

Food and Drug Administration, HHS

§ 82.5

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 81.30, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at www.fdsys.gov.

§ 81.32 Limitation of certificates.

Certificates issued for the color additives listed in § 81.25 and for all mixtures containing these color additives are limited to the conditions stated in § 81.25. The use of these color additives in drugs and cosmetics in any other manner will result in adulteration. Each of these color additives shall bear a label statement of the tolerance and use limitations applicable to it.

[44 FR 48966, Aug. 21, 1979]

PART 82—LISTING OF CERTIFIED PROVISIONALLY LISTED COLORS AND SPECIFICATIONS

Subpart A—General Provisions

- Sec.
82.3 Definitions.
82.5 General specifications for straight colors.
82.6 Certifiable mixtures.

Subpart B—Foods, Drugs, and Cosmetics

- 82.50 General.
82.51 Lakes (FD&C).
82.101 FD&C Blue No. 1.
82.102 FD&C Blue No. 2.
82.203 FD&C Green No. 3.
82.304 FD&C Red No. 4.
82.705 FD&C Yellow No. 5.
82.706 FD&C Yellow No. 6.

Subpart C—Drugs and Cosmetics

- 82.1050 General.
82.1051 Lakes (D&C).
82.1104 D&C Blue No. 4.
82.1205 D&C Green No. 5.
82.1206 D&C Green No. 6.
82.1254 D&C Orange No. 4.
82.1255 D&C Orange No. 5.
82.1260 D&C Orange No. 10.
82.1261 D&C Orange No. 11.
82.1306 D&C Red No. 6.
82.1307 D&C Red No. 7.
82.1317 D&C Red No. 17.
82.1321 D&C Red No. 21.
82.1322 D&C Red No. 22.
82.1327 D&C Red No. 27.
82.1328 D&C Red No. 28.
82.1330 D&C Red No. 30.
82.1331 D&C Red No. 31.
82.1333 D&C Red No. 33.
82.1334 D&C Red No. 34.

- 82.1336 D&C Red No. 36.
82.1602 D&C Violet No. 2.
82.1707 D&C Yellow No. 7.
82.1708 D&C Yellow No. 8.
82.1710 D&C Yellow No. 10.

Subpart D—Externally Applied Drugs and Cosmetics

- 82.2050 General.
82.2051 Lakes (Ext. D&C).
82.2707a Ext. D&C Yellow No. 7.

AUTHORITY: 21 U.S.C. 371, 379e, 379e note.

SOURCE: 42 FR 15669, Mar. 22, 1977, unless otherwise noted.

Subpart A—General Provisions

§ 82.3 Definitions.

For the purposes of this part:

- (a)–(f) [Reserved]
(g) The term *alumina* means a suspension in water of precipitated aluminum hydroxide.
(h) The term *blanc fixe* means a suspension in water of precipitated barium sulfate.
(i) The term *gloss white* means a suspension in water of co-precipitated aluminum hydroxide and barium sulfate.
(j) The term *mixed oxides* means the sum of the quantities of aluminum, iron, calcium, and magnesium (in whatever combination they may exist in a coal-tar color) calculated as aluminum trioxide, ferric oxide, calcium oxide, and magnesium oxide.

(k)–(m) [Reserved]

(n) The term *externally applied drugs and cosmetics* means drugs and cosmetics which are applied only to external parts of the body and not to the lips or any body surface covered by mucous membrane.

(o)–(p) [Reserved]

(q) The definitions and interpretations of terms contained in section 201 of the Federal Food, Drug, and Cosmetic Act shall be applicable also to such terms when used in this part.

§ 82.5 General specifications for straight colors.

No batch of a straight color listed in subpart B, C, or D shall be certified under this part unless:

- (a) It is free from all impurities (other than those named in paragraph (b) of this section or in the specifications set forth in such paragraph for