

## 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 on GPO Access.

### § 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

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82.1255 D&C Orange No. 5.  
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82.1317 D&C Red No. 17.  
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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