§ 82.1333 D&C Red No. 33.

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

(b) All lakes of D&C Red. No. 33 shall be manufactured from previously certified batches of the straight color additive.

[53 FR 38121, Aug. 30, 1988]

§ 82.1334 D&C Red No. 34.

Calcium salt of 3-hydroxy-4-(1-sulfo-2-naphthalenyl)azol-2-naphthalene-carboxylic acid.

Sum of volatile matter (at 135 °C) and chlorides and sulfates (calculated as 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.

Total color not less than 85 percent.

§ 82.1336 D&C Red No. 36.

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

(b) All lakes of D&C Red No. 36 shall be manufactured from previously certified batches of the straight color additive.

[53 FR 29031, Aug. 2, 1988]

§ 82.1602 D&C Violet No. 2.

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

§ 82.1707 D&C Yellow No. 7.

The color additive D&C Yellow No. 7 shall conform in identity and specifications to the requirements of §74.1707(a)(1) and (b) of this chapter. D&C Yellow No. 7 is restricted to use in externally applied drugs and cosmetics.

§ 82.1708 D&C Yellow No. 8.

The color additive D&C Yellow No. 8 shall conform in identity and specifications to the requirements of §74.1707(a)(1) and (b) of this chapter. D&C Yellow No. 8 is restricted to use in externally applied drugs and cosmetics.

§ 82.1710 D&C Yellow No. 10.

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

[48 FR 39220, Aug. 30, 1983]

Subpart D—Externally Applied Drugs and Cosmetics

§ 82.2050 General.

A batch of a straight color listed in this subpart may be certified, in accordance with the provisions of this part, for use in externally applied drugs and cosmetics, if such batch conforms to the requirements of §82.5 and to the specifications set forth in this subpart for such color.

§ 82.2051 Lakes (Ext. D&C).

(a)(1) General. Any lake made by extending on a substratum of alumina, blanc fixe, gloss white, clay, titanium dioxide, zinc oxide, talc, rosin, aluminum benzoate, calcium carbonate, or on any combination of two or more of these (i) one of the straight colors hereinbefore listed in this subpart, which color is a salt in which is combined the basic radical sodium, potassium, barium, calcium, strontium, or zirconium; or (ii) a salt prepared from one of the straight colors hereinbefore listed in this subpart by combining such color with the basic radical sodium, potassium, barium, calcium, strontium, or zirconium.

(2) Specifications.

Ether extracts, not more than 0.5 percent.

Soluble chlorides and sulfates (as sodium salts), not more than 3.0 percent.

Intermediates, not more than 0.2 percent.

(b) Each lake made as prescribed in paragraph (a) of this section shall be considered to be a straight color and to be listed therein under the name which is formed as follows:

(1) The listed name of the color from which the lake is prepared;
(2) The name of the basic radical combined in such color; and
(3) The word “Lake.” (For example, the name of a lake prepared by extending the color Ext. D&C Yellow No. 2 upon a substratum is “Ext. D&C Yellow No. 2—Calcium Lake,” and a lake
§ 82.2707a

prepared by extending the barium salt prepared from Ext. D&C Red No. 2 upon the substratum is "Ext. D&C Red No. 2—Barium Lake.")

§ 82.2707a Ext. D&C Yellow No. 7.

The color additive Ext. D&C Yellow No. 7 shall conform in identity with specifications to the requirements of §74.1707a(a)(1) and (b) of this chapter. Ext. D&C Yellow No. 7 is restricted to use in externally applied drugs and cosmetics.

PARTS 83–98 [RESERVED]

PART 99—DISSEMINATION OF INFORMATION ON UNAPPROVED/NEW USES FOR MARKETED DRUGS, BIOLOGICS, AND DEVICES

Subpart A—General Information

Sec. 99.1 Scope.
99.3 Definitions.

Subpart B—Information To Be Disseminated

99.101 Information that may be disseminated.
99.103 Mandatory statements and information.
99.105 Recipients of information.

Subpart C—Manufacturer’s Submissions, Requests, and Applications

99.201 Manufacturer’s submission to the agency.
99.203 Request to extend the time for completing planned studies.
99.205 Application for exemption from the requirement to file a supplemental application.

Subpart D—FDA Action on Submissions, Requests, and Applications

99.301 Agency action on a submission.
99.303 Extension of time for completing planned studies.
99.305 Exemption from the requirement to file a supplemental application.

Subpart E—Corrective Actions and Cessation of Dissemination

99.401 Corrective actions and cessation of dissemination of information.
99.403 Termination of approvals of applications for exemption.

99.405 Applicability of labeling, adulteration, and misbranding authority.

Subpart F—Recordkeeping and Reports

99.501 Recordkeeping and reports.

PART 99—DISSEMINATION OF INFORMATION ON UNAPPROVED/NEW USES FOR MARKETED DRUGS, BIOLOGICS, AND DEVICES

Subpart A—General Information

§ 99.1 Scope.

(a) This part applies to the dissemination of information on human drugs, including biologics, and devices where the information to be disseminated:

(1) Concerns the safety, effectiveness, or benefit of a use that is not included in the approved labeling for a drug or device approved by the Food and Drug Administration for marketing or in the statement of intended use for a device cleared by the Food and Drug Administration for marketing; and

(2) Will be disseminated to a health care practitioner, pharmacy benefit manager, health insurance issuer, group health plan, or Federal or State Government agency.

(b) This part does not apply to a manufacturer’s dissemination of information that responds to a health care practitioner’s unsolicited request.

§ 99.3 Definitions.

(a) Agency or FDA means the Food and Drug Administration.

(b) For purposes of this part, a clinical investigation is an investigation in humans that tests a specific clinical hypothesis.

(c) Group health plan means an employee welfare benefit plan (as defined in section 3(1) of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1002(1))) to the extent that the plan provides medical care (as defined in paragraphs (c)(1) through (c)(3) of this section and including items and services paid for as medical care) to employees or their dependents (as defined under the terms of the plan) directly or through insurance, reimbursement, or otherwise. For purposes of this part, the term medical care means: