

Pt. 81

21 CFR Ch. I (4–1–14 Edition)

and the name and post-office address of the person to whom such shipment or delivery was made.

(c) The records required to be kept by paragraph (a) of this section shall be kept separately from all other records.

PART 81—GENERAL SPECIFICATIONS AND GENERAL RESTRICTIONS FOR PROVISIONAL COLOR ADDITIVES FOR USE IN FOODS, DRUGS, AND COSMETICS

Sec.

- 81.1 Provisional lists of color additives.
- 81.10 Termination of provisional listings of color additives.
- 81.30 Cancellation of certificates.
- 81.32 Limitation of certificates.

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

§81.1 Provisional lists of color additives.

The Commissioner of Food and Drugs finds that the following lists of color additives are provisionally listed under section 203(b) of the Color Additive Amendments of 1960 (sec. 203(b), 74 Stat. 405 (21 U.S.C. 379e note)). Except for color additives for which petitions have been filed, progress reports are required by January 1, 1968, and at 6-month intervals thereafter. Specifications for color additives listed in paragraphs (a), (b), and (c) of this section appear in the respective designated sections. The listing of color additives in this section is not to be construed as a listing for surgical suture use unless color additive petitions have been submitted for such use or the Commissioner has been notified of studies underway to establish the safety of the color additive for such use. The color additives listed in paragraphs (a), (b), and (c) of this section may not be used in products which are intended to be used in the area of the eye. The color additives listed in paragraphs (a), (b), and (c) of this section are provisionally listed until the closing dates set forth therein.

(a) *Color additives previously and presently subject to certification and provisionally listed for food, drug, and cosmetic use.*

Color additive	Closing date		Restrictions
	Food use	Drug and cosmetic use	

Lakes (FD&C) (sec. 82.51 of this chapter).

(b) *Color additives previously and presently subject to certification and provisionally listed for drug and cosmetic use.*

Closing date	Restrictions
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Lakes (D&C) (Sec. 82.2051 of this chapter).

(c) *Color additives previously and presently subject to certification and provisionally listed for use in externally applied drugs and cosmetics.*

Closing date	Restrictions
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Lakes (Ext. D&C) (sec. 82.105(1) of this chapter)

[42 FR 15665, Mar. 22, 1977]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting §81.1, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at www.fdsys.gov.

§81.10 Termination of provisional listings of color additives.

(a) *Ext. D&C Yellow Nos. 9 and 10.* These colors cannot be produced with any assurance that they do not contain β-naphthylamine as an impurity. While it has been asserted that the two colors can be produced without the impurity named, no method of analysis has been suggested to establish the fact. β-Naphthylamine is a known carcinogen; therefore, there is no scientific evidence that will support a safe tolerance for these colors in products to be used in contact with the skin. The Commissioner of Food and Drugs, having concluded that such action is necessary to protect the public health, hereby terminated the provisional listing of Ext. D&C Yellow No. 9 and Ext. D&C Yellow No. 10.

(b) [Reserved]

(c) *FD&C Red No. 1.* Results of recent feeding tests of this color additive have demonstrated it to be toxic upon ingestion: