§ 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.
82.790 FD&C Yellow No. 6.

Subpart C—Drugs and Cosmetics
82.1050 General.
82.1051 Lakes (D&C).
82.1104 D&C Green 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.
82.1290 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. 16.
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.
82.1332 D&C Red No. 32.
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.
82.1719 D&C Yellow No. 10.
82.2050 General.
82.2051 Lakes (Ext. D&C).
82.2707a Ext. D&C Yellow No. 7.

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

Subpart D—Externally Applied Drugs and Cosmetics
82.2050 General.
82.2051 Lakes (Ext. D&C).
82.2707a Ext. D&C Yellow No. 7.

PART 82—LISTING OF CERTIFIED PROVISIONALLY LISTED COLORS AND SPECIFICATIONS

Subpart A—General Provisions
Sec.
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