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.


§ 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 re-
quired by January 1, 1968, and at 6-
month intervals thereafter. Specifica-
tions for color additives listed in para-
graphs (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 sub-
mitted for such use or the Commis-
sioner has been notified of studies un-
derway 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 pres-
ently subject to certification and provision-
ally listed for food, drug, and cosmetic
use.

<table>
<thead>
<tr>
<th>Color additive</th>
<th>Closing date</th>
<th>Restrictions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lakes (FD&amp;C) (sec. 82.51 of this chapter)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Color additive</th>
<th>Closing date</th>
<th>Restrictions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lakes (D&amp;C) (Sec. 82.2051 of this chapter)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Color additive</th>
<th>Closing date</th>
<th>Restrictions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lakes (Ext. D&amp;C) (sec. 82.105(1) of this chapter)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

[42 FR 15665, Mar. 22, 1977]

EDITORIAL NOTE: For Federal Register cit-
ations 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 list-
ings 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
\( \beta \)-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. \( \beta \)-Naph-
thylamine is a known carcinogen; there-
fore, there is no scientific evi-
dence that will support a safe tolerance
for these colors in products to be used
in contact with the skin. The Commis-
sioner of Food and Drugs, having con-
cluded that such action is necessary to
protect the public health, hereby ter-
minated 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 inges-
tion: