DEPARTMENT OF LABOR

Employment and Training Administration

Occupational Safety and Health Administration

Office of Federal Contract Compliance Programs

20 CFR Part 655

29 CFR Part 1903

41 CFR Part 60-1

Notice of Further Deferral of Effective Dates of Regulations

AGENCY: Department of Labor.

ACTION: Notice of further deferral of effective dates of regulations.

SUMMARY: The Department of Labor further defers the effective dates of three final rules from March 30, 1981 (see 46 FR 11253, Feb. 6, 1981), until the dates set forth below.

This action is taken in order to permit reconsideration of these rules in accordance with Executive Order 12291 and in order to permit proposed rulemaking.

For complete information on these actions see the following **Federal Register** documents in the Proposed Rules section of this issue of the **Federal Register**:

1. 81-9411 (ETA)
2. 81-9412 (OSHA)
3. 81-9410 (OFCCP)

DATE: The effective date of this deferral is March 27, 1981.

ADDRESS: Gail Lively, Director, Executive Secretariat, Room S-2519, Frances Perkins Building, U.S. Department of Labor, 200 Constitution Avenue, N.W., Washington, D.C. 20210.

FOR FURTHER INFORMATION CONTACT: (1) For the Employment and Training Administration (ETA)—Mr. Kenneth Bell—Telephone: 202-376-6297. (2) For the Occupational Safety and Health Administration (OSHA)—Mr. H. Berrien Zettler—Telephone 202-523-7725. (3) For the Office of Federal Contract Compliance Programs—Mr. James W. Cisco—Telephone 202-523-9426.

Rule and agency	Subject	Old effective date	New effective date
1. 20 CFR Part 655 ETA (Originally published on Jan. 16, 1981 at 46 FR 4568).	Labor Certification Process for the Temporary Employment of Aliens in Agriculture: Adverse Effect Wage Rate Methodology.	Mar. 30, 1981	Deferred until action taken on today's proposed rules.
2. 29 CFR Part 1903 OSHA (Originally published on Jan. 16, 1981 at 46 FR 3852).	Walkaround Compensation	do	May 30, 1981.
3. 41 CFR Part 60-1 OFCCP (Originally published on Jan. 16, 1981 at 46 FR 3892).	Payment of Membership Fees and Other Expenses to Private Organizations.	do	Deferred until action taken on today's proposed rules.

Signed at Washington, D.C. this 25th day of March, 1981.

Raymond J. Donovan,

Secretary of Labor.

[FR Doc. 81-9523 Filed 3-26-81; 8:45 am]

BILLING CODE 4510-23-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 50

[Docket No. 78N-0049]

Protection of Human Subjects; Prisoners Used as Subjects in Research; Delay of Effective Date

AGENCY: Food and Drug Administration.

ACTION: Final rule; delay of effective date.

SUMMARY: The Food and Drug Administration (FDA) is delaying the effective date of its regulations on the use of prisoners as subjects in research to a date to be announced in a later issue of the **Federal Register**.

DATE: The delay is effective March 27, 1981.

FOR FURTHER INFORMATION CONTACT: Halyna P. Breslawec, Office of Health Affairs (HFY-2), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-1382.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of May 5, 1978 (43 FR 19417), the Food and Drug Administration (FDA) proposed to adopt regulations to provide protection for prisoners involved in research activities that fall within the agency's jurisdiction. After considering the comments it received on this proposal, in the **Federal Register** of May 30, 1980 (45 FR 36386), FDA adopted the final rule on the use of prisoners in research. At that time, the agency announced that the regulations would become effective on June 1, 1981.

On July 29, 1980, suit was brought in the United States District Court for the Eastern District of Michigan to have these regulations declared invalid. See *Fante and the Upjohn Company* v. *Department of Health and Human Services, et al.*, Civil Action No. 80-72778. Because of the nature and circumstances of this litigation, the agency has determined that it is appropriate to delay the effective date of these regulations. Therefore, FDA announces that unless the District Court declares these regulations to be invalid, the final rule will become effective 5 months from the date of the District Court's final judgment on the merits of the suit. The agency will publish an appropriate notice in the **Federal Register**, as soon as the District Court rules.

The regulation is affected by Executive Order 12291, dated February 17, 1981 (46 FR 13193, February 19, 1981). If the District Court holds that the final rule is valid, and a decision is made to put the regulation into effect, the agency will comply with Section 7 of the Executive Order and report this regulation to the Director of the Office of Management and Budget before it becomes effective. The report will be filed under Section 7 (a) or (b) of the Executive Order, depending on the final determination as to whether the regulation is a major rule. Based on the amended regulatory analysis assessment of the regulation, which was prepared before its promulgation, and on the criteria for a major rule in Section 1(b) of the Executive Order, it appears that this regulation may not be a major rule. (It should be noted that FDA-regulated research is being conducted at only three prisons.)

Dated: March 17, 1981.

Mark Novitch,

Acting Commissioner of Food and Drugs.

[FR Doc. 81-9005 Filed 3-26-81; 8:45 am]

BILLING CODE 4110-03-M

21 CFR Parts 74, 81, and 82

[Docket No. 76C-0044]

D&C Orange No. 10 and D&C Orange No. 11

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is permanently listing D&C Orange No. 10 and D&C Orange No. 11 for use in externally applied drugs and cosmetics. This document responds to a petition filed by the Cosmetic, Toiletry, and Fragrance Association, Inc. (CTFA) for use of the colors in drugs and cosmetics. This rule

will remove these color additives from the provisionally approved listing for all uses in drugs and cosmetics after April 28, 1981, and D&C Orange No. 10 and D&C Orange No. 11 may not be added to ingested drugs and cosmetics after the date.

DATES: Effective April 28, 1981; objections by April 27, 1981.

ADDRESS: Written objections may be sent to the Dockets Management Branch (formerly the Hearing Clerk's office) (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Andrew D. Laumbach, Bureau of Foods (HFF–334), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–472–5690.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of August 6, 1973 (38 FR 21199), FDA announced that a petition (CAP 6C0042) for the permanent listing of D&C Orange No. 10 and D&C Orange No. 11 as color additives for use in drugs and cosmetics had been filed by the Cosmetic, Toiletry, and Fragrance Association, Inc. (1133 15th St. NW., Washington, DC 20005), c/o Hazleton Laboratories, Inc., 9200 Leesburg Turnpike, Vienna, VA 22180. The petition was filed pursuant to section 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 376). A subsequent notice published in the **Federal Register** of March 5, 1976 (41 FR 9584) amended the filing of this petition to include the additional use of D&C Orange No. 10 in cosmetics intended for use in the area of the eye. FDA did not receive any comments in response to these notices.

FDA has evaluated data in the petition and concludes that D&C Orange No. 10 and D&C Orange No. 11 are safe under the conditions set forth below for use in externally applied drugs and cosmetics, and that certification is necessary for the protection of the public health. This order permanently lists D&C Orange No. 10 and D&C Orange No. 11 for use in externally applied drugs and cosmetics under §§ 74.1260, 74.1261, 74.2260, and 74.2261 (21 CFR 74.1260, 74.1261, 74.2260, and 74.2261), respectively.

The provisional regulations published in the **Federal Register** of February 4, 1977 (42 FR 6992) required new chronic toxicity studies for D&C Orange No. 10 and D&C Orange No. 11, as a condition of their continued provisional listing for ingested uses. The closing date for the provisional listing of the color additives was postponed until January 31, 1981, for completion of those studies. The petitioner was also notified by letter of the need for data to support the use of D&C Orange No. 10 in cosmetics intended for use in the area of the eye. The petitioner subsequently notified FDA that it did not intend to test the colors as would be required for continued provisional listing for ingested uses and amended the petition for these colors to request the listing of D&C Orange No. 10 and D&C Orange No. 11 for use only in externally applied drugs and cosmetics. Because there is no petition for the listing of D&C Orange No. 10 and D&C Orange No. 11 for use in drugs and cosmetics that may be ingested, FDA finds that there no longer exists a basis for the continuation of the provisional listing for this use.

The agency therefore concludes that the current provisional listing of these two colors should be terminated when the permanent listing of these color additives for external uses takes effect. In addition, the provisional listing of D&C Orange No. 10 and D&C Orange No. 11 for use in drugs and cosmetics under § 81.1(b), which was extended to January 31, 1981 by regulation published in the **Federal Register** of February 4, 1977, and which has been further extended to June 25, 1981 by a regulation, will be deleted when this order becomes effective on April 28, 1981 unless it is stayed by the timely filing of objections.

The petitioner was notified in a letter of August 17, 1978, that consideration of the petitioned use of D&C Orange No. 10 in cosmetics intended for use in the area of the eye would require the submission and evaluation of data adequate to support such use. The required data for eye area use have not been submitted to the agency. Therefore, that portion of the petition that was amended by filing on March 5, 1976 (Docket No. 76C–0044), to include the permanent listing of D&C Orange No. 10 for eye area use, is now considered by the agency to be withdrawn without prejudice in accordance with the provisions of § 71.4 (21 CFR 71.4). This section of the regulations requires that such requested information be submitted within 180 days after filing of the petition or will be considered withdrawn without prejudice. Use of D&C Orange No. 10 in the area of the eye has never been covered by provisional listing. Future consideration of the permanent listing of D&C Orange No. 10 for eye area use will require the submission of a new color additive petition for that use. Listing of a color additive for use in externally applied drugs and cosmetics does not encompass eye area use.

All certificates heretofore issued for batches of D&C Orange No. 10 and D&C Orange No. 11 and their lakes for ingested use are revoked, and the addition of the colors and their lakes to ingested drugs or to ingested cosmetics after April 28, 1981 will cause such products to be adulterated within the meaning of the Federal Food, Drug, and Cosmetic Act (22 U.S.C. 301 et seq.), and the products and the persons causing the violation may be subject to regulatory action. This prohibition applies to the use of the straight colors, their lakes, and color additive mixtures containing D&C Orange Nos. 10 or 11. The agency concludes that the protection of the public health does not require the removal from the market of drugs and cosmetics containing the color additives for ingested use or the destruction of drugs or cosmetics that are being manufactured to which these color additives have been added on or before April 28, 1981.

Manufacturers of new drugs and new animal drugs (including certifiable antibiotics for animal use) that may be ingested and that contain D&C Orange Nos. 10 or 11 may either cease adding the color additives or substitute a different color in accordance with the provisions of § 314.8(d)(3) and (e) or § 514.8(d)(3) and (e) (21 CFR 314.8(d)(3) and (e) or 21 CFR 514.8(d)(3) and (e)), as appropriate. If a substitute color is used, the manufacturer shall file with FDA a Supplemental New Drug Application or Supplemental New Animal Drug Application, which contains data describing the new composition and showing that the change in composition does not interfere with any assay and control procedures used in manufacturing the drug, or that the assay and control procedures used in manufacturing the drug have been revised to make them adequate. The applicant shall also submit data that establish the stability of the revised formulation or, if the data are too limited to support a conclusion that the drug will retain its declared potency for the reasonable marketing period, a commitment to test the stability of marketed batches at reasonable intervals, to submit the data as they become available, and to recall from the market any batch found to fall outside the approved specification for the drug.

Each sponsor of a notice of claimed investigational exemption for a new drug (IND) or a notice of claimed investigational exemption for a new animal drug (INAD) containing the subject color should promptly amend the IND or INAD to indicate that the color additives have been deleted or a different color additive substituted.

The agency is aware that supplies of alternative color additives may be difficult to obtain immediately. Consequently, drug and cosmetic labeling that states that the product contains "artificial color," or that specifically identifies D&C Orange Nos. 10 or 11 may continue to be used with uncolored products, or products containing substitute colors, during the time necessary to obtain supplies of revised labeling or until April 28, 1982, whichever occurs first.

The agency has determined under 21 CFR 25.24(b)(12) and 21 CFR 25.24(d)(5) (proposed December 11, 1979; 44 FR 71742) that this action is of a type that does not individually or cumulatively have a significant effect on the environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

A Regulatory Flexibility Analysis is not required for this final rule. Color additive regulations, such as this one, which are initiated by an industry petition, are promulgated without a proposed rule as specified under section 706(d)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 376(d)(1)). The requirement to perform a Regulatory Flexibility Analysis under sections 601(2) and 604(a) of the Regulatory Flexibility Act does not apply to final rules that are published without the need for a notice of proposed rulemaking. In addition, the filing notice on which this rule is based was published prior to the January 1, 1981 effective date of the provisions of the Regulatory Flexibility Act that require preparation of initial and final regulatory flexibility analyses (5 U.S.C. 603 and 604).

This final rule is also exempt from the requirement to perform a Regulatory Impact Analysis under section 3(a) of Executive Order 12291 because this rulemaking is subject to the formal rulemaking provisions of 5 U.S.C. 556 and 557 by virtue of sections 706(d) and 701(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 376(d) and 371(e)). See section 1(a)(1) of Executive Order 12291.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 706 (b), (c), and (d), 74 Stat. 399–403 (21 U.S.C. 376 (b), (c), and (d))), the formal rulemaking provisions of sec. 701(e), 70 Stat. 919 as amended 21 U.S.C. 371(e)); the Transitional Provisions of the Color Additive Amendments of 1960 [Title II, Pub. L. 86–618, sec. 203, 74 Stat. 404–407 (21 U.S.C. 376, note)]; and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), Parts 74, 81, and 82 are amended as follows:

PART 74—LISTING OF COLOR ADDITIVES SUBJECT TO CERTIFICATION

1. Part 74 is amended:

a. By adding new § 74.1260 to Subpart B, to read as follows:

§ 74.1260 D&C Orange No. 10.

(a) *Identity.* (1) The color additive D&C Orange No. 10 is a mixture consisting principally of 4',5'-diiodofluorescein, 2',4',5'-triiodofluorescein, and 2',4',5',7'-tetraiodofluorescein.

(2) Color additive mixtures for drug use made with D&C Orange No. 10 may contain only those diluents listed in this subpart as safe and suitable for use in color additive mixtures for coloring externally applied drugs.

(b) *Specifications.* D&C Orange No. 10 shall conform to the following specifications and shall be free from impurities other than those named to the extent that such other impurities may be avoided by good manufacturing practice:

Sum of volatile matter (at 135° C) and halides and sulfates (calculated as sodium salts), not more than 8 percent.

Insoluble matter (alkaline solution), not more than 0.5 percent.

Phthalic acid, not more than 0.5 percent.

2-[3',5'-Diiodo-2',4'-dihydroxybenzoyl] benzoic acid, not more than 0.5 percent.

Fluorescein, not more than 1 percent.

4'-Iodofluorescein, not more than 3 percent.

2',4'-Diiodofluorescein and 2',5'-diiodofluorescein, not more than 2 percent.

2',4',5'-Triiodofluorescein, not more than 35 percent.

2',4',5',7'-Tetraiodofluorescein, not more than 10 percent.

4',5'-Diiodofluorescein, not less than 60 percent and not more than 95 percent.

Lead (as Pb), not more than 20 parts per million.

Arsenic (as As), not more than 3 parts per million.

Mercury (as Hg), not more than 1 part per million.

Total color, not less than 92 percent.

(c) *Uses and restrictions.* D&C Orange No. 10 may be safely used for coloring externally applied drugs in amounts consistent with good manufacturing practice.

(d) *Labeling requirements.* The label of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification.* All batches of D&C Orange No. 10 shall be certified in accordance with regulations in Part 80 of this chapter.

b. By adding new § 74.1261 to Subpart B, to read as follows:

§ 74.1261 D&C Orange No. 11.

(a) *Identity.* (1) The color additive D&C Orange No. 11 is a mixture consisting principally of the disodium salts of 4',5'-diiodofluorescein, 2',4',5'-triiodofluorescein and 2',4',5',7'-tetraiodofluorescein.

(2) Color additive mixtures for drug use made with D&C Orange No. 11 may contain only those diluents listed in this subpart as safe and suitable for use in color additive mixtures for coloring externally applied drugs.

(b) *Specifications.* The color additive D&C Orange No. 11 shall conform to the following specifications and shall be free from impurities other than those named to the extent that such impurities may be avoided by good manufacturing practice:

Sum of volatile matter (at 135° C) and halides and sulfates (calculated as sodium salts), not more than 8 percent.

Water-insoluble matter, not more than 0.5 percent.

Phthalic acid, not more than 0.5 percent.

2-[3',5'-Diiodo-2',4'-dihydroxybenzoyl] benzoic acid, sodium salt, not more than 0.5 percent.

Fluorescein, disodium salt, not more than 1 percent.

4'-Iodofluorescein, disodium salt, not more than 3 percent.

2',4'-Diiodofluorescein and 2',5'-diiodofluorescein, not more than 2 percent.

2',4',5'-Triiodofluorescein, not more than 35 percent.

2',4',5',7'-Tetraiodofluorescein, disodium salt, not more than 10 percent.

4',5'-Diiodofluorescein, disodium salt, not less than 60 percent and not more than 95 percent.

Lead (as Pb), not more than 20 parts per million.

Arsenic (as As), not more than 3 parts per million.

Mercury (as Hg), not more than 1 part per million.

Total color, not less than 92 percent.

(c) *Uses and restrictions.* D&C Orange No. 11 may be safely used for coloring externally applied drugs in amounts consistent with good manufacturing practice.

(d) *Labeling requirements.* The label of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification.* All batches of D&C Orange No. 11 shall be certified in accordance with regulations in Part 80 of this chapter.

c. By adding new § 74.2260 to Subpart C, to read as follow:

§ 74.2260 D&C Orange No. 10.

(a) *Identity and specifications.* The color additive D&C Orange No. 10 shall conform in identity and specifications to the requirements of § 74.1260(a)(1) and (b).

(b) *Uses and restrictions.* D&C Orange No. 10 may be safely used for coloring externally applied cosmetics in amounts consistent with good manufacturing practice.

(c) *Labeling requirements.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Certification.* All batches of D&C Orange No. 11 shall be certified in accordance with regulations in Part 80 of this chapter.

d. By adding new § 74.2261 to Subpart C, to read as follows:

§ 74.2261 D&C Orange No. 11.

(a) *Identity and specifications.* The color additive D&C Orange No. 11 shall conform in identity and specifications to the requirements of § 74.1261(a)(1) and (b).

(b) *Uses and restrictions.* D&C Orange No. 11 may be safely used for coloring externally applied cosmetics in amounts consistent with good manufacturing practice.

(c) *Labeling requirements.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Certification.* All batches of D&C Orange No. 11 shall be certified in accordance with regulations in Part 80 of this chapter.

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

2. Part 81 is amended:

§ 81.1 [Amended]

a. In paragraph (b) of § 81.1 *Provisional lists of color additives* by removing the entries for "D&C Orange No. 10" and D&C Orange No. 11."

b. In § 81.10 by adding new paragraph (m), to read as follows:

§ 81.10 Termination of provisional listing of color additives.

* * * * *

(m) *D&C Orange Nos. 10 and 11.* In the absense of a petition to list D&C Orange No. 10 and D&C Orange No. 11 for use in ingested drugs and cosmetics, there no longer exists a basis for provisional listing for such uses. Therefore, FDA is terminating the provisional listing of D&C Orange No. 10 and D&C Orange No. 11 for use in ingested drugs and cosmetics, effective April 28, 1981.

c. In § 81.30 by adding new paragraph (n), to read as follows:

§ 81.30 Cancellation of certificates.

* * * * *

(n)(1) Certificates issued for D&C Orange No. 10, D&C Orange No. 11, their lakes, and all mixtures containing these color additives are cancelled and have no effect as pertains to their use in ingested drugs and cosmetics after April 28, 1981 and use of these color additives in the manufacture of ingested drugs or cosmetics after this date will result in adulteration.

(2) The agency finds, on the basis of the scientific evidence before it, that no action has to be taken to remove from the market drugs and cosmetics to which the color additives were added on or before April 28, 1981.

PART 82—LISTING OF CERTIFIED PROVISIONALLY LISTED COLORS AND SPECIFICATIONS

3. Part 82 is amended:

a. By revising § 82.1260, to read as follows:

§ 82.1260 D&C Orange No. 10.

The color additive D&C Orange No. 10 shall conform in identity and specifications to the requirements to § 74.1260(a)(1) and (b) of this chapter. D&C Orange No. 10 is restricted to use in externally applied drugs and cosmetics.

b. By revising § 82.1261, to read as follows:

§ 82.1261 D&C Orange No. 11.

The color additive D&C Orange No. 11 shall conform in identity and specifications to the requirements of § 74.1261(a)(1) and (b) of this chapter. D&C Orange No. 11 is restricted to use in externally applied drugs and cosmetics.

Any person who will be adversely affected by the foregoing regulation may at any time on or before April 27, 1981 file with the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written objections thereto. Objections shall show wherein the person filing will be adversely affected by the regulation, specify with particularity the provisions of the regulation deemed objectionable, and state the grounds for the objections. Objections shall be filed in accordance with the requirements of 21 CFR 71.30. If a hearing is requested, the objections shall state the issues for the hearing, shall be supported by grounds factually and legally sufficient to justify the relief sought, and shall include a detailed description and analysis of the factual information intended to be presented in support of the objections in the event that a hearing is held. Four copies of all documents shall be filed and shall be identified with the docket number found in brackets in the heading of this regulation. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Effective date. This regulation shall become effective April 28, 1981, except as to any provisions that may be stayed by the filing of proper objections. All affected products initially introduced or initially delivered for introduction into interstate commerce on or after April 28, 1982 shall fully comply with this regulation. Notice of the filing of objections or lack thereof will be announced by publication in the **Federal Register.**

(Sec. 706(b), (c), and (d), 74 Stat. 399–403 (21 U.S.C. 376(b), (c), and (d)); sec. 203, Pub. L. 86–618, 74 Stat. 404–407 (21 U.S.C. 376, note))

Dated: March 24, 1981.

Joseph P. Hile,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 81-9351 Filed 3-26-81; 3:55 pm]

BILLING CODE 4110-03-M

---

21 CFR Part 81

[Docket No. 76N-0366]

Provisional List of Certain Color Additives; Extension of Closing Dates

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: In response to three citizen petitions, the Food and Drug Administration (FDA) in this document is extending the closing dates for the use of 23 provisionally listed color additives beyond January 31, 1981. The extension is conditioned upon the timely completion of ongoing scientific investigations and the submission of data to FDA on a prescribed schedule.

EFFECTIVE DATE: March 27, 1981.

FOR FURTHER INFORMATION CONTACT: Marvin D. Mack, Bureau of Foods (HFF–334), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–472–5740.

SUPPLEMENTARY INFORMATION: Under Title II of the Color Additive Amendments of 1960, Pub. L. 86-618, sec. 203(a)(2), 74 Stat. 405 (21 U.S.C. 376, note) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), FDA is authorized to extend a closing date for the provisional listing of a color additive on its own initiative or upon the application of an interested person. Section 203(d)(1) of Title II of the Color Additive Amendments requires the issuance of regulations or amended regulations establishing, insofar as practicable, a current listing of color additives and the particular uses considered to be provisionally listed.

In the **Federal Register** of February 4, 1977 (42 FR 6392), FDA extended the closing dates for 52 provisionally listed color additives based upon the agency's conclusion that the postponement was consistent with the objective of carrying to completion, in good faith, and as soon as reasonably practicable, the scientific investigations necessary for making a determinations as to listing these color additives under section 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 376) (the act). This action was part of the agency's publicly stated commitment, published in the **Federal Register** of January 5, 1976 (41 FR 754), to make final determination about the permanent listing of the provisionally listed colors and to take steps to resolve the status of each of the provisionally listed color additives. Since February 4, 1977, final action has been taken on 24 provisionally listed color additives.

In April 1980, FDA received three citizen petitions from the Cosmetic, Toiletry, and Fragrance Association, Inc. (CTFA), 1133 15th St. NW., Washington, DC 20005, the Pharmaceutical Manufacturers Association, Inc. (PMA), 1155 15th St. NW., Washington, DC 20004, and the Certified Color Manufacturers Association, Inc. (CCMA), 900 17th St. NW., Washington, DC 20006, requesting the Commissioner to amend §§ 81.1 and 81.27 (21 CFR 81.1 and 81.27) to postpone the closing dates for the provisional listing of 23 color additives for which they have submitted color additive petitions requesting permanent listing. These petitions requested postponements in order that ongoing chronic feeding studies can be completed on each additive.

The February 4, 1977 **Federal Register** announcement required the initiation of these chronic feeding studies for the 23 color additives because earlier chronic studies in the 1950's and 1960's on those colors were not considered adequate to conclusively determine their safety when judged by contemporary scientific standards (see 42 FR 6992; February 4, 1977). However, due to unavoidable and unforeseen delays occurring in the conduct of these chronic feeding studies, the petitioners sought the instant postponements.

In response to the CTFA, PMA, and CCMA citizen petitions, the agency in the **Federal Register** of November 14, 1980 (45 FR 75226) proposed to postpone the closing dates for the 23 provisionally listed color additives under test beyond January 31, 1981, the closing date established in the regulation published on February 4, 1977. In the preamble of the November 14, 1980 proposal, the agency set forth its views on why, under the peculiar circumstances surrounding the ongoing chronic feeding studies, such postponements were reasonable, necessary, and consistent with its statutory mandate of carrying to completion as soon as reasonably practicable the safety determinations for the additives at issue. The specific bases for the postponements set forth in that notice will not be repeated herein, except to the extent necessary to respond to the three comments submitted in response to it.

Although the agency had decided to postpone the closing date for these colors before it expired, FDA did not publish and make effective the final rule before President Reagan signed his Executive Memorandum of January 29, 1981, which directed agencies to postpone for 60 days all pending regulations, with certain exemptions inapplicable to postponements of closing dates for provisionally listed colors. Therefore, the provisional listing of these colors lapsed. However, because the agency fully intended to extend the provisional list at the first opportunity, on February 2, 1981, the agency notified the three trade associations that had petitioned the agency for an extension of the provisional listing of the 23 color additives that it intended to extend the list, and that it would not take any regulatory action against the provisionally listed color additives during the period the list was technically not in effect. The Office of Management and Budget has now granted FDA an exemption to publish these regulations, even though the 60-day period has not expired.

FDA believes that it is appropriate and consistent with Congress's intent in enacting the Color Additive Amendments of 1960 to extend the provisional listing of these color additives at this time. Section 203(a)(1) of Title II of Pub. L. 86-618 states:

> The purpose of this section is to make possible, on an interim basis for a reasonable period through provisional listings, the use of commercially established color additives to the extent consistent with the public health, pending the completion of the scientific investigations needed as a basis for making determinations as to listing of such additives under the basic Act [the Federal Food, Drug, and Cosmetic Act] as amended by this Act.

As explained below, FDA has given individual consideration to each color additive and has found no public health reason that requires the immediate cessation of use of any of the colors. The scientific investigations that will provide the basis for a final determination on the safety of these color additives have not been unreasonably prolonged. Therefore, the fact that the agency was prevented from extending the closing date for the provisional list in a timely manner because that closing date, established over 3 years ago, happened to coincide with a Presidential directive not to issue new regulations, provides no basis for not continuing to make these color additives available. FDA has determined that these colors should remain provisionally listed until the agency has had an opportunity to make an appropriate determination about their listing under section 706 of the act (21 U.S.C. 376).

The November 14, 1980 proposal generated the submission of two supportive comments from trade associations and one comment from a citizens group which challenges FDA's legal authority to postpone the closing date of the provisional list for the 23 color additives. These comments and FDA's responses are summarized below.

1. One comment from a trade association agreed with FDA's account in the November 14, 1980, preamble to the proposed postponements concerning the petitioners' good faith efforts to comply with the original timetable for completing the ongoing chronic toxicological studies on the 23 color additives. The association also agreed with each conclusion in the preamble concerning the justification for the postponements and that the postponement of deadlines is consistent with the protection of the public health. This comment further endorsed the proposed staggered extension schedule because it would allow both the agency and the testing laboratories flexibility in allocating their available resources more efficiently to prepare and review the final study reports. In conclusion, the association agreed that the requested postponements are consistent with FDA's "statutory 'objective of carrying to completion in good faith, as soon as

reasonably practicable, the scientific investigations necessary for making a determination as to listing' the 23 color additives. 21 U.S.C. 376, note." The other trade association reiterated the conclusion made by the first association that the proposed postponements were consistent with FDA's statutory responsibilities under the transitional provisions of the Color Additive Amendments of 1960.

2. The comment from the citizen's group, while alleging that the agency does not possess the authority to make the proposed postponements, did not make a per se challenge to FDA's statutory authority to extend the color additive provisional list. Rather, this comment implied that there exists no rational nexus between the facts found to be underlying the proposed postponements and the choices made by FDA. The comment asserted that FDA had failed to show that any "extraordinary circumstances" exist for granting the proposed extensions. Thus, the comment suggested that FDA would be acting in an arbitrary and capricious manner if it promulgated the proposed postponements. In addition, the comment attempted to bolster its primary legal argument by citing a "Stipulation" between FDA and the Health Research Group (HRG), which was entered into after a district court found that FDA had the authority to postpone the provisional list to allow for the performance of "new" animal feeding studies. See *Health Research Group* v. *Califano*, Civ. No. 77–293 (D.D.C. 1977). In that stipulation the agency agreed that any further postponement of the closing dates would be made on consideration of each color additive individually. The comment concluded that the proposed postponements are "generic" and based upon "general considerations". Thus, the comment contended that the proposed postponements violate the stipulation. For the reasons set forth below the agency rejects this entire comment.

FDA possesses broad discretion in granting postponements of the provisional listing for color additives. An examination of the legislative history, the statute, and the case law supports this conclusion.

In vesting FDA with the authority to administer the transitional provisions of the Color Additive Amendments, Congress did not impose a rigid formula on the manner in which the agency must apply its expertise to the development and evaluation of safety data on provisionally listed color additives. The House of Representatives' report on the transitional provisions does not express any intent to constrict the agency's discretionary authority to postpone the provisional list for color additives. It clearly indicated that provisional listings are to be used "pending the development of the scientific data required for a definitive determination as to the listing of those colors under the permanent provisions of the bill." H.R. Rep. No. 1761, 86th Cong., 2d Sess. 10 (1960). Here, the completion of the ongoing chronic-feeding studies are necessary, so that definitive safety determinations can be made based upon the most current and accurate scientific data.

The statute itself also provides for the exercise of judgmental and discretionary functions:

> The [Commissioner] may by regulation * * * from time to time postpone the original closing date with respect to a provisional listing * * * for such period or periods as he finds necessary to carry out the purpose of this section, if in the [Commissioner's] judgment such action is consistent with the objective of carrying to completion in good faith, as soon as reasonably practicable, the scientific investigations necessary for making a determination as to listing such additive * * *.

Section 203(a)(2) of Color Additive Amendments of 1960.

The case law confirms the broad discretionary powers vested in FDA in making judgments on whether to postpone a color additive provisional listing. In *Health Research Group* v. *Califano, supra*, the court found that the agency possessed the authority to extend the provisional list not only in cases where the studies are ongoing, as here, but also possesses the authority to extend such listing when new studies are required:

> It is clear, then, that the Color Additive Amendments of 1960 do not limit the Commissioner's authority to extend provisional listings only in cases where it is necessary to complete ongoing tests. Rather, the Commissioner has discretion to postpone the closing dates of provisional listings so long as the postponements are consistent with his statutory mandate to protect the public health.

Id. at 4. See also *Certified Color Manufacturers Ass'n* v. *Mathews*, 543 F. 2d 284, 294 (D.C. Cir. 1976).

Thus, it is clear from the legislative history, the statute, and the case law that if reasonable grounds exist, the extension of the provisional list for the purpose of completing the ongoing chronic feeding studies for the 23 color additives is, as a matter of law, proper.

However, the comment further contended that the proposed postponements violate FDA's own announced standards for evaluating all further requests for provisional list extensions; namely, the existence of "unavoidable, unforeseen, and extraordinary circumstances." (See 42 FR 6998; Feb. 4, 1977). Therefore, the comment implied that no reasonable grounds exist for the proposed postponements.[1] The agency disagrees.

The November 14, 1980 proposal identified several unanticipated and unavoidable delays surrounding the conduct of the current chronic feeding studies, which lead the agency to conclude, in its considered judgment, that "extraordinary circumstances" exist and warrant extension of the closing date for the 23 color additives. Those unforeseen and unavoidable circumstances are as follows:

1. FDA needed additional time to approve the protocols and dosage levels.

2. FDA changed the high-dose levels after the studies were initiated, necessitating the addition of another dose level to some studies.

3. There were laboratory delays in preparing the test protocols and final reports.

4. There were shortages of some color additives midway through the testing program.

Because of the novel protocols involved in these studies, one source of unexpected delay was the lack of historical data to assist the petitioners and FDA toxicologists in accurately predetermining the dose levels that should be fed to the test animals, including *in utero* exposure. The stringent timetable forced the petitioners to begin the chronic feeding studies before FDA had approved the dose levels to be fed. FDA later disagreed with the choice of dose levels involving 13 of the color additives. The petitioners and FDA agreed at that time that an additional higher dose level with a concurrent control group would be initiated for each of the color additives involved as soon as possible. In each case, however, the data on the first three dose levels were to be submitted to FDA by August 4, 1980. FDA would then evaluate the data on the three dose levels submitted to determine whether provisional listing should continue until the final report containing the data on the fourth and highest dose was submitted.

[1] The comment does not contravene by the submission of data or other evidence any of the factual circumstances set forth in the November 14, 1980, proposal. Rather, it only makes broad conclusory suggestions that such circumstances may not exist. Thus, the factual findings which, in the agency's opinion, constitute "unavoidable, unforeseen, and extraordinary circumstances," stand uncontroverted.

Unavoidable delays were also caused by the shortage of adequate animal testing laboratories and, especially, trained pathologists in this country and abroad at a time when Congress and many Federal agencies are requiring more and more animal safety testing. This shortage has caused large work backlogs in these laboratories. In addition, the implementation of FDA's Good Laboratory Practice regulations in Part 58 (21 CFR Part 58) has increased this backlog by decreasing the number of acceptable testing facilities. These unavoidable occurrences lead the agency to conclude that "extraordinary circumstances" exist, and that the postponement of the provisional list is reasonable.

It must be pointed out that it was not known by FDA at the beginning of these safety studies that these circumstances would occur and necessitate postponing the closing dates. Once these delays occurred they first had to be overcome, so that FDA would be able to make the safety determinations based upon the best available data. Thus, this action is consistent with the overriding objective of Congress in enacting the transitional provisions of Color Additive Amendments.

The final aspect of this comment concerned the FDA/HRG stipulation, which states that FDA must grant further extensions of the provisional list only on an individual basis. Consideration of each individual color additive by FDA has occurred here. The closing dates, as listed in the November 14, 1980 proposal were individually evaluated before proposing these varying dates, including consideration of the original starting date for the study, the need to add additional dosage groups to the study, the difficulties that have occurred in the conduct of specific studies, and the unavailability of pathologists. FDA has also concluded that varying the closing dates is necessary because of the current status of each chronic feeding study, and because a staggered system is better suited to the needs of the testing laboratories.

The agency has established a closing date for each color additive that is 1 year after the date of the final report is due from the petitioner. The agency has established this 1-year period to ensure that there is sufficient time for it to complete its evaluation of the data and for it to take final action on the petition. The agency will endeavor to act on petitions as quickly as possible, however, and if the agency is able to take final action on a petition before its closing date, FDA will exercise its authority under section 223(a)(2) of Title II of Pub. L. 86-618 and terminate the extension of the closing date at that time.

The staggered final report dates would also allow the four animal testing laboratories sufficient time, considering their available resources, to evaluate and prepare final reports. The agency will be required to review the histopathological slides from these studies, in addition to the related study reports, in order to make its safety determinations. After review of these data, FDA must issue final decisions as to whether these color additives will be listed under section 706 of the act.

In addition to the foregoing, and as also agreed to in the FDA/HRG stipulation, FDA continues to advise HRG when copies of petitioners' progress reports on individual color additive studies are submitted to the agency, when FDA evaluates and makes reports on each of the progress reports, and when applications for extension of the January 31, 1981, closing date for any of the provisionally listed color additives are received.

Progress reports on color additives, FDA's evaluation of those reports, and applications for extensions of the closing date are also placed on file with FDA's Dockets Management Branch for public review. The agency has received no objections or comments stating that the evaluations on the progress reports indicate that a public health problem exists. Indeed, the agency concludes that its review of progress reports on each color under test demonstrates that there continues to be no public health or safety concerns with any of the 23 color additives. Thus, extension of the provisional list is consistent with FDA's statutory mandate to protect the public health.

Having evaluated the comments, the agency concludes that the extension of the closing dates for provisionally listed color additives in §§ 81.1 and 81.27 (21 CFR 81.1 and 81.27) is reasonable and in the public interest.

The agency notes that this document does not extend the provisional listing for D&C Orange No. 10, D&C Orange No. 11, D&C Green No. 6, and caramel. Elsewhere in this issue of the **Federal Register**, the provisional listings for these color additives are being extended. With respect to the color additive caramel, this document deletes the requirement for a lifetime mouse skin-painting study to make that listing consistent with the decision on caramel contained elsewhere in this edition of the **Federal Register.** In addition, this document adds the restriction of "External use only" for D&C Green No. 6 in accordance with the agency's decision found elsewhere in this issue of the **Federal Register.**

Therefore, under the transitional provisions of the Color Additive Amendments of 1960 (Title II, Pub. L. 86-618, 74 Stat. 404-407 (21 U.S.C. 376, note)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), Part 81 of Subchapter A of Title 21 of the Code of Federal Regulations is amended as follows:

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

1. In § 81.1 the tables in paragraphs (a), (b), and (c) are revised to read as follows:

§ 81.1 Provisional lists of color additives.

* * * * *

(a) * * *

	Closing date		Restrictions
	Food use	Drug and cosmetic use	
FD&C Blue No. 1 (sec. 74.101 of this chapter).	Oct. 30, 1982[1]	Oct. 30, 1982	
FD&C Blue No. 2 (sec. 74.1102 of this chapter).	Oct. 30, 1982	do	Food and ingested drugs.
FD&C Green No. 3 (sec. 82.203 of this chapter).	Nov. 16, 1982	Nov. 16, 1982	
FD&C Red No. 3 (sec. 74.303 of this chapter).	Oct. 2, 1983[1]	Oct. 2, 1983	
FD&C Yellow No. 5 (sec. 74.705 of this chapter).	Oct. 7, 1983[1]	Oct. 7, 1983	
FD&C Yellow No. 6 (sec. 82.706 of this chapter).	Feb. 28, 1984	Feb. 28, 1984	
Lakes (FD&C) (sec. 82.51 of this chapter).			

[1] Lakes only.

	Closing date	Restrictions
(b) * * *		

	Closing date	Restrictions
D&C Green No. 5 (sec. 74.1205 of this chapter).	May 30,1982	
D&C Green No. 6 (sec. 74.1206 (a) and (b) of this chapter).	Jan. 31, 1981	External use only
D&C Orange No. 5 (sec. 82.1255 of this chapter).	Oct. 30, 1982	Sec. 81.25
D&C Orange No. 10 (sec. 82.1260 of this chapter).	Jan. 31, 1981	
D&C Orange No. 11 (sec. 82.1261 of this chapter).	....do	
D&C Orange No. 17 (sec. 82.1267 of this chapter).	Mar. 31, 1983	Do.
D&C Red No. 6 (sec. 82.1306 of this chapter).	Dec. 31, 1982	
D&C Red No. 7 (sec. 82.1307 of this chapter).	....do	
D&C Red No. 8 (sec. 82.1308 of this chapter).	Sept. 30, 1983	Sec. 81.25
D&C Red No. 9 (sec. 82.1309 of this chapter).	....do	Do.
D&C Red No. 19 (sec. 82.1319 of this chapter).	Feb. 28, 1983	Sec. 81.25
D&C Red No. 21 (sec. 82.1321 of this chapter).	Nov. 30, 1982	
D&C Red No. 22 (sec. 82.1322 of this chapter).	....do	
D&C Red No. 27 (sec. 82.1327 of this chapter).	Oct. 30, 1982	
D&C Red No. 28 (sec. 82.1328 of this chapter).	....do	
D&C Red No. 30 (sec. 82.1330 of this chapter).	May 30, 1982	
D&C Red No. 33 (sec. 82.1333 of this chapter).	Mar. 31, 1983	Sec. 81.25
D&C Red No. 36 (sec. 82.1336 of this chapter).	Sept. 30, 1984	Do.
D&C Red No. 37 (sec. 82.1337 of this chapter).	Feb. 28, 1983	Do.
D&C Yellow No. 10 (sec. 82.1710 of this chapter).	Apr. 30, 1983	Do.
Lakes (D&C) (Sec. 82.2051 of this chapter).		

	Closing date	Restrictions
(c) * * *		
Lake (ext. D&C) (sec. 82.105(1) of this chapter)		

2. In § 81.27 by revising the introductory text of paragraph (d), paragraph (d)(3), the introductory text of paragraph (e), and paragraph (e)(2), to read as follows:

§ 81.27 Conditions of provisional listing.

* * * * *

(d) The closing dates and dates for final reports for the following 23 color additives are postponed in accordance with the following list while chronic toxicity feeding studies are conducted and evaluated and subject to compliance with the requirements of this paragraph:

	Final report due	Closing date
FD&C Blue No. 1	Oct. 30, 1981	Oct. 30, 1982.
FD&C Blue No. 2	Oct. 30, 1981	Oct. 30, 1982.
FD&C Green No. 3	Nov. 16, 1981	Nov. 16, 1982.
D&C Green No. 5	May 30, 1981	May 30, 1982.
D&C Orange No. 5	Oct. 30, 1981	Oct. 30, 1982.
D&C Orange No. 17.	Mar. 31, 1982	Mar. 31, 1983.
FD&C Red No. 3	Oct. 2, 1982	Oct. 2, 1983.
D&C Red No. 6	Dec. 31, 1981	Dec. 31, 1982.
D&C Red No. 7	Dec. 31, 1981	Dec. 31, 1982.
D&C Red No. 8	Sept. 30, 1982	Sept. 30, 1983.
D&C Red No. 9	Sept. 30, 1982	Sept. 30, 1983.
D&C Red No. 19	Feb. 28, 1982	Feb. 28, 1983.
D&C Red No. 21	Nov. 30, 1981	Nov. 30, 1982.
D&C Red No. 22	Nov. 30, 1981	Nov. 30, 1982.
D&C Red No. 27	Oct. 30, 1981	Oct. 30, 1982.
D&C Red No. 28	Oct. 30, 1981	Oct. 30, 1982.
D&C Red No. 30	May 30, 1981	May 30, 1982.
D&C Red No. 33	Mar. 31, 1982	Mar. 31, 1983.
D&C Red No. 36	Sept. 30, 1983	Sept. 30, 1984.
D&C Red No. 37	Feb. 28, 1982	Feb. 28, 1983.
FD&C Yellow No. 5	Oct. 7, 1982	Oct. 7, 1983.
FD&C Yellow No. 6	Feb. 28, 1983	Feb. 28, 1984.
D&C Yellow No. 10	Apr. 30, 1982	Apr. 30, 1983.

* * * * *

(3) An initial progress report of the studies on the color additives shall be submitted to the Division of Food and Color Additives by December 31, 1977. Further progress reports shall be submitted at 6-month intervals thereafter.

* * * * *

(e) The closing date for FD&C Red No. 3 and D&C Red No. 33 are postponed until October 2, 1983 and March 31, 1983, respectively, while multigeneration reproduction studies are conducted and evaluated, and subject to compliance with the requirements of this paragraph.

* * * * *

(2) An initial progress report of the studies on the color additives shall be submitted by July 1, 1978 and at 6-month intervals thereafter. A full report of the studies conducted on the color additives shall be submitted to the Division of Food and Color Additives in accordance with the scheduled dates in paragraph (d) of this section.

* * * * *

Effective date. This regulation becomes effective March 27, 1981.

(Title II of Pub. L. 86-618, sec. 203(c), (d), 74 Stat. 405 (21 U.S.C. 376 note))

Dated: March 24, 1981.

Joseph P. Hile,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 81-9347 Filed 3-26-81; 3:58 pm]

BILLING CODE 4110-03-M

21 CFR Part 81

[Docket No. 76N-0366]

Extension of Closing Dates for Provisional Listings; D&C Orange No. 10, D&C Orange No. 11, D&C Green No. 6, and Caramel

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is extending for 90 days from the date of publication of this document the closing dates for the provisional listings of D&C Orange No. 10 and D&C Orange No. 11 for use as color additives in externally applied drugs and cosmetics. This order will permit the continued use of these color additives until the new closing dates. The new closing date for D&C Orange No. 10 and D&C Orange No. 11 is being established to provide time for completing final action on the petitions for the listing of these color additives for use in externally applied drugs and cosmetics. The agency is also extending for 120 days from the date of publication of this document the closing dates for the provisional listings of D&C Green No. 6 and caramel. The brief extension for D&C Green No. 6 will provide time for FDA to issue a final decision either to approve or to deny the petition for permanent listing of this color additive. The 120-day extension of the closing date for caramel will provide the agency with a brief period that is necessary to complete final action on the petition for caramel as a color additive for general use in cosmetics.

DATES: Effective March 27, 1981, the new closing date for D&C Orange No. 10 and D&C Orange No. 11 will be June 25, 1981, the new closing date for D&C Green No. 6 and caramel will be July 27, 1981.

FOR FURTHER INFORMATION CONTACT: Andrew D. Laumbach, Bureau of Foods (HFF-334), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-472-5690.

SUPPLEMENTARY INFORMATION: These regulations extend the provisional listings of D&C Orange No. 10, D&C Orange No. 11, D&C Green No. 6, and caramel. The closing date for the provisional listing of these color