 of this chapter.

(b) *Specifications.* FD&C Red No. 40 shall conform to the following speci-

21 CFR Ch. I (4-1-25 Edition)

fications and shall be free from impurities other than those named to the extent that such other 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 14.0 percent.
Water-insoluble matter, not more than 0.2 percent.
Higher sulfonated subsidiary colors (as sodium salts), not more than 1.0 percent.
Lower sulfonated subsidiary colors (as sodium salts), not more than 1.0 percent.
Disodium salt of 6-hydroxy-5-[(2-methoxy-5-methyl-4-sulfophenyl)azo]-8-(2-methoxy-5-methyl-4-sulfophenoxy)-2-naphthalenesulfonic acid, not more than 1.0 percent.
Sodium salt of 6-hydroxy-2-naphthalenesulfonic acid (Schaeffer's salt), not more than 0.3 percent.
4-Amino-5-methoxy-*o*-toluenesulfonic acid, not more than 0.2 percent.
Disodium salt of 6,6'-oxybis (2-naphthalenesulfonic acid), not more than 1.0 percent.
Lead (as Pb), not more than 10 parts per million.
Arsenic (as As), not more than 3 parts per million.
Total color, not less than 85.0 percent.

(c) *Uses and restrictions.* FD&C Red No. 40 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 lakes or 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 Red No. 40 and lakes thereof shall be certified in accordance with regulations in part 80 of this chapter.

§ 74.705 FD&C Yellow No. 5.

(a) *Identity.* (1) The color additive FD&C Yellow No. 5 is principally the trisodium salt of 4,5-dihydro-5-oxo-1-(4-sulfophenyl)-4-[4-sulfophenyl-azo]-1*H*-pyrazole-3-carboxylic acid (CAS Reg. No. 1934-21-0). To manufacture the additive, 4-amino-benzenesulfonic acid is diazotized using hydrochloric acid and

sodium nitrite. The diazo compound is coupled with 4,5-dihydro-5-oxo-1-(4-sulfophenyl)-1*H*-pyrazole-3-carboxylic acid or with the methyl ester, the ethyl ester, or a salt of this carboxylic acid. The resulting dye is purified and isolated as the sodium salt.

(2) Color additive mixtures for food use made with FD&C Yellow No. 5 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 Yellow No. 5 shall conform to the following specifications and shall be free from impurities other than those named to the extent that such other impurities may be avoided by good manufacturing practice:

Sum of volatile matter at 135 °C (275 °F) and chlorides and sulfates (calculated as sodium salts), not more than 13 percent.

Water-insoluble matter, not more than 0.2 percent.

4,4'-[4,5-Dihydro-5-oxo-4-[(4-sulfophenyl)hydrazono]-1*H*-pyrazol-1,3-diyl]bis[benzenesulfonic acid], trisodium salt, not more than 1 percent.

4-[(4',5-Disulfo[1,1'-biphenyl]-2-yl)hydrazono]-4,5-dihydro-5-oxo-1-(4-sulfophenyl)-1*H*-pyrazole-3-carboxylic acid, tetrasodium salt, not more than 1 percent.

Ethyl or methyl 4,5-dihydro-5-oxo-1-(4-sulfophenyl)-4-[(4-sulfophenyl)hydrazono]-1*H*-pyrazole-3-carboxylate, disodium salt, not more than 1 percent.

Sum of 4,5-dihydro-5-oxo-1-phenyl-4-[(4-sulfophenyl)azo]-1*H*-pyrazole-3-carboxylic acid, disodium salt, and 4,5-dihydro-5-oxo-4-(phenylazo)-1-(4-sulfophenyl)-1*H*-pyrazole-3-carboxylic acid, disodium salt, not more than 0.5 percent.

4-Aminobenzenesulfonic acid, sodium salt, not more than 0.2 percent.

4,5-Dihydro-5-oxo-1-(4-sulfophenyl)-1*H*-pyrazole-3-carboxylic acid, disodium salt, not more than 0.2 percent.

Ethyl or methyl 4,5-dihydro-5-oxo-1-(4-sulfophenyl)-1*H*-pyrazole-3-carboxylate, sodium salt, not more than 0.1 percent.

4,4'-(1-Triazene-1,3-diyl)bis[benzenesulfonic acid], disodium salt, not more than 0.05 percent.

4-Aminoazobenzene, not more than 75 parts per billion.

4-Aminobiphenyl, not more than 5 parts per billion.

Aniline, not more than 100 parts per billion.
Azobenzene, not more than 40 parts per billion.

Benzidine, not more than 1 part per billion.
1,3-Diphenyltriazene, not more than 40 parts per billion.

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.* FD&C Yellow No. 5 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 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) Foods for human use that contain FD&C Yellow No. 5, including butter, cheese, and ice cream, shall specifically declare the presence of FD&C Yellow No. 5 by listing the color additive as FD&C Yellow No. 5 among the list of ingredients.

(e) *Certification.* All batches of FD&C Yellow No. 5 shall be certified in accordance with regulations in part 80 of this chapter.

[42 FR 15654, Mar. 22, 1977; 44 FR 17658, Mar. 23, 1979, as amended at 44 FR 37220, June 26, 1979; 51 FR 24519, July 7, 1986]

§ 74.706 FD&C Yellow No. 6.

(a) *Identity.* (1) The color additive FD&C Yellow No. 6 is principally the disodium salt of 6-hydroxy-5-[(4-sulfophenyl)azo]-2-naphthalenesulfonic acid (CAS Reg. No. 2783-94-0). The trisodium salt of 3-hydroxy-4-[(4-sulfophenyl)azo]-2,7-naphthalenedisulfonic acid (CAS Reg. No. 50880-65-4) may be added in small amounts. The color additive is manufactured by diazotizing 4-aminobenzenesulfonic acid using hydrochloric acid and sodium nitrite or sulfuric acid and sodium nitrite. The diazo compound is coupled with 6-hydroxy-2-naphthalene-sulfonic acid. The dye is isolated as the sodium salt and dried. The trisodium salt of 3-hydroxy-4-[(4-sulfophenyl)azo]-2,7-naphthalenedisulfonic acid which may

§74.1101

21 CFR Ch. I (4–1–25 Edition)

be blended with the principal color is prepared in the same manner except the diazo benzenesulfonic acid is coupled with 3-hydroxy-2,7-naphthalenedisulfonic acid.

(2) Color additive mixtures for food 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 as safe for use in color additive mixtures for coloring foods.

(b) *Specifications.* The color additive FD&C Yellow No. 6 shall conform to the following specifications and shall be free from impurities 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 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. 23, 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

21 CFR Ch. I (4-1-25 Edition)

§ 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 - anthrazine-tetrone.

(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 avoided by good manufacturing practice:

Volatile matter (at 135 °C.), not more than 3 percent.

Matter extractable by alcoholic HCl (0.1 ml of concentrated hydrochloric acid per 50 ml of 95 percent ethyl alcohol), not more than 1 percent.

2-Amino anthraquinone, not more than 0.2 percent.

Organically combined chlorine in pure dye, 13.0-14.8 percent.

Lead (as Pb), not more than 20 p/m.

Arsenic (as As), not more than 3 p/m.

Total color, not less than 97 percent.

(c) *Uses and restrictions.* D&C Blue No. 9 may be safely used for coloring cotton and silk surgical sutures, including sutures for ophthalmic use, subject to the following restrictions:

(1) The dyed suture shall conform in all respects to the requirements of the United States Pharmacopeia XX (1980).

(2) The quantity of the color additive does not exceed 2.5 percent by weight of the suture.

(3) When the sutures are used for the purposes specified in their labeling, the color additive does not migrate to the surrounding tissue.

(4) If the suture is a new drug, a new-drug application approved pursuant to section 505 of the act is in effect for it.

(d) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification.* All batches of D&C Blue No. 9 shall be certified in accordance with regulations in part 80 of this chapter.

[42 FR 15654, Mar. 22, 1977, as amended at 49 FR 10090, Mar. 19, 1984; 58 FR 17098, Apr. 1, 1993]

§ 74.1203 FD&C Green No. 3.

(a) *Identity and specifications.* (1) The color additive FD&C Green No. 3 shall conform in identity and specifications

to the requirements of § 74.203(a)(1) and (b).

(2) Color additive mixtures for drug use made with FD&C Green No. 3 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) *Uses and restrictions.* The color additive FD&C Green No. 3 may be safely used for coloring drugs generally in amounts consistent with current good manufacturing practice.

(c) *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.

(d) *Certification.* All batches of FD&C Green No. 3 shall be certified in accordance with regulations in part 80 of this chapter.

[47 FR 52144, Nov. 19, 1982]

§ 74.1205 D&C Green No. 5.

(a) *Identity.* (1) The color additive D&C Green No. 5 is principally the disodium salt of 2,2'-[(9,10-dihydro-9,10-dioxo-1,4-anthracenediyl)diimino]bis-[5-methylbenzenesulfonic acid] (CAS Reg. No. 4403-90-1).

(2) Color additive mixtures for use in drugs made with D&C Green No. 5 may contain only those diluents that are suitable and those that are listed in part 73 of this chapter for use in color additive mixtures for coloring drugs.

(b) *Specifications.* (1) D&C Green No. 5 for use in coloring surgical sutures 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 20 percent.

Water insoluble matter, not more than 0.2 percent.

1,4-Dihydroxyanthraquinone, not more than 0.2 percent.

2-Amino-*m*-toluenesulfonic acid, not more than 0.2 percent.

Subsidiary colors, not more than 5 percent.

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

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

Total color, not less than 80 percent.

(2) D&C Green No. 5 for use in coloring drugs shall conform to the following specifications and shall be free from impurities 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 20 percent.
 Water-insoluble matter, not more than 0.2 percent.
 1,4-Dihydroxyanthraquinone, not more than 0.2 percent.
 Sulfonated toluidines, total not more than 0.2 percent.
p-Toluidine, not more than 0.0015 percent.
 Sum of monosulfonated D&C Green No. 6 and Ext. D&C Violet No. 2, not more than 3 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 80 percent.

(c) *Use and restrictions.* (1) D&C Green No. 5 may be safely used to color nylon 66 (the copolymer of adipic acid and hexamethylenediamine) and/or nylon 6[poly-(*ε*-caprolactam)]nonabsorbable surgical sutures for use in general surgery, subject to the following restrictions:

(i) The quantity of color additive does not exceed 0.6 percent by weight of the suture.

(ii) When the sutures are used for the purposes specified in their labeling, there is no migration of the color additive to the surrounding tissue.

(iii) If the suture is a new drug, an approved new drug application, under section 505 of the act, is in effect for it.

(2) D&C Green No. 5 may be safely used for coloring drugs generally, including drugs intended for use in the area of the eye, in amounts consistent with current good manufacturing practice.

(d) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification.* All batches of D&C Green No. 5 shall be certified in accordance

with regulations in part 80 of this chapter.

[47 FR 24284, June 4, 1982; 47 FR 27551, June 25, 1982, as amended at 59 FR 40805, Aug. 10, 1994]

§ 74.1206 D&C Green No. 6.

(a) *Identity.* The color additive D&C Green No. 6 is 1,4-bis[(4-methylphenyl)amino]-9,10-anthracenedione (CAS. Reg. No. 128-80-3).

(b) *Specifications.* The color additive D&C Green No. 6 for use in coloring externally applied drugs shall conform to the following specifications and shall be free from impurities other than those named to the extent that such other impurities may be avoided by current good manufacturing practice:

Volatile matter (at 135 °C), not more than 2.0 percent.
 Water-soluble matter, not more than 0.3 percent.
 Matter insoluble in carbon tetrachloride, not more than 1.5 percent.
p-Toluidine, not more than 0.1 percent.
 1,4-Dihydroxyanthraquinone, not more than 0.2 percent.
 1-Hydroxy-4-[(4-methylphenyl)amino]-9, 10-anthracenedione, not more than 5.0 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 96.0 percent.

(c) *Uses and restrictions.* The color additive D&C Green No. 6 may be safely used for coloring externally applied drugs in amounts consistent with current good manufacturing practice.

(d) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

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

[42 FR 15654, Mar. 22, 1977, as amended at 47 FR 14146, Apr. 2, 1982; 47 FR 24278, June 4, 1982; 51 FR 9784, Mar. 21, 1986]

§ 74.1208 D&C Green No. 8.

(a) *Identity.* (1) The color additive D&C Green No. 8 is principally the trisodium salt of 8-hydroxy-1,3,6-pyrene-trisulfonic acid.

§ 74.1254

(2) Color additive mixtures for use in externally applied drugs made with D&C Green No. 8 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 Green No. 8 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 practices:

- Volatile matter (at 135 °C), not more than 15 percent.
- Water-insoluble matter, not more than 0.2 percent.
- Chlorides and sulfates (calculated as sodium salt), not more than 20 percent.
- The trisodium salt of 1,3,6-pyrenetrisulfonic acid, not more than 6 percent.
- The tetrasodium salt of 1,3,6,8-pyrenetetrasulfonic acid, not more than 1 percent.
- Pyrene, not more than 0.2 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 65 percent.

(c) *Uses and restrictions.* D&C Green No. 8 may be safely used in externally applied drugs in amounts not exceeding 0.01 percent by weight of the finished product.

(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 Green No. 8 shall be certified in accordance with regulations in part 80 of this chapter.

§ 74.1254 D&C Orange No. 4.

(a) *Identity.* (1) the color additive D&C Orange No. 4 is principally the sodium salt of 4-[(2-hydroxy-1-naphthalenyl)azo]benzenesulfonic acid.

(2) Color additive mixtures for use in externally applied drugs made with D&C Orange 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.

21 CFR Ch. I (4-1-25 Edition)

(b) *Specifications.* D&C Orange 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 13 percent.
- Water-insoluble matter, not more than 0.2 percent.
- 2-Naphthol, not more than 0.4 percent.
- Sulfanilic acid, sodium salt, not more than 0.2 percent.
- Subsidiary colors, not more than 3 percent.
- 4,4'-(Diazoamino)-dibzenesulfonic acid, not more than 0.1 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 87 percent.

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

[42 FR 52396, Sept. 30, 1977, as amended at 43 FR 14642, Apr. 7, 1978; 46 FR 8461, Jan. 27, 1981]

§ 74.1255 D&C Orange No. 5.

(a) *Identity.* (1) the color additive D&C Orange No. 5 is a mixture consisting principally the sodium salt of 4',5'-dibromofluorescein (CAS Reg. No. 596-03-2) and 2',4',5'-tribromofluorescein (CAS Reg. No. 25709-83-5) and 2',4',5',7'-tetrabromofluorescein (CAS Reg. No. 15086-94-9). D&C Orange No. 5 is manufactured by brominating fluorescein with elemental bromine. The fluorescein is manufactured by the acid condensation of resorcinol and phthalic acid or its anhydride. The fluorescein is isolated and partially purified prior to bromination.

(2) Color additive mixtures for drug use made with D&C Orange No. 5 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) *Specifications.* D&C Orange No. 5 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.

4',5'-dibromofluorescein, not less than 50 percent and not more than 65 percent.

2',4',5'-tribromofluorescein, not less than 30 percent and not more than 40 percent.

2',4',5',7'-tetrabromofluorescein, not more than 10 percent.

Sum of 2',4'-dibromofluorescein and 2',5'-dibromofluorescein, not more than 2 percent.

4'-Bromofluorescein, not more than 2 percent.

Fluorescein, not more than 1 percent.

Phthalic acid, not more than 1 percent.

2-(3,5-Dibromo-2,4-dihydroxybenzoyl) benzoic acid, not more than 0.5 percent.

Brominated resorcinol, not more than 0.4 percent.

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

Insoluble matter (alkaline solution), not more than 0.3 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 90 percent.

(c) *Uses and restrictions.* D&C Orange No. 5 may be safely used for coloring mouthwashes and dentifrices that are ingested drugs in amounts consistent with current good manufacturing practice. D&C Orange No. 5 may be safely used in externally applied drugs in amounts not exceeding 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 Orange No. 5 shall be certified in ac-

cordance with regulations in part 80 of this chapter.

[47 FR 44635, Nov. 2, 1982, as amended at 49 FR 13342, Apr. 4, 1984]

§ 74.1260 D&C Orange No. 10.

(a) *Identity.* (1) The color additive D&C Orange No. 10 is a mixture consisting principally of 4',5'-diiodofluorescein, 2',4',5'-triiodofluorescein, and 2',4',5',7'-tetraiodofluorescein.

(2) Color additive mixtures for drug use made with D&C Orange No. 10 may contain only those diluents listed in this subpart as safe and suitable for use in color additive mixtures for coloring externally applied drugs.

(b) *Specifications.* D&C Orange No. 10 shall conform to the following specifications and shall be free from impurities other than those named to the extent that such other impurities may be avoided by good manufacturing practice:

Sum of volatile matter (at 135 °C) and halides and sulfates (calculated as sodium salts), not more than 8 percent.

Insoluble matter (alkaline solution), not more than 0.5 percent.

Phthalic acid, not more than 0.5 percent.

2-[3',5'-Diiodo-2',4'-dihydroxybenzoyl] benzoic acid, not more than 0.5 percent.

Fluorescein, not more than 1 percent.

4'-Iodofluorescein, not more than 3 percent.

2',4'-Diiodofluorescein and 2',5'-diiodofluorescein, not more than 2 percent.

2',4',5'-Triiodofluorescein, not more than 35 percent.

2',4',5',7'-Tetraiodofluorescein, not more than 10 percent.

4',5'-Diiodofluorescein, not less than 60 percent and not more than 95 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 92 percent.

(c) *Uses and restrictions.* D&C Orange No. 10 may be safely used for coloring externally applied drugs in amounts consistent with good manufacturing practice.

(d) *Labeling requirements.* 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.

§ 74.1261

(e) *Certification.* All batches of D&C Orange No. 10 shall be certified in accordance with regulations in part 80 of this chapter.

[46 FR 18953, Mar. 27, 1981]

§ 74.1261 D&C Orange No. 11.

(a) *Identity.* (1) The color additive D&C Orange No. 11 is a mixture consisting principally of the disodium salts of 4',5'-diiodofluorescein, 2',4',5'-triiodofluorescein and 2',4',5',7'-tetraiodofluorescein.

(2) Color additive mixtures for drug use made with D&C Orange No. 11 may contain only those diluents listed in this subpart as safe and suitable for use in color additive mixtures for coloring externally applied drugs.

(b) *Specifications.* The color additive D&C Orange No. 11 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 halides and sulfates (calculated as sodium salts), not more than 8 percent.

Water-insoluble matter, not more than 0.5 percent.

Phthalic acid, not more than 0.5 percent.

2-[3',5'-Diiodo-2',4'-dihydroxybenzoyl] benzoic acid, sodium salt, not more than 0.5 percent.

Fluorescein, disodium salt, not more than 1 percent.

4'-Iodofluorescein, disodium salt, not more than 3 percent.

2',4'-Diiodofluorescein and 2',5'-diiodofluorescein, not more than 2 percent.

2',4',5'-Triiodofluorescein, not more than 35 percent.

2',4',5',7'-Tetraiodofluorescein, disodium salt, not more than 10 percent.

4',5'-Diiodofluorescein, disodium salt, not less than 60 percent and not more than 95 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 92 percent.

(c) *Uses and restrictions.* D&C Orange No. 11 may be safely used for coloring externally applied drugs in amounts consistent with good manufacturing practice.

21 CFR Ch. I (4–1–25 Edition)

(d) *Labeling requirements.* 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 Orange No. 11 shall be certified in accordance with regulations in part 80 of this chapter.

[46 FR 18953, Mar. 27, 1981]

§ 74.1303 FD&C Red No. 3.

(a) *Identity and specifications.* (1) The color additive FD&C Red No. 3 shall conform in identity and specifications to the requirements of § 74.303(a)(1) and (b).

(2) Color additive mixtures for ingested drug used made with FD&C Red No. 3 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 ingested drugs.

(b) *Uses and restrictions.* FD&C Red No. 3 may be safely used for coloring ingested drugs in amounts consistent with good manufacturing practice.

(c) *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.

(d) *Certification.* All batches of FD&C Red No. 3 shall be certified in accordance with regulations in part 80 of this chapter.

EFFECTIVE DATE NOTE: Amendments to § 74.1303 were published at 89 4634, Jan. 16, 2025, effective Jan. 15, 2027 and Jan. 18, 2028.

§ 74.1304 FD&C Red No. 4.

(a) *Identity.* (1) The color additive FD&C Red No. 4 is principally the disodium salt of 3-[(2,4-dimethyl-5-sulfophenyl)azo]-4-hydroxy-1-naphthalenesulfonic acid.

(2) Color additive mixtures for use in externally applied drugs made with FD&C Red 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.* FD&C Red 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 13 percent.

Water-insoluble matter, not more than 0.2 percent.

5-Amino-2,4-dimethyl-1-benzenesulfonic acid, sodium salt, not more than 0.2 percent.

4-Hydroxy-1-naphthalenesulfonic acid, sodium salt, not more than 0.2 percent.

Subsidiary colors, not more than 2 percent.

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.* FD&C Red 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 FD&C Red No. 4 shall be certified in accordance with regulations in part 80 of this chapter.

§ 74.1306 D&C Red No. 6.

(a) *Identity.* (1) The color additive D&C Red No. 6 is principally the disodium salt of 3-hydroxy-4-[(4-methyl-2-sulfophenyl)azo]-2-naphthalenecarboxylic acid (CAS Reg. No. 5858-81-1). 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-naphthalenecarboxylic acid. The resulting dye precipitates as the disodium salt.

(2) Color additive mixtures for drug use made with D&C Red No. 6 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. 6 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.

1-[(4-methylphenyl)azo]-2-naphthalenol, not more than 0.015 percent.

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

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

3-Hydroxy-4-[(4-methylphenyl)azo]-2-naphthalenecarboxylic 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. 6 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. 6 shall be certified in accordance with regulations in part 80 of this chapter.

[47 FR 57687, Dec. 28, 1982, as amended at 77 FR 39923, July 6, 2012]

§ 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-naphthalenecarboxylic 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-naphthalenecarboxylic acid

§ 74.1317

21 CFR Ch. I (4-1-25 Edition)

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.
- 1-[(4-methylphenyl)azo]-2-naphthalenol, not more than 0.015 percent.
- 2-Amino-5-methylbenzenesulfonic acid, calcium salt, not more than 0.2 percent.
- 3-Hydroxy-2-naphthalenecarboxylic acid, calcium salt, not more than 0.4 percent.
- 3-Hydroxy-4-[(4-methylphenyl)azo]-2-naphthalenecarboxylic 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. 28, 1982, as amended at 77 FR 39923, July 6, 2012]

§ 74.1317 D&C Red No. 17.

(a) *Identity.* (1) The color additive D&C Red No. 17 is principally 1-[[4-(phenylazo)phenyl]azo]-2-naphthalenol.

(2) Color additive mixtures for drug use made with D&C Red No. 17 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 externally applied drugs.

(b) *Specifications.* D&C Red No. 17 shall conform to the following specifications and shall be free from impurities, other than those named, to the extent that such other impurities may be avoided by good manufacturing practice:

- Volatile matter (at 135 °C), not more than 5 percent.
- Matter insoluble in both toluene and water (color additive mixed in toluene and the resultant residue isolated and mixed with water to obtain the matter insoluble in both toluene and water), not more than 0.5 percent.
- Chlorides and sulfates (calculated as sodium salts), not more than 3 percent.
- Aniline, not more than 0.2 percent.
- 4-Aminoazobenzene, not more than 0.1 percent.
- 2-Naphthol, not more than 0.2 percent.
- 1-(Phenylazo)-2-naphthol, not more than 3 percent.
- 1-[[2-(phenylazo) phenyl]azo]-2-naphthalenol, not more than 2 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 90 percent.

(c) *Uses and restrictions.* D&C Red No. 17 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 Red No. 17 shall be certified in accordance with regulations in part 80 of this chapter.

[42 FR 15654, Mar. 22, 1977, as amended at 42 FR 27225, May 27, 1977]

§ 74.1321 D&C Red No. 21.

(a) *Identity.* (1) The color additive D&C Red No. 21 is principally 2',4',5',7'-tetrabromofluorescein (CAS Reg. No. 15086-94-9), and may contain smaller amounts of 2',4',5'-tribromofluorescein (CAS Reg. No. 25709-83-5) and 2',4',7'-tribromofluorescein (CAS Reg. No.

25709-84-6). The color additive is manufactured by brominating fluorescein with elemental bromine. The fluorescein is manufactured by the acid condensation of resorcinol and phthalic acid or its anhydride. The fluorescein is isolated and partially purified prior to bromination.

(2) Color additive mixtures for drug use made with D&C Red No. 21 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. 21 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 halides and sulfates (calculated as sodium salts), not more than 10 percent.

Insoluble matter (alkaline solution), not more than 0.5 percent.

Phthalic acid, not more than 1 percent.

2-(3,5-Dibromo-2,4-dihydroxybenzoyl) benzoic acid, not more than 0.5 percent.

2',4',5',7'-Tetrabromofluorescein, ethyl ester, not more than 1 percent.

Brominated resorcinol, not more than 0.4 percent.

Fluorescein, not more than 0.2 percent.

Sum of mono- and dibromofluoresceins, not more than 2 percent.

Tribromofluoresceins, not more than 11 percent.

2',4',5',7'-Tetrabromofluorescein, not less than 87 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 90 percent.

(c) *Uses and restrictions.* The color additive D&C Red No. 21 may be safely used for coloring drugs generally 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 D&C Red No. 21 shall be certified in accord-

ance with regulations in part 80 of this chapter.

[47 FR 53846, Nov. 30, 1982]

§ 74.1322 D&C Red No. 22.

(a) *Identity.* (1) The color additive D&C Red No. 22 is principally the disodium salt of 2',4',5',7'-tetrabromofluorescein (CAS Reg. No. 17372-87-1) and may contain smaller amounts of the disodium salts of 2',4',5'-tribromofluorescein and 2',4',7'-tribromofluorescein. The color additive is manufactured by alkaline hydrolysis of 2',4',5',7'-tetrabromofluorescein. 2',4',5',7'-Tetrabromofluorescein is manufactured by brominating fluorescein with elemental bromine. The fluorescein is manufactured by the acid condensation of resorcinol and phthalic acid or its anhydride. Fluorescein is isolated and partially purified prior to bromination.

(2) Color additive mixtures for drug use made with Red No. 22 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. 22 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 halides and sulfates (calculated as sodium salts), not more than 10 percent.

Water-insoluble matter not more than 0.5 percent.

Disodium salt of phthalic acid, not more than 1 percent.

Sodium salt of 2-(3,5-Dibromo-2,4-dihydroxybenzoyl)benzoic acid, not more than 0.5 percent.

2',4',5',7'-Tetrabromofluorescein, ethyl ester, not more than 1 percent.

Brominated resorcinol, not more than 0.4 percent.

Sum of disodium salts of mono- and dibromofluoresceins, not more than 2 percent.

Sum of disodium salts of tribromofluoresceins, not more than 25 percent.

Disodium salt of 2',4',5',7'-Tetrabromofluorescein, not less than 72 percent.

Lead (as Pb), not more than 20 parts per million.

§ 74.1327

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. 22 may be safely used for coloring drugs generally 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 D&C Red No. 22 shall be certified in accordance with regulations in part 80 of this chapter.

[47 FR 53846, Nov. 30, 1982]

§ 74.1327 D&C Red No. 27.

(a) *Identity.* (1) The color additive D&C Red No. 27 is principally 2',4',5',7'-tetrabromo-4,5,6,7-tetrachlorofluorescein (CAS Reg. No. 13473-26-2). The color additive is manufactured by brominating 4,5,6,7-tetrachlorofluorescein with elemental bromine. The 4,5,6,7-

tetrachlorofluorescein is manufactured by the acid condensation of resorcinol and tetrachlorophthalic acid or its anhydride. The 4,5,6,7-tetrachlorofluorescein is isolated and partially purified prior to bromination.

(2) Color additive mixtures for drug use made with D&C Red No. 27 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.* D&C Red No. 27 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 halides and sulfates (calculated as sodium salts), not more than 10 percent.

Insoluble matter (alkaline solution), not more than 0.5 percent.

Tetrachlorophthalic acid, not more than 1.2 percent.

Brominated resorcinol, not more than 0.4 percent.

21 CFR Ch. I (4-1-25 Edition)

2,3,4,5-Tetrachloro-6-(3,5-dibromo-2,4-dihydroxybenzoyl) benzoic acid, not more than 0.7 percent.

2',4',5',7'-Tetrabromo-4,5,6,7-tetrachlorofluorescein, ethyl ester, not more than 2 percent.

Lower halogenated subsidiary colors, not more than 4 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 90 percent.

(c) *Uses and restrictions.* D&C Red No. 27 may be safely used for coloring drugs generally 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 D&C Red No. 27 shall be certified in accordance with regulations in part 80 of this chapter.

[47 FR 42567, Sept. 28, 1982; 47 FR 51106, Nov. 12, 1982]

§ 74.1328 D&C Red No. 28.

(a) *Identity.* (1) The color additive D&C Red No. 28 is principally the disodium salt of 2',4',5',7'-tetrabromo-4,5,6,7-tetrachlorofluorescein (CAS Reg. No. 18472-87-2) formed by alkaline hydrolysis of the parent tetrabromotetrachlorofluorescein.

(2) Color additive mixtures for drug use made with D&C Red No. 28 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.* D&C Red No. 28 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 halides and sulfates (calculated as sodium salts), not more than 15 percent.

Insoluble matter (alkaline solution), not more than 0.5 percent.

Tetrachlorophthalic acid, not more than 1.2 percent.

Food and Drug Administration, HHS

§ 74.1331

Brominated resorcinol, not more than 0.4 percent.
2,3,4,5-Tetrachloro-6-(3,5-dibromo-2,4-dihydroxybenzoyl)benzoic acid, not more than 0.7 percent.
2',4',5',7'-Tetrabromo-4,5,6,7-tetrachlorofluorescein, ethyl ester, not more than 2 percent.
Lower halogenated subsidiary colors, not more than 4 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 85 percent.

(c) *Uses and restrictions.* D&C Red No. 28 may be safely used for coloring drugs generally 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 D&C Red No. 28 shall be certified in accordance with regulations in part 80 of this chapter.

[47 FR 42568, Sept. 28, 1982]

§ 74.1330 D&C Red No. 30.

(a) *Identity.* (1) The color additive D&C Red No. 30 is principally 6-chloro-2-(6-chloro-4-methyl-3-oxobenzo[b]thien-2(3*H*)-ylidene)-4-methyl-benzo[b]thiophen-3(2*H*)-one (CAS Reg. No. 2379-74-0).

(2) Color additive mixtures for drug use made with D&C Red No. 30 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.* D&C Red No. 30 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:

Volatile matter (at 135 °C), not more than 5 percent.
Chlorides and sulfates (calculated as sodium salts), not more than 3 percent.
Matter soluble in acetone, not more than 5 percent.
Total color, not less than 90 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.

(c) *Uses and restrictions.* D&C Red No. 30 may be safely used for coloring drugs generally 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 D&C Red No. 30 shall be certified in accordance with regulations in part 80 of this chapter.

[47 FR 22510, May 25, 1982]

§ 74.1331 D&C Red No. 31.

(a) *Identity.* (1) The color additive D&C Red No. 31 is principally the calcium salt of 3-hydroxy-4-(phenylazo)-2-naphthalenecarboxylic acid.

(2) Color additive mixtures for drug use made with D&C Red No. 31 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 externally applied drugs.

(b) *Specifications.* D&C Red No. 31 shall conform to the following specifications and shall be free from impurities, other than those named, to the extent that such other 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 10 percent.
Aniline, not more than 0.2 percent.
3-Hydroxy-2-naphthoic acid, calcium salt, not more than 0.4 percent.
Subsidiary colors, not more than 1 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 90 percent.

(c) *Uses and restrictions.* D&C Red No. 31 may be safely used in externally applied drugs in amounts consistent with good manufacturing practice.

§ 74.1333

21 CFR Ch. I (4-1-25 Edition)

(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. 31 shall be certified in accordance with regulations in part 80 of this chapter.

§ 74.1333 D&C Red No. 33.

(a) *Identity.* (1) The color additive D&C Red No. 33 is principally the disodium salt of 5-amino-4-hydroxy-3-(phenylazo)-2,7-naphthalenedisulfonic acid (CAS Reg. No. 3567-66-6). To manufacture the additive, the product obtained from the nitrous acid diazotization of aniline is coupled with 4-hydroxy-5-amino-2,7-naphthalenedisulfonic acid in an alkaline aqueous medium. The color additive is isolated as the sodium salt.

(2) Color additive mixtures for drug use made with D&C Red No. 33 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.* D&C Red No. 33 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 practices:

- Sum of volatile matter at 135 °C (275 °F) and chlorides and sulfates (calculated as sodium salts), not more than 18 percent.
- Water-insoluble matter, not more than 0.3 percent.
- 4-Amino-5-hydroxy-2,7-naphthalenedisulfonic acid, disodium salt, not more than 0.3 percent.
- 4,5-Dihydroxy-3-(phenylazo)-2,7-naphthalenedisulfonic acid, disodium salt, not more than 3.0 percent.
- Aniline, not more than 25 parts per million.
- 4-Aminoazobenzene, not more than 100 parts per billion.
- 1,3-Diphenyltriazene, not more than 125 parts per billion.
- 4-Aminobiphenyl, not more than 275 parts per billion.
- Azobenzene, not more than 1 part per million.
- Benzdine, not more than 20 parts per billion.
- 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 82 percent.

(c) *Uses and restrictions.* The color additive D&C Red. No 33 may be safely used for coloring ingested drugs, other than mouthwashes and dentifrices, in amounts not to exceed 0.75 milligram per daily dose of the drug. D&C Red No. 33 may be safely used for coloring externally applied drugs, mouthwashes, and dentifrices in amounts consistent with current good manufacturing practice.

(d) *Labeling requirements.* 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. 33 shall be certified in accordance with regulations in part 80 of this chapter.

[53 FR 33120, Aug. 30, 1988]

§ 74.1334 D&C Red No. 34.

(a) *Identity.* (1) The color additive D&C Red No. 34 is principally the calcium salt of 3-hydroxy-4-[(1-sulfo-2-naphthalenyl)azo]-2-naphthalene-carboxylic acid.

(2) Color additive mixtures for drug use made with D&C Red No. 34 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 externally applied drugs.

(b) *Specifications.* D&C Red No. 34 shall conform to the following specifications and shall be free from impurities, other than those named, to the extent that such other impurities may be avoided by good manufacturing practice:

- Sum of volatile matter (at 135 °C) and chlorides and sulfates (calculated at sodium salts), not more than 15 percent.
- 2-Amino-1-naphthalenesulfonic acid, calcium salt, not more than 0.2 percent.
- 3-Hydroxy-2-naphthoic acid, not more than 0.4 percent.
- Subsidiary colors, not more than 4 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.

Food and Drug Administration, HHS

§ 74.1339

Total color not less than 85 percent.

(c) *Uses and restrictions.* The color additive D&C Red No. 34 may be safely used for coloring 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 Red No. 34 shall be certified in accordance with regulations in part 80 of this chapter.

§ 74.1336 D&C Red No. 36.

(a) *Identity.* (1) The color additive D&C Red No. 36 is 1-[(2-chloro-4-nitrophenyl)azo]-2-naphthalenol (CAS Reg. No. 2814-77-9). The color additive is manufactured by diazotization of 2-chloro-4-nitrobenzenamine in acid medium and coupling with 2-naphthalenol in acid medium.

(2) Color additive mixtures for drug use made with D&C Red No. 36 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.* D&C Red No. 36 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:

- Volatile matter at 135 °C (275 °F), not more than 1.5 percent.
- Matter insoluble in toluene, not more than 1.5 percent.
- 2-Chloro-4-nitrobenzenamine, not more than 0.3 percent.
- 2-Naphthalenol, not more than 1 percent.
- 2,4-Dinitrobenzenamine, not more than 0.02 percent.
- 1-[(2,4-Dinitrophenyl)azo]-2-naphthalenol, not more than 0.5 percent.
- 4-[(2-Chloro-4-nitrophenyl)azo]-1-naphthalenol, not more than 0.5 percent.
- 1-[(4-Nitrophenyl)azo]-2-naphthalenol, not more than 0.3 percent.
- 1-[(4-Chloro-2-nitrophenyl)azo]-2-naphthalenol, not more than 0.3 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 95 percent.

(c) *Uses and restrictions.* The color additive D&C Red No. 36 may be safely used for coloring ingested drugs, other than mouthwashes and dentifrices, in amounts not to exceed 1.7 milligrams per daily dose of the drug for drugs that are taken continuously only for less than 1 year. For drugs taken continuously for longer than 1 year, the color additive shall not be used in amounts to exceed 1.0 milligram per daily dose of the drug. D&C Red No. 36 may be safely used for coloring externally applied drugs in amounts consistent with current good manufacturing practice.

(d) *Labeling requirements.* 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. 36 shall be certified in accordance with regulations in part 80 of this chapter.

[53 FR 29031, Aug. 2, 1988; 53 FR 35255, Sept. 12, 1988, as amended at 53 FR 52130, Dec. 27, 1988]

§ 74.1339 D&C Red No. 39.

(a) *Identity.* (1) The color additive D&C Red No. 39 is *o*-[*p*(β,β'-dihydroxy-diethylamino)-phenylazo]-benzoic acid.

(2) Color additive mixtures made with D&C Red No. 39 may contain the following diluents: Water, acetone, isopropyl alcohol, and specially denatured alcohols used in accordance with 26 CFR part 212.

(b) *Specifications.* D&C Red No. 39 shall conform to the following specifications and shall be free from impurities other than those named to the extent that such other impurities may be avoided by good manufacturing practice:

- Volatile matter (at 100 °C.), not more than 2.0 percent.
- Matter insoluble in acetone, not more than 1.0 percent.
- Anthranilic acid, not more than 0.2 percent.
- N,N*-(β,β'-Dihydroxy-diethyl) aniline, not more than 0.2 percent.
- Subsidiary colors, not more than 3.0 percent.
- Lead (as Pb), not more than 20 parts per million.

§ 74.1340

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

Total color, not less than 95.0 percent.

(c) *Uses and restrictions.* The color additive D&C Red No. 39 may be safely used for the coloring of quaternary ammonium type germicidal solutions intended for external application only, and subject to the further restriction that the quantity of the color additive does not exceed 0.1 percent by weight of the finished drug product.

(d) *Labeling.* The label of the color additive and any mixtures prepared therefrom and 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. 39 shall be certified in accordance with regulations promulgated under part 80 of this chapter.

§ 74.1340 FD&C Red No. 40.

(a) *Identity and specifications.* (1) The color additive FD&C Red No. 40 shall conform in identity and specifications to the requirements of § 74.340(a)(1) and (b).

(2) Color additive mixtures for drug use made with FD&C Red No. 40 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.

(3) The listing of this color additive includes lakes prepared as described in §§ 82.51 and 82.1051 of this chapter, except that the color additive used is FD&C Red No. 40 and the resultant lakes meet the specification and labeling requirements prescribed by §§ 82.51 or 82.1051 of this chapter.)

(b) *Uses and restrictions.* (1) FD&C Red No. 40 and FD&C Red No. 40 Aluminum Lake may be safely used in coloring drugs, including those intended for use in the area of the eye, subject to the restrictions on the use of color additives in § 70.5(b) and (c) of this chapter, in amounts consistent with current good manufacturing practice.

(2) Other lakes of FD&C Red No. 40 may be safely used in coloring drugs, subject to the restrictions on the use of color additives in § 70.5 of this chapter, in amounts consistent with current good manufacturing practice.

21 CFR Ch. I (4-1-25 Edition)

(c) *Labeling.* The label of the color additive and any lakes or mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(d) *Certification.* All batches of FD&C Red No. 40 and lakes thereof shall be certified in accordance with regulations, in part 80 of this chapter.

[42 FR 15654, Mar. 22, 1977, as amended at 59 FR 7636, Feb. 16, 1994]

§ 74.1602 D&C Violet No. 2.

(a) *Identity.* (1) The color additive D&C Violet No. 2 is principally 1-hydroxy -4-[(4-methylphenyl)amino]-9,10-anthracenedione.

(2) Color additive mixtures for use in externally applied drugs made with D&C Violet 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 externally applied drugs.

(b) *Specifications.* D&C Violet No. 2 shall conform to the following specifications and shall be free from impurities, other than those named, to the extent that such other impurities can be avoided by good manufacturing practice:

Volatile matter (at 135 °C.), not more than 2.0 percent.

Matter insoluble in both carbon tetrachloride and water, not more than 0.5 percent.

p-Toluidine, not more than 0.2 percent.

1-Hydroxy-9,10-anthracenedione, not more than 0.5 percent.

1,4-Dihydroxy-9,10-anthracenedione, not more than 0.5 percent.

Subsidiary colors, not more than 1.0 percent.

Lead (as Pb), not more than 20 parts per million.

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

Total color, not less than 96.0 percent.

(c) *Uses and restrictions.* The color additive D&C Violet No. 2 may be safely used for coloring 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 Violet No. 2 shall be certified in accordance with regulations in part 80 of this chapter.

[42 FR 15654, Mar. 22, 1977, as amended at 45 FR 62978, Sept. 23, 1980; 55 FR 18868, May 7, 1990]

§ 74.1705 FD&C Yellow No. 5.

(a) *Identity and specifications.* (1) The color additive FD&C Yellow No. 5 shall conform in identity and specifications to the requirements of § 74.705 (a)(1) and (b).

(2) FD&C Yellow No. 5 Aluminum Lake shall be prepared in accordance with the requirements of § 82.51 of this chapter.

(3) Color additive mixtures for drug use made with FD&C Yellow No. 5 may contain only those diluents that are suitable and are listed in part 73 of this chapter as safe for use in color additive mixtures for coloring drugs.

(b) *Uses and restrictions.* (1) FD&C Yellow No. 5 may be safely used for coloring drugs generally, including drugs intended for use in the area of the eye, in amounts consistent with current good manufacturing practice.

(2) FD&C Yellow No. 5 Aluminum Lake may be safely used for coloring drugs intended for use in the area of the eye, when prepared in accordance with § 82.51 of this chapter.

(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) The label of OTC and prescription drug products intended for human use administered orally, nasally, rectally, or vaginally, or for use in the area of the eye, containing FD&C Yellow No. 5 shall specifically declare the presence of FD&C Yellow No. 5 by listing the color additive using the names FD&C Yellow No. 5 and tartrazine. The label shall bear a statement such as "Contains FD&C Yellow No. 5 (tartrazine) as a color additive" or "Contains color additives including FD&C Yellow No. 5 (tartrazine)." The labels of certain drug products subject to this labeling requirement that are also cosmetics, such as: antibacterial mouthwashes and fluoride toothpastes, need not com-

ply with this requirement provided they comply with the requirements of § 701.3 of this chapter.

(3) For prescription drugs for human use containing FD&C Yellow No. 5 that are administered orally, nasally, vaginally, or rectally, or for use in the area of the eye, the labeling required by § 201.100(d) of this chapter shall, in addition to the label statement required under paragraph (c)(2) of this section, bear the warning statement "This product contains FD&C Yellow No. 5 (tartrazine) which may cause allergic-type reactions (including bronchial asthma) in certain susceptible persons. Although the overall incidence of FD&C Yellow No. 5 (tartrazine) sensitivity in the general population is low, it is frequently seen in patients who also have aspirin hypersensitivity." This warning statement shall appear in the "Precautions" section of the labeling.

(d) *Certification.* All batches of FD&C Yellow No. 5 shall be certified in accordance with regulations in part 80 of this chapter.

[42 FR 15654, Mar. 22, 1977, as amended at 44 FR 37220, June 26, 1979; 50 FR 35782, Sept. 4, 1985; 51 FR 24519, July 7, 1986; 59 FR 60897, Nov. 29, 1994]

§ 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 as safe 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]

§ 74.1707

21 CFR Ch. I (4-1-25 Edition)

(d) *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]

§ 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 8-hydroxy-5,7-dinitro-2-naphthalenesulfonic acid.

(2) Color additive mixtures for drug use made with Ext. D&C Yellow 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 externally applied drugs.

(b) *Specifications.* Ext. 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 other 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.

1-Naphthol, not more than 0.2 percent.

2,4-Dinitro-1-naphthol, not more than 0.03 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 85 percent.

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

§ 74.1708 D&C Yellow No. 8.

(a) *Identity.* (1) The color additive D&C Yellow No. 8 is principally the disodium salt of fluorescein.

(2) Color additive mixtures for use in externally applied drugs made with D&C Yellow No. 8 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. 8 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 15 percent.

Matter insoluble in alkaline water, not more than 0.3 percent.

Resorcinol, not more than 0.5 percent.

Phthalic acid, not more than 1 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 85 percent.

(c) *Uses and restrictions.* D&C Yellow No. 8 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. 8 shall be certified in accordance with regulations in part 80 of this chapter.

§ 74.1710 D&C Yellow No. 10.

(a) *Identity.* (1) The color additive D&C Yellow No. 10 is a mixture of the sodium salts of the mono- and disulfonic acids of 2-(2-quinolinyl)-1*H*-indene-1,3 (2*H*)-dione consisting principally of the sodium salts of 2-(2,3-dihydro-1,3-dioxo-1*H*-indene-2-yl)-6-quinolinesulfonic acid and 2-(2,3-dihydro-1,3-dioxo-1*H*-indene-2-yl)-8-quinolinesulfonic acid with lesser amounts of the disodium salts of the disulfonic acids of 2-(2-quinolinyl)-1*H*-indene-1,3(2*H*)-dione (CAS Reg. No. 8004-92-0). D&C Yellow No. 10 is manufactured by condensing quinaldine with phthalic anhydride to give the unsulfonated dye, which is then sulfonated with oleum.

(2) Color additive mixtures made with D&C Yellow No. 10 for drug use 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 Yellow No. 10 shall conform to the

following specifications and shall be free from impurities 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 (275 °F) and chlorides and sulfates (calculated as sodium salts), not more than 15 percent.

Matter insoluble in both water and chloroform, not more than 0.2 percent.

Total sulfonated quinaldines, sodium salts, not more than 0.2 percent.

Total sulfonated phthalic acids, sodium salts, not more than 0.2 percent.

2-(2-Quinolinyl)-1*H*-indene-1,3 (2*H*)-dione, not more than 4 parts per million.

Sum of sodium salts of the monosulfonates of 2-(2-quinolinyl)-1*H*-indene-1,3 (2*H*)-dione, not less than 75 percent.

Sum of sodium salts of the disulfonates of 2-(2-quinolinyl)-1*H*-indene-1,3 (2*H*)-dione, not more than 15 percent.

2-(2,3-Dihydro-1,3-dioxo-1*H*-indene-2-yl)-6, 8-quinolinedisulfonic acid, disodium salt, not more than 3 percent.

Diethyl ether soluble matter other than that specified, not more than 2 parts per million, using added 2-(2-quinolinyl)-1*H*-indene-1,3 (2*H*)-dione for calibration.

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.* The color additive D&C Yellow No. 10 may be safely used for coloring drugs generally in amounts consistent with current good manufacturing practice.

(d) *Labeling.* The label of the color additive and any mixtures prepared therefrom and 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. 10 shall be certified in accordance with regulations in part 80 of this chapter.

[48 FR 39219, Aug. 30, 1983, as amended at 49 FR 8432, Mar. 7, 1984]

§ 74.1711 D&C Yellow No. 11.

(a) *Identity.* (1) The color additive D&C Yellow No. 11 is principally 2-(2-quinolyl)-1,3-indandione.

(2) Color additive mixtures, for drug use made with D&C Yellow No. 11 may contain only those diluents that are

§ 74.2052

21 CFR Ch. I (4–1–25 Edition)

suitable and that are listed in part 73 of this chapter as safe for use in color additive mixtures for coloring externally applied drugs.

(b) *Specifications.* D&C Yellow No. 11 shall conform to the following specifications and shall be free from impurities, other than those named, to the extent that such other impurities may be avoided by good manufacturing practice:

Volatile matter (at 135 °C), not more than 1 percent.

Ethyl alcohol-insoluble matter, not more than 0.4 percent.

Phthalic acid, not more than 0.3 percent.

Quinaldine, not more than 0.2 percent.

Subsidiary colors, not more than 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 96 percent.

(c) *Uses and restrictions.* D&C Yellow No. 11 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. 11 shall be certified in accordance with regulations in part 80 of this chapter.

Subpart C—Cosmetics

§ 74.2052 **D&C Black No. 2.**

(a) *Identity.* The color additive D&C Black No. 2 is a high-purity carbon black prepared by the oil furnace process. It is manufactured by the combustion of aromatic petroleum oil feedstock and consists essentially of pure carbon, formed as aggregated fine particles with a surface area range of 200 to 260 meters (m)²/gram.

(b) *Specifications.* D&C Black No. 2 shall conform to the following specifications and shall be free from impurities other than those named to the extent that such other impurities may be avoided by good manufacturing practice:

(1) Surface area by nitrogen BET (Brunauer, Emmett, Teller) method, 200 to 260 m²/gram.

(2) Weight loss on heating at 950 °C for 7 minutes (predried for 1 hour at 125 °C), not more than 2 percent.

(3) Ash content, not more than 0.15 percent.

(4) Arsenic (total), not more than 3 milligrams per kilogram (mg/kg) (3 parts per million).

(5) Lead (total), not more than 10 mg/kg (10 parts per million).

(6) Mercury (total), not more than 1 mg/kg (1 part per million).

(7) Total sulfur, not more than 0.65 percent.

(8) Total PAHs, not more than 0.5 mg/kg (500 parts per billion).

(9) Benzo[*a*]pyrene, not more than 0.005 mg/kg (5 parts per billion).

(10) Dibenz[*a,h*]anthracene, not more than 0.005 mg/kg (5 parts per billion).

(11) Total color (as carbon), not less than 95 percent.

(c) *Uses and restrictions.* D&C Black No. 2 may be safely used for coloring the following cosmetics in amounts consistent with current good manufacturing practice: Eyeliner, brush-on-brow, eye shadow, mascara, lipstick, blushers and rouge, makeup and foundation, and nail enamel.

(d) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification.* All batches of D&C Black No. 2 shall be certified in accordance with regulations in part 80 of this chapter.

[69 FR 44930, July 28, 2004, as amended at 72 FR 10357]

§ 74.2053 **D&C Black No. 3.**

(a) *Identity.* The color additive D&C Black No. 3 is a washed bone char prepared from calcined cattle bones. The bones are twice heated in excess of 700 °C for at least 6 hours.

(b) *Specifications.* D&C Black No. 3 shall conform to the following specifications and shall be free from impurities other than those named, to the extent that such other impurities may be avoided by current good manufacturing practices:

(1) Calcium hydroxyapatite (CaO and P₂O₅), not less than 75 percent and not more than 84 percent;

(2) Elemental carbon, not less than 7 percent;

(3) Moisture, not more than 7 percent;

(4) Silica (SiO₂), not more than 5 percent;

(5) Arsenic, not more than 3 milligrams (mg)/kilogram (kg) (3 parts per million (ppm));

(6) Lead, not more than 10 mg/kg (10 ppm); and

(7) Total polycyclic aromatic hydrocarbons (PAHs), not more than 5 mg/kg (5 ppm).

(c) *Uses and restrictions.* Cosmetics containing D&C Black No. 3 must comply with § 700.27 of this chapter with respect to prohibited cattle materials in cosmetic products. D&C Black No. 3 may be safely used for coloring the following cosmetics in amounts consistent with current good manufacturing practice: Eyeliner, eye shadow, mascara, and face powder.

(d) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification.* All batches of D&C Black No. 3 shall be certified in accordance with regulations in part 80 of this chapter.

[72 FR 33666, June 19, 2007]

§ 74.2101 FD&C Blue No. 1.

(a) *Identity.* The color additive FD&C Blue No. 1 is principally the disodium salt of ethyl[4-[p-[ethyl(*m*-sulfo benzyl)amino]- α -(*o*-sulfo phenyl)benzylidene]-2,5-cyclohexadien-1-ylidene](*m*-sulfo benzyl)ammonium hydroxide inner salt with smaller amounts of the isomeric disodium salts of ethyl[4-[p-[ethyl(*p*-sulfo benzyl)amino]- α -(*o*-sulfo phenyl)benzylidene]-2,5-cyclohexadien-1-ylidene](*p*-sulfo benzyl)ammonium hydroxide inner salt and ethyl[4-[p-[ethyl(*o*-sulfo benzyl)amino]- α -(*o*-sulfo phenyl)benzylidene]-2,5-cyclohexadien-1-ylidene](*o*-sulfo benzyl)ammonium hydroxide inner salt. Additionally, FD&C Blue No. 1 is manufactured by the acid catalyzed condensation of one mole of sodium 2-formylbenzenesulfonate with two moles from a mixture consisting principally of 3-[(ethylphenylamino)methyl]

benzenesulfonic acid, and smaller amounts of 4-[(ethylphenylamino)methyl]benzenesulfonic acid and 2-[(ethylphenylamino)methyl]benzenesulfonic acid to form the leuco base. The leuco base is then oxidized with lead dioxide and acid, or with dichromate and acid, or with manganese dioxide and acid to form the dye. The intermediate sodium 2-formylbenzenesulfonate is prepared from 2-chlorobenzaldehyde and sodium sulfite.

(b) *Specifications.* (1) The color additive FD&C Blue No. 1 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 cosmetics generally, including cosmetics 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 cosmetics intended for use in the area of the eye, in amounts consistent with current good manufacturing practice.

(d) *Labeling.* The label of the color additive 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 58 FR 17511, Apr. 5, 1993; 59 FR 7638, Feb. 16, 1994]

§ 74.2104 D&C Blue No. 4.

(a) *Identity and specifications.* The color additive D&C Blue No. 4 shall conform in identity and specifications to the requirements of § 74.1104(a)(1) and (b).

(b) *Uses and restrictions.* D&C Blue No. 4 may be safely used for coloring externally applied cosmetics in amounts consistent with good manufacturing practice.

(c) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

§ 74.2151

(d) *Certification.* All batches of D&C Blue No. 4 shall be certified in accordance with regulations in part 80 of this chapter.

§ 74.2151 D&C Brown No. 1.

(a) *Identity.* The color additive D&C Brown No. 1 is a mixture of the sodium salts of 4[[5-[(dialkylphenyl)-azo]-2,4-dihydroxyphenyl]azo]-benzene sulfonic acid. The alkyl group is principally the methyl group.

(b) *Specifications.* D&C Brown No. 1 shall conform to the following specifications and shall be free from impurities other than those named to the extent that such other 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 16 percent.
- Water-insoluble matter, not more than 0.2 percent.
- Sulfanilic acid, sodium salt, not more than 0.2 percent.
- Resorcinol, not more than 0.2 percent.
- Xylidines, not more than 0.2 percent.
- Disodium salt of 4[[5-[(4-sulfoxyphenyl)-azo]-2,4-dihydroxyphenyl]azo] benzenesulfonic acid, not more than 3 percent.
- Monosodium salt of 4[[5-[(2,4-dimethylphenyl)azo]-2,4-dihydroxyphenyl]azo] benzenesulfonic acid, not less than 29 percent and not more than 39 percent.
- Monosodium salt of 4[[5-[(2,5-dimethylphenyl)azo]-2,4-dihydroxyphenyl]azo] benzenesulfonic acid, not less than 12 percent and not more than 17 percent.
- Monosodium salt of 4[[5-[(2,3-dimethylphenyl)azo]-2,4-dihydroxyphenyl]azo] benzenesulfonic acid, not less than 6 percent and not more than 13 percent.
- Monosodium salt of 4[[5-[(2-ethylphenyl)-azo]-2,4-dihydroxyphenyl]-azo] benzenesulfonic acid, not less than 5 percent and not more than 12 percent.
- Monosodium salt of 4[[5-[(3,4-dimethylphenyl)azo]-2,4-dihydroxyphenyl]azo] benzenesulfonic acid, not less than 3 percent and not more than 9 percent.
- Monosodium salt of 4[[5-[(2,6-dimethylphenyl)azo]-2,4-dihydroxyphenyl]azo] benzenesulfonic acid, not less than 3 percent and not more than 8 percent.
- Monosodium salt of 4[[5-[(4-ethylphenyl)azo]-2,4-dihydroxyphenyl]-azo] benzenesulfonic acid, not less than 2 percent and not more than 8 percent.
- Lead (as Pb), not more than 20 parts per million.
- Arsenic (as As), not more than 3 parts per million.

21 CFR Ch. I (4-1-25 Edition)

Mercury (as Hg), not more than 1 part per million.

Total color, not less than 84 percent.

(c) *Uses and restrictions.* D&C Brown No. 1 may be safely used for coloring externally applied cosmetics in amounts consistent with good manufacturing practice.

(d) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification.* All batches of D&C Brown No. 1 shall be certified in accordance with regulations in part 80 of this chapter.

§ 74.2203 FD&C Green No. 3.

(a) *Identity and specifications.* The color additive FD&C Green No. 3 shall conform in identity and specifications to the requirements of § 74.203(a)(1) and (b).

(b) *Uses and restrictions.* The color additive FD&C Green No. 3 may be safely used for coloring cosmetics generally in amounts consistent with current good manufacturing practice.

(c) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Certification.* All batches of FD&C Green No. 3 shall be certified in accordance with regulations in part 80 of this chapter.

[47 FR 52144, Nov. 19, 1982]

§ 74.2205 D&C Green No. 5.

(a) *Identity and specifications.* The color additive D&C Green No. 5 shall conform in identity and specifications to the requirements of § 74.1205 (a)(1) and (b)(2).

(b) *Uses and restrictions.* D&C Green No. 5 may be safely used for coloring cosmetics generally, including cosmetics intended for use in the area of the eye, in amounts consistent with current good manufacturing practice.

(c) *Labeling requirements.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Certification.* All batches of D&C Green No. 5 shall be certified in accordance with regulations in part 80 of this chapter.

[47 FR 24285, June 4, 1982, as amended at 59 FR 40805, Aug. 10, 1994]

§ 74.2206 D&C Green No. 6.

(a) *Identity and specifications.* The color additive D&C Green No. 6 shall conform in identity and specifications to the requirements of § 74.1206 (a) and (b).

(b) *Uses and restrictions.* D&C Green No. 6 may be safely used for coloring externally applied cosmetics in amounts consistent with good manufacturing practice.

(c) *Labeling requirements.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

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

[47 FR 14146, Apr. 4, 1982, as amended at 51 FR 9784, Mar. 21, 1986]

§ 74.2208 D&C Green No. 8.

(a) *Identity and specifications.* The color additive D&C Green No. 8 shall conform in identity and specifications to the requirements of § 74.1208(a)(1) and (b).

(b) *Uses and restrictions.* D&C Green No. 8 may be safely used for coloring externally applied cosmetics in amounts not exceeding 0.01 percent by weight of the finished cosmetic product.

(c) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Certification.* All batches of D&C Green No. 8 shall be certified in accordance with regulations in part 80 of this chapter.

§ 74.2254 D&C Orange No. 4.

(a) *Identity and specifications.* The color additive D&C Orange No. 4 shall conform in identity and specifications to the requirements of § 74.1254 (a)(1) and (b).

(b) *Uses and restrictions.* D&C Orange No. 4 may be safely used for coloring externally applied cosmetics in amounts consistent with good manufacturing practice.

(c) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Certification.* All batches of D&C Orange No. 4 shall be certified in ac-

cordance with regulations in part 80 of this chapter.

[42 FR 52396, Sept. 30, 1977]

§ 74.2255 D&C Orange No. 5.

(a) *Identity and specifications.* The color additive D&C Orange No. 5 shall conform in identity and specifications to the requirements of § 74.1255 (a)(1) and (b).

(b) *Uses and restrictions.* D&C Orange No. 5 may be safely used for coloring mouthwashes and dentifrices that are ingested cosmetics in amounts consistent with current good manufacturing practice. D&C Orange No. 5 may be safely used for coloring lipsticks and other cosmetics intended to be applied to the lips in amounts not exceeding 5.0 percent by weight of the finished cosmetic products. D&C Orange No. 5 may be safely used for coloring externally applied cosmetics in amounts consistent with current good manufacturing practice.

(c) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Certification.* All batches of D&C Orange No. 5 shall be certified in accordance with regulations in part 80 of this chapter.

[47 FR 49635, Nov. 2, 1982, as amended at 49 FR 13342, Apr. 4, 1984]

§ 74.2260 D&C Orange No. 10.

(a) *Identity and specifications.* The color additive D&C Orange No. 10 shall conform in identity and specifications to the requirements of § 74.1260(a)(1) and (b).

(b) *Uses and restrictions.* D&C Orange No. 10 may be safely used for coloring externally applied cosmetics in amounts consistent with good manufacturing practice.

(c) *Labeling requirements.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Certification.* All batches of D&C Orange No. 11 shall be certified in accordance with regulations in part 80 of this chapter.

[46 FR 18954, Mar. 27, 1981]

§ 74.2261 D&C Orange No. 11.

(a) *Identity and specifications.* The color additive D&C Orange No. 11 shall

§ 74.2304

conform in identity and specifications to the requirements of §74.1261(a)(1) and (b).

(b) *Uses and restrictions.* D&C Orange No. 11 may be safely used for coloring externally applied cosmetics in amounts consistent with good manufacturing practice.

(c) *Labeling requirements.* The label of the color additive shall conform to the requirements of §70.25 of this chapter.

(d) *Certification.* All batches of D&C Orange No. 11 shall be certified in accordance with regulations in part 80 of this chapter.

[46 FR 18954, Mar. 27, 1981]

§ 74.2304 FD&C Red No. 4.

(a) *Identity and specifications.* The color additive FD&C Red No. 4 shall conform in identity and specifications to the requirements of §74.1304(a)(1) and (b).

(b) *Uses and restrictions.* FD&C Red No. 4 may be safely used for coloring externally applied cosmetics in amounts consistent with good manufacturing practice.

(c) *Labeling.* The label of the color additive shall conform to the requirements of §70.25 of this chapter.

(d) *Certification.* All batches of FD&C Red No. 4 shall be certified in accordance with regulations in part 80 of this chapter.

§ 74.2306 D&C Red No. 6.

(a) *Identity and specifications.* The color additive D&C Red No. 6 shall conform in identity and specifications to the requirements of §74.1306 (a)(1) and (b).

(b) *Uses and restrictions.* The color additive D&C Red No. 6 may be safely used for coloring cosmetics generally in amounts consistent with current good manufacturing practice.

(c) *Labeling requirements.* The label of the color additive shall conform to the requirements of §70.25 of this chapter.

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

[47 FR 57688, Dec. 28, 1982]

21 CFR Ch. I (4–1–25 Edition)

§ 74.2307 D&C Red No. 7

(a) *Identity and specifications.* The color additive D&C Red No. 7 shall conform in identity and specifications to the requirements of §74.1307 (a)(1) and (b).

(b) *Uses and restrictions.* The color additive D&C Red No. 7 may be safely used for coloring cosmetics generally in amounts consistent with current good manufacturing practice.

(c) *Labeling requirements.* The label of the color additive shall conform to the requirements of §70.25 of this chapter.

(d) *Certification.* All batches of D&C Red No. 7 shall be certified in accordance with regulations in part 80 of this chapter.

[47 FR 57688, Dec. 28, 1982]

§ 74.2317 D&C Red No. 17.

(a) *Identity and specifications.* The color additive D&C Red No. 17 shall conform in identity and specifications to the requirements of §74.1317(a)(1) and (b).

(b) *Uses and restrictions.* D&C Red No. 17 may be safely used for coloring externally applied cosmetics in amounts consistent with good manufacturing practice.

(c) *Labeling.* The label of the color additive shall conform to the requirements of §70.25 of this chapter.

(d) *Certification.* All batches of D&C Red No. 17 shall be certified in accordance with regulations in part 80 of this chapter.

§ 74.2321 D&C Red No. 21.

(a) *Identity and specifications.* The color additive D&C Red No. 21 shall conform in identity and specifications to the requirements of §74.1321(a)(1) and (b).

(b) *Uses and restrictions.* The color additive D&C Red No. 21 may be safely used for coloring cosmetics generally in amounts consistent with current good manufacturing practice.

(c) *Labeling requirements.* The label of the color additive shall conform to the requirements of §70.25 of this chapter.

(d) *Certification.* All batches of D&C Red No. 21 shall be certified in accordance with regulations in part 80 of this chapter.

[47 FR 53846, Nov. 30, 1982]

§ 74.2322 D&C Red No. 22.

(a) *Identity and specifications.* The color additive D&C Red No. 22 shall conform in identity and specifications to the requirements of §74.1322(a)(1) and (b).

(b) *Uses and restrictions.* The color additive D&C Red No. 22 may be safely used for coloring cosmetics generally in amounts consistent with current good manufacturing practice.

(c) *Labeling requirements.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Certification.* All batches of D&C Red No. 22 shall be certified in accordance with regulations in part 80 of this chapter.

[47 FR 53846, Nov. 30, 1982]

§ 74.2327 D&C Red No. 27.

(a) *Identity and specifications.* The color additive D&C Red No. 27 shall conform in identity and specifications to the requirements of §74.1327 (a)(1) and (b).

(b) *Uses and restrictions.* D&C Red No. 27 may be safely used for coloring cosmetics generally in amounts consistent with current good manufacturing practice.

(c) *Labeling requirements.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Certification.* All batches of D&C Red No. 27 shall be certified in accordance with regulations in part 80 of this chapter.

[47 FR 42568, Sept. 28, 1982]

§ 74.2328 D&C Red No. 28.

(a) *Identity and specifications.* The color additive D&C Red No. 28 shall conform in identity and specifications to the requirements of §74.1328 (a)(1) and (b).

(b) *Uses and restrictions.* D&C Red No. 28 may be safely used for coloring cosmetics generally in amounts consistent with current good manufacturing practice.

(c) *Labeling requirements.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Certification.* All batches of D&C Red No. 28 shall be certified in accord-

ance with regulations in part 80 of this chapter.

[47 FR 42568, Sept. 28, 1982]

§ 74.2330 D&C Red No. 30.

(a) *Identity and specifications.* The color additive D&C Red No. 30 shall conform in identity and specifications to the requirements of §74.1330 (a)(1) and (b).

(b) *Uses and restrictions.* D&C Red No. 30 may be safely used for coloring cosmetics generally in amounts consistent with current good manufacturing practice.

(c) *Labeling requirements.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Certification.* All batches of D&C Red No. 30 shall be certified in accordance with regulations in part 80 of this chapter.

[47 FR 22511, May 25, 1982]

§ 74.2331 D&C Red No. 31.

(a) *Identity and specifications.* The color additive D&C Red No. 31 shall conform in identity and specifications to the requirements of §74.1331(a)(1) and (b).

(b) *Uses and restrictions.* D&C Red No. 31 may be safely used for coloring externally applied cosmetics in amounts consistent with good manufacturing practice.

(c) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Certification.* All batches of D&C Red No. 31 shall be certified in accordance with regulations in part 80 of this chapter.

§ 74.2333 D&C Red No. 33.

(a) *Identity and specifications.* The color additive D&C Red No. 33 shall conform in identity and specifications to the requirements of §74.1333(a) (1) and (b).

(b) *Uses and restrictions.* The color additive D&C Red No. 33 may be safely used for coloring cosmetic lip products in amounts not to exceed 3 percent total color by weight of the finished cosmetic products. D&C Red No. 33 may be safely used for coloring

§ 74.2334

mouthwashes (including breath fresheners), dentifrices, and externally applied cosmetics in amounts consistent with current good manufacturing practice.

(c) *Labeling requirements.* 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.

(d) *Certification.* All batches of D&C Red No. 33 shall be certified in accordance with regulations in part 80 of this chapter.

[53 FR 33120, Aug. 30, 1988]

§ 74.2334 D&C Red No. 34.

(a) *Identity and specifications.* The color additive D&C Red No. 34 shall conform in identity and specifications to the requirements of § 74.1334(a)(1) and (b).

(b) *Uses and restrictions.* D&C Red No. 34 may be safely used for coloring externally applied cosmetics in amounts consistent with good manufacturing practice.

(c) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Certification.* All batches of D&C Red No. 34 shall be certified in accordance with regulations in part 80 of this chapter.

§ 74.2336 D&C Red No. 36.

(a) *Identity and specifications.* The color additive D&C Red No. 36 shall conform in identity and specifications to the requirements of § 74.1336 (a)(1) and (b).

(b) *Uses and restrictions.* The color additive D&C Red No. 36 may be safely used for coloring cosmetic lip products in amounts not to exceed 3 percent total color by weight of the finished cosmetic products. D&C Red No. 36 may be safely used for coloring externally applied cosmetics in amounts consistent with current good manufacturing practice.

(c) *Labeling requirements.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Certification.* All batches of D&C Red No. 36 shall be certified in accord-

21 CFR Ch. I (4–1–25 Edition)

ance with regulations in part 80 of this chapter.

[53 FR 29031, Aug. 2, 1988]

§ 74.2340 FD&C Red No. 40.

(a) *Identity and specifications.* (1) The color additive FD&C Red No. 40 shall conform in identity and specifications to the requirements of § 74.340(a)(1) and (b) of this chapter.

(2) The listing of this color additive includes lakes prepared as described in §§ 82.51 and 82.1051 of this chapter, except that the color additive used is FD&C Red No. 40 and the resultant lakes meet the specification and labeling requirements prescribed by § 82.51 or § 82.1051 of this chapter.

(b) *Uses and restrictions.* FD&C Red No. 40 may be safely used in coloring cosmetics generally, except that only FD&C Red No. 40 and FD&C Red No. 40 Aluminum Lake may be safely used in coloring cosmetics intended for use in the area of the eye. These uses are subject to the following restrictions:

(1) The color additive may be used in amounts consistent with current good manufacturing practice.

(2) The color additive shall not be exposed to oxidizing or reducing agents that may affect the integrity of the color additives or any other condition that may affect their integrity.

(c) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Certification.* All batches of FD&C Red No. 40 shall be certified in accordance with regulations in part 80 of this chapter.

[42 FR 15654, Mar. 22, 1977, as amended at 59 FR 7636, Feb. 16, 1994]

§ 74.2602 D&C Violet No. 2.

(a) *Identity and specifications.* The color additive D&C Violet No. 2 shall conform in identity and specifications to the requirements of § 74.1602(a)(1) and (b).

(b) *Uses and restrictions.* The color additive D&C Violet No. 2 may be safely used for coloring externally applied cosmetics in amounts consistent with good manufacturing practice.

(c) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Certification.* All batches of D&C Violet No. 2 shall be certified in accordance with regulations in part 80 of this chapter.

§ 74.2602a Ext. D&C Violet No. 2.

(a) *Identity.* The color additive Ext. D&C Violet No. 2 is principally the monosodium salt of 2-[(9,10-dihydro-4-hydroxy-9,10-dioxo-1-anthracenyl)amino]-5-methyl-benzenesulfonic acid.

(b) *Specifications.* Ext. D&C Violet No. 2 shall conform to the following specifications and shall be free from impurities, other than those named, to the extent that such other 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 18 percent.

Water-insoluble matter, not more than 0.4 percent.

1-Hydroxy-9,10-anthracenedione, not more than 0.2 percent.

1,4-Dihydroxy-9,10-anthracenedione, not more than 0.2 percent.

p-Toluidine, not more than 0.1 percent.

p-Toluidine sulfonic acids, sodium salts, not more than 0.2 percent.

Subsidiary colors, not more than 1 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 80 percent.

(c) *Uses and restrictions.* The color additive Ext. D&C Violet No. 2 may be safely used for coloring externally applied cosmetics in amounts consistent with good manufacturing practice.

(d) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification.* All batches of Ext. D&C Violet No. 2 shall be certified in accordance with regulations in part 80 of this chapter.

§ 74.2705 FD&C Yellow No. 5.

(a) *Identity.* The color additive FD&C Yellow No. 5 is principally the trisodium salt of 4,5-dihydro-5-oxo-(1-(4-sulfophenyl)-4-[(4-sulfophenyl)azo]-1*H*-pyrazole-3-carboxylic acid (CAS Reg. No. 1934-21-0). To manufacture the additive, 4-aminobenzenesulfonic acid is diazotized using hydrochloric acid and

sodium nitrite. The diazo compound is coupled with 4,5-dihydro-5-oxo-1-(4-sulfophenyl)-1*H*-pyrazole-3-carboxylic acid or with the methyl ester, the ethyl ester, or a salt of this carboxylic acid. The resulting dye is purified and isolated as the sodium salt.

(b) *Specifications.* (1) FD&C Yellow No. 5 shall conform to the following specifications and shall be free from impurities other than those named to the extent that such other impurities may be avoided by good manufacturing practice:

Sum of volatile matter at 135 °C (275 °F) and chlorides and sulfates (calculated as sodium salts), not more than 13 percent.

Water-insoluble matter, not more than 0.2 percent.

4,4'-[4,5-Dihydro-5-oxo-4-[(4-sulfophenyl)hydrazono]-1*H*-pyrazol-1,3-diyl]bis[benzenesulfonic acid], trisodium salt, not more than 1 percent.

4-[(4',5'-Disulfo[1,1'-biphenyl]-2-yl)hydrazono]-4,5-dihydro-5-oxo-1-(4-sulfophenyl)-1*H*-pyrazole-3-carboxylic acid, tetrasodium salt, not more than 1 percent.

Ethyl or methyl 4,5-dihydro-5-oxo-1-(4-sulfophenyl)-4-[(4-sulfophenyl)hydrazono]-1*H*-pyrazole-3-carboxylate, disodium salt, not more than 1 percent.

Sum of 4,5-dihydro-5-oxo-1-phenyl-4-[(4-sulfophenyl)azo]-1*H*-pyrazole-3-carboxylic acid, disodium salt, and 4,5-dihydro-5-oxo-4-(phenylazo)-1-(4-sulfophenyl)-1*H*-pyrazole-3-carboxylic acid, disodium salt, not more than 0.5 percent.

4-Aminobenzenesulfonic acid, sodium salt, not more than 0.2 percent.

4,5-Dihydro-5-oxo-1-(4-sulfophenyl)-1*H*-pyrazole-3-carboxylic acid, disodium salt, not more than 0.2 percent.

Ethyl or methyl 4,5-dihydro-5-oxo-1-(4-sulfophenyl)-1*H*-pyrazole-3-carboxylate, sodium salt, not more than 0.1 percent.

4,4'-(1-Triazene-1,3-diyl)bis[benzenesulfonic acid], disodium salt, not more than 0.05 percent.

4-Aminoazobenzene, not more than 75 parts per billion.

4-Aminobiphenyl, not more than 5 parts per billion.

Aniline, not more than 100 parts per billion.

Azobenzene, not more than 40 parts per billion.

Benzidine, not more than 1 part per billion.

1,3-Diphenyltriazene, not more than 40 parts per billion.

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.

§ 74.2706

Total color, not less than 87 percent.

(2) FD&C Yellow No. 5 Aluminum Lake shall be prepared in accordance with the requirements of § 82.51 of this chapter.

(c) *Uses and restrictions.* (1) FD&C Yellow No. 5 may be safely used for coloring cosmetics generally, including cosmetics intended for use in the area of the eye, in amounts consistent with current good manufacturing practice.

(2) FD&C Yellow No. 5 Aluminum Lake may be safely used for coloring cosmetics intended for use in the area of the eye, subject to the restrictions on use of color additives in § 70.5(b) and (c) of this chapter, in amounts consistent with current good manufacturing practice.

(d) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification.* All batches of FD&C Yellow No. 5 shall be certified in accordance with regulations in part 80 of this chapter.

[50 FR 35782, Sept. 4, 1985, as amended at 51 FR 24524, July 7, 1986; 59 FR 60898, Nov. 29, 1994]

§ 74.2706 FD&C Yellow No. 6.

(a) *Identity and specifications.* The color additive FD&C Yellow No. 6 shall conform in identity and specifications to the requirements of § 74.706 (a)(1) and (b).

(b) *Uses and restrictions.* FD&C Yellow No. 6 may be safely used for coloring cosmetics generally in amounts consistent with current good manufacturing practice.

(c) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *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]

§ 74.2707 D&C Yellow No. 7.

(a) *Identity and specifications.* The color additive D&C Yellow No. 7 shall conform in identity and specifications to the requirements of § 74.1707(a)(1) and (b).

(b) *Uses and restrictions.* D&C Yellow No. 7 may be safely used for coloring

21 CFR Ch. I (4–1–25 Edition)

externally applied cosmetics in amounts consistent with good manufacturing practice.

(c) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Certification.* All batches of D&C Yellow No. 7 shall be certified in accordance with regulations in part 80 of this chapter.

§ 74.2707a Ext. D&C Yellow No. 7.

(a) *Identity and specifications.* The color additive Ext. D&C Yellow No. 7 shall conform in identity and specifications to the requirements of § 74.1707a (a)(1) and (b).

(b) *Uses and restrictions.* Ext. D&C Yellow No. 7 may be safely used for coloring externally applied cosmetics in amounts consistent with good manufacturing practice.

(c) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Certification.* All batches of Ext. D&C Yellow No. 7 shall be certified in accordance with regulations in part 80 of this chapter.

§ 74.2708 D&C Yellow No. 8.

(a) *Identity and specifications.* The color additive D&C Yellow No. 8 shall conform in identity and specifications to the requirements of § 74.1708(a)(1) and (b).

(b) *Uses and restrictions.* D&C Yellow No. 8 may be safely used for coloring externally applied cosmetics in amounts consistent with good manufacturing practice.

(c) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Certification.* All batches of D&C Yellow No. 8 shall be certified in accordance with regulations in part 80 of this chapter.

§ 74.2710 D&C Yellow No. 10.

(a) *Identity and specifications.* The color additive D&C Yellow No. 10 shall conform in identity and specifications to the requirements of § 74.1710(a)(1) and (b).

(b) *Uses and restrictions.* The color additive D&C Yellow No. 10 may be safely used for coloring cosmetics generally

in amounts consistent with current good manufacturing practice.

(c) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Certification.* All batches of D&C Yellow No. 10 shall be certified in accordance with regulations in part 80 of this chapter.

[48 FR 39220, Aug. 30, 1983, as amended at 49 FR 8432, Mar. 7, 1984]

§ 74.2711 D&C Yellow No. 11.

(a) *Identity and specifications.* The color additive D&C Yellow No. 11 shall conform in identity and specifications to the requirements of § 74.1711(a)(1) and (b).

(b) *Uses and restrictions.* D&C Yellow No. 11 may be safely used for coloring externally applied cosmetics in amounts consistent with good manufacturing practice.

(c) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Certification.* All batches of D&C Yellow No. 11 shall be certified in accordance with regulations in part 80 of this chapter.

Subpart D—Medical Devices

§ 74.3045 [Phthalocyaninato(2-)] copper.

(a) *Identity.* The color additive is [phthalocyaninato(2-)] copper (CAS Reg. No. 147-14-8) having the structure shown in Colour Index No. 74160.

(b) *Specifications.* The color additive [phthalocyaninato(2-)] copper 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:

Volatile matter 135 °C (275 °F), not more than 0.3 percent.

Salt content (as NaCl), not more than 0.3 percent.

Alcohol soluble matter, not more than 0.5 percent.

Organic chlorine, not more than 0.5 percent.
Aromatic amines, not more than 0.05 percent.

Lead (as Pb), not more than 40 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 98.5 percent.

(c) *Uses and restrictions.* (1) The color additive [phthalocyaninato(2-)] copper may be safely used to color polypropylene sutures, polybutester (the generic designation for the suture fabricated from 1,4-benzenedicarboxylic acid, polymer with 1,4-butanediol and *alpha*-hydro-*omega*-hydroxypoly(oxy-1,4-butanediyl), CAS Reg. No. 37282-12-5) nonabsorbable sutures for use in general and ophthalmic surgery, polybutylene terephthalate nonabsorbable monofilament sutures for general and ophthalmic surgery, nonabsorbable sutures made from poly(vinylidene fluoride) and poly(vinylidene fluoride-co-hexafluoropropylene) for general and ophthalmic surgery, polymethylmethacrylate monofilament used as supporting haptics for intraocular lenses, and polymers used in orientation marks for intraocular lenses, subject to the following restrictions:

(i) The quantity of the color additive does not exceed 0.5 percent by weight of the suture, haptic material, or orientation mark.

(ii) The dyed suture shall conform in all respects to the requirements of the U.S. Pharmacopeia.

(2) The color additive [phthalocyaninato(2-)] copper may be safely used for coloring contact lenses in amounts not to exceed the minimum reasonably required to accomplish the intended coloring effect.

(3) Authorization for these uses shall not be construed as waiving any of the requirements of section 510(k), 515, or 520(g) the Federal Food, Drug, and Cosmetic Act with respect to the medical device in which [phthalocyaninato(2-)] copper is used.

(d) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification.* All batches of [phthalocyaninato (2-)] copper shall be

§ 74.3054

certified in accordance with regulations in part 80 of this chapter.

[48 FR 34947, Aug. 2, 1983, as amended at 50 FR 16228, Apr. 25, 1985; 51 FR 22929, June 24, 1986; 51 FR 28930, Aug. 13, 1986; 51 FR 39371, Oct. 28, 1986; 52 FR 15945, May 1, 1987; 55 FR 19620, May 10, 1990; 64 FR 23186, Apr. 30, 1999; 81 FR 75692, Nov. 1, 2016]

§ 74.3054 D&C Black No. 4.

(a) *Identity.* The color additive D&C Black No. 4 is a high-purity carbon black prepared by the oil furnace process. It is manufactured by the combustion of aromatic petroleum oil feedstock and consists essentially of pure carbon, formed as aggregated fine particles with a surface area range of 50 to 260 meters (m)²/gram.

(b) *Specifications.* D&C Black No. 4 must conform to the following specifications and must be free from impurities other than those named to the extent that such other impurities may be avoided by good manufacturing practice:

(1) Surface area by nitrogen BET (Brunauer, Emmett, Teller) method, 50 to 260 m²/gram.

(2) Weight loss on heating at 950 °C for 7 minutes (predried for 1 hour at 125 °C), not more than 2 percent.

(3) Ash content, not more than 0.15 percent.

(4) Arsenic (total), not more than 3 milligrams per kilogram (mg/kg) (3 parts per million).

(5) Lead (total), not more than 10 mg/kg (10 parts per million).

(6) Mercury (total), not more than 1 mg/kg (1 part per million).

(7) Total sulfur, not more than 0.65 percent.

(8) Total polycyclic aromatic hydrocarbons (PAHs), not more than 0.5 mg/kg (500 parts per billion).

(9) Benzo[*a*]pyrene, not more than 0.005 mg/kg (5 parts per billion).

(10) Dibenz[*a,h*]anthracene, not more than 0.005 mg/kg (5 parts per billion).

(11) Total color (as carbon), not less than 95 percent.

(c) *Uses and restrictions.* (1) D&C Black No. 4 may be safely used at a level not to exceed 1.0 percent by weight of the suture material for coloring ultra-high molecular weight polyethylene non-absorbable sutures for general surgical use.

21 CFR Ch. I (4–1–25 Edition)

(2) Authorization and compliance with this use must not be construed as waiving any of the requirements of sections 510(k), 515, and 520(g) of the Federal Food, Drug, and Cosmetic Act with respect to the ultra-high molecular weight polyethylene surgical sutures in which D&C Black No. 4 is used.

(d) *Labeling.* The label of the color additive must conform to the requirements of § 70.25 of this chapter.

(e) *Certification.* All batches of D&C Black No. 4 must be certified in accordance with regulations in part 80 of this chapter.

[83 FR 26359, June 7, 2018]

§ 74.3102 FD&C Blue No. 2.

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

(b) *Specifications.* (1) The color additive FD&C Blue No. 2 for use in coloring surgical sutures 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 (275 °F) and chlorides and sulfates (calculated as sodium salts), not more than 15 percent.

Water insoluble matter, not more than 0.4 percent.

Isatin-5-sulfonic acid, not more than 0.4 percent.

Isomeric colors, not more than 18 percent.

Lower sulfonated subsidiary colors, not more than 5 percent.

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

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

Total color, not less than 85 percent.

(2) The color additive FD&C Blue No. 2–Aluminum Lake on alumina for use in bone cement shall be prepared in accordance with the requirements of § 82.51 of this chapter.

(c) *Uses and restrictions.* (1) The color additive FD&C Blue No. 2 may be safely used for coloring nylon (the copolymer of adipic acid and hexamethylene diamine) surgical sutures for use in general surgery subject to the following restrictions:

(i) The quantity of color additive does not exceed 1 percent by weight of the suture;

(ii) The dyed suture shall conform in all respects to the requirements of the United States Pharmacopeia XX (1980); and

(iii) When the sutures are used for the purposes specified in their labeling, the color additive does not migrate to the surrounding tissues.

(2) The color additive FD&C Blue No. 2-Aluminum Lake on alumina may be safely used for coloring bone cement at a level not to exceed 0.1 percent by weight of the bone cement.

(3) Authorization and compliance with these uses shall not be construed as waiving any of the requirements of sections 510(k), 515, and 520(g) of the Federal Food, Drug, and Cosmetic Act with respect to the medical device in which the color additive FD&C Blue No. 2 and the color additive FD&C Blue No. 2-Aluminum Lake on alumina are used.

(d) *Labeling.* The labels of the color additive FD&C Blue No. 2 and the color additive FD&C Blue No. 2-Aluminum Lake on alumina shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification.* All batches of FD&C Blue No. 2 and its lake shall be certified in accordance with regulations in part 80 of this chapter.

[64 FR 48290, Sept. 3, 1999]

§ 74.3106 D&C Blue No. 6.

(a) *Identity.* The color additive D&C Blue No. 6 is principally [A2,2'-biindoline]-3,3' dione (CAS Reg. No. 482-89-3).

(b) *Specifications.* D&C Blue No. 6 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:

Volatile matter at 135 °C (275 °F), not more than 3 percent.

Matter insoluble in *N,N*-dimethylformamide, not more than 1 percent.

Isatin, not more than 0.3 percent.

Anthranilic acid, not more than 0.3 percent.

Indirubin, not more than 1 percent.

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 95 percent.

(c) *Uses and restrictions.* (1) D&C Blue No. 6 may be safely used at a level—

(i) Not to exceed 0.2 percent by weight of the suture material for coloring polyethylene terephthalate surgical sutures for general surgical use;

(ii) Not to exceed 0.25 percent by weight of the suture material for coloring plain or chromic collagen absorbable sutures for general surgical use;

(iii) Not to exceed 0.5 percent by weight of the suture material for coloring plain or chromic collagen absorbable sutures for ophthalmic surgical use;

(iv) Not to exceed 0.5 percent by weight of the suture material for coloring polypropylene surgical sutures for general surgical use; and

(v) Not to exceed 0.5 percent by weight of the suture material for coloring polydioxanone synthetic absorbable sutures for ophthalmic and general surgical use.

(2) Authorization for these uses shall not be construed as waiving any of the requirements of sections 510(k), 515, and 520(g) of the Federal Food, Drug, and Cosmetic Act with respect to the medical device in which the color additive is used.

(d) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

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

[49 FR 29956, July 25, 1984; 49 FR 34447, Aug. 31, 1984, as amended at 50 FR 30698, July 29, 1985]

§ 74.3206 D&C Green No. 6.

(a) *Identity.* The color additive D&C Green No. 6 shall conform in identity to the requirements of § 74.1206(a).

(b) *Specifications.* The color additive D&C Green No. 6 for use in medical devices shall conform to the specifications of § 74.1206(b).

(c) *Uses and restrictions.* (1) The color additive D&C Green No. 6 may be safely used at a level

(i) Not to exceed 0.03 percent by weight of the lens material for coloring contact lenses;

§ 74.3230

(ii) Not to exceed 0.75 percent by weight of the suture material for coloring polyethylene terephthalate surgical sutures, including sutures for ophthalmic use;

(iii) Not to exceed 0.1 percent by weight of the suture material for coloring polyglycolic acid surgical sutures with diameter greater than U.S.P. size 8-0, including sutures for ophthalmic use;

(iv) Not to exceed 0.5 percent by weight of the suture material for coloring polyglycolic acid surgical sutures with diameter not greater than U.S.P. size 8-0, including sutures for ophthalmic use;

(v) Not to exceed 0.21 percent by weight of the suture material for coloring poly(glycolic acid-co-trimethylene carbonate) sutures (also referred to as 1,4-dioxan-2,5-dione polymer with 1,3-dioxan-2-one) for general surgical use; and

(vi) Not to exceed 0.10 percent by weight of the haptic material for coloring polymethylmethacrylate support haptics of intraocular lenses.

(2) Authorization for these uses shall not be construed as waiving any of the requirements of sections 510(k), 515, and 520(g) of the Federal Food, Drug, and Cosmetic Act with respect to the medical device in which D&C Green No. 6 is used.

(d) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

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

[48 FR 13022, Mar. 29, 1983, as amended at 51 FR 9784, Mar. 21, 1986; 51 FR 37909, Oct. 27, 1986; 58 FR 21542, Apr. 22, 1993]

§ 74.3230 D&C Red No. 17.

(a) *Identity and specifications.* The color additive D&C Red No. 17 shall conform in identity and specifications to the requirements of § 74.1317(a)(1) and (b).

(b) *Uses and restrictions.* (1) The substance listed in paragraph (a) of this section may be used as a color additive in contact lens in amounts not to exceed the minimum reasonably required to accomplish the intended coloring effect.

21 CFR Ch. I (4-1-25 Edition)

(2) Authorization for this use shall not be construed as waiving any of the requirements of section 510(k), 515, and 520(g) of the Federal Food, Drug, and Cosmetic Act with respect to the contact lens in which the color additive is used.

(c) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Certification.* All batches of D&C Red No. 17 shall be certified in accordance with regulations in part 80 of this chapter.

[55 FR 22898, June 5, 1990]

§ 74.3602 D&C Violet No. 2.

(a) *Identity and specifications.* The color additive D&C Violet No. 2 shall conform in identity and specifications to the requirements of § 74.1602(a)(1) and (b).

(b) *Uses and restrictions.* (1) The color additive, D&C Violet No. 2, may be safely used for coloring contact lenses in amounts not to exceed the minimum reasonably required to accomplish the intended coloring effect.

(2) D&C Violet No. 2 may be safely used for coloring sutures for use in surgery subject to the following conditions:

(i) At a level not to exceed 0.2 percent by weight of the suture material for coloring copolymers of 90 percent glycolide and 10 percent L-lactide synthetic absorbable sutures for use in general and ophthalmic surgery; and

(ii) At a level not to exceed 0.3 percent by weight of the suture material for coloring polydioxanone synthetic absorbable sutures for use in general and ophthalmic surgery.

(iii) At a level not to exceed 0.25 percent by weight of the suture material for coloring poliglecaprone 25 (ε-caprolactone/glycolide copolymer) synthetic absorbable sutures for use in general surgery.

(iv) At a level not to exceed 0.1 percent by weight of the suture material for coloring poly(ε-caprolactone) absorbable sutures for use in general surgery.

(v) At a level not to exceed 0.2 percent by weight of the suture material for coloring glycolide/dioxanone/

trimethylene carbonate tripolymer absorbable sutures for use in general surgery.

(vi) At a level not to exceed 0.2 percent by weight of the suture material for coloring absorbable sutures prepared from homopolymers of glycolide for use in general surgery.

(3) The color additive, D&C Violet No. 2, may be safely used for coloring polymethylmethacrylate intraocular lens haptics at a level not to exceed 0.2 percent by weight of the haptic material.

(4) The color additive, D&C Violet No. 2, may be safely used for coloring absorbable meniscal tacks made from poly (L-lactic acid) at a level not to exceed 0.15 percent by weight of the tack material.

(5) Authorization for these uses shall not be construed as waiving any of the requirements of sections 510(k), 515, and 520(g) of the Federal Food, Drug, and Cosmetic Act with respect to the medical devices in which the color additive is used.

(c) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Certification.* All batches of D&C Violet No. 2 shall be certified in accordance with regulations in part 80 of this chapter.

[52 FR 19722, May 27, 1987, as amended at 55 FR 18868, May 7, 1990; 58 FR 60109, Nov. 15, 1993; 59 FR 11720, Mar. 14, 1994; 63 FR 20098, Apr. 23, 1998; 64 FR 32805, June 18, 1999; 65 FR 46344, July 28, 2000]

§ 74.3708 D&C Yellow No. 8.

(a) *Identity and specifications.* The color additive D&C Yellow No. 8 shall conform in identity and specifications to the requirements of § 74.1708(a)(1) and (b).

(b) *Uses and restrictions.* (1) D&C Yellow No. 8 may be safely used for coloring contact lens solution for coloring disposable daily-wear hydrogel-based soft (hydrophilic) contact lenses at a level not to exceed 0.044 percent in the contact lens solution. Following excitation by ultraviolet light, the colored contact lenses fluoresce a yellow-green color. The contact lens solution colored with D&C Yellow No. 8 is distributed by prescription only and used in accordance with the supplied direc-

tions for use. Contact lens solutions containing D&C Yellow No. 8 are intended for use only for coloring contact lenses that are worn for infrequent, celebratory occasions, and not for regular or daily use.

(2) Authorization for this use shall not be construed as waiving any of the requirements of sections 510(k), 515, and 520(g) of the Federal Food, Drug, and Cosmetic Act with respect to the contact lens solution in which the color additive is used.

(c) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Certification.* All batches of D&C Yellow No. 8 shall be certified in accordance with regulations in part 80 of this chapter.

[83 FR 48375, Sept. 25, 2018]

§ 74.3710 D&C Yellow No. 10.

(a) *Identity.* The color additive D&C Yellow No. 10 shall conform to the identity requirements of § 74.1710(a).

(b) *Specifications.* The color additive D&C Yellow No. 10 for use in contact lenses shall conform to the specifications of § 74.1710(b).

(c) *Uses and restrictions.* (1) The color additive D&C Yellow No. 10 may be used for coloring contact lenses in amounts not to exceed the minimum reasonably required to accomplish the intended coloring effect.

(2) Authorization for this use shall not be construed as waiving any of the requirements of sections 510(k), 515, and 520(g) of the Federal Food, Drug, and Cosmetic Act with respect to the contact lens in which the color additive is used.

(d) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification.* All batches of D&C Yellow No. 10 shall be certified in accordance with regulations in part 80 of this chapter.

[52 FR 28690, Aug. 3, 1987]

PART 80—COLOR ADDITIVE CERTIFICATION

Subpart A—General Provisions

Sec.
80.10 Fees for certification services.