indicating any conditions which the registrant must meet in order to obtain or retain the property. If held by leases or options, the expiration dates of such leases or options should be stated. Appropriate maps may be used to portray the locations of significant properties.

(3) A brief history of previous operations, including the names of previous operators, insofar as known.

(4)(a) A brief description of the present condition of property, the work completed by the registrant on the property, the registrant's proposed program of exploration and development, and the current state of exploration and/or development of the property. Mines should be identified as either open-pit or underground. If the property is without known reserves and the proposed program is exploratory in nature, a statement to that effect shall be made.

(b) The age, details as to modernization and physical condition of the plant and equipment, including subsurface improvements and equipment. Further, the total cost for each property and its associated plant and equipment should be stated. The source of power utilized with respect to each property should also be disclosed.

(5) A brief description of the rock formations and mineralization of existing or potential economic significance on the property, including the identity of the principal metallic or other constituents insofar as known. If proven (measured) or probable (indicated) reserves have been established, state (i) the estimated tonnages and grades (or quality, where appropriate) of such classes of reserves, and (ii) the name of the person making the estimates and the nature of his relationship to the registrant.

Instructions

1. It should be stated whether the reserve estimate is of in-place material or of recoverable material. Any in-place estimate should be qualified to show the anticipated losses resulting from mining methods and beneficiation or preparation.

2. The summation of proven (measured) and probable (indicated) ore reserves is acceptable if the difference in degree of assurance between the two classes of reserves cannot be reliably defined.

3. No estimates or reserves of lesser assurance than proven (measured) and probable (indicated) such as "possible" or "inferred" should be set forth.

(6) If technical terms relating to geology, mining or related matters whose definitions cannot be readily found in conventional dictionaries (as opposed to technical dictionaries or glossaries) are used, an appropriate glossary should be included in the registration statement.

(7) Detailed geological maps and reports, feasibility studies and other highly technical data should not be included in the registration statement but should be, to the degree appropriate and necessary for the Commission's understanding of the registrant's presentation of business and property matters, furnished as supplemental information.

(c) *Supplemental Information:*

(1) If an estimate of proven (measured) or probable (indicated) reserves is set forth in the registration statement, furnish:

(i) maps drawn to scale showing any mine workings and the outlines of the reserve blocks involved together with the pertinent sample-assay thereon,

(ii) all pertinent drill data and related maps,

(iii) the calculations whereby the basic sample-assay or drill data were translated into the estimates made of the grade and tonnage of reserves in each block and in the complete reserve estimate.

Instructions—Maps and other drawings submitted to the staff should include:

1. A legend or explanation showing, by means of pattern or symbol, every pattern or symbol used on the map or drawing; the use of the symbols used by the U.S. Geological Survey is encouraged;

2. A graphical bar scale should be included; additional representations of scale such as "one inch equals one mile" may be utilized provided the original scale of the map has not been altered;

3. A north arrow on maps;

4. An index map showing where the property is situated in relationship to the state or province, etc., in which it was located;

5. A title of the map or drawing and the date on which it was drawn;

6. In the event interpretive data is submitted in conjunction with any map, the identity of the geologist or engineer that prepared such data;

7. Any drawing should be simple enough or of sufficiently large scale to clearly show all features on the drawing.

(2) Furnish a complete copy of every material engineering, geological or metallurgical report concerning the registrant's property, including governmental reports, which are known and available to the registrant. Every such report should include the name of its author and the date of its preparation, if known to the registrant.

Any of the above-required reports as to which the staff has access need not be submitted. In this regard, issuers should consult with the staff prior to filing the registration statement. Any reports not submitted should be identified in a list furnished to the staff. This list should also identify any known governmental reports concerning the registrant's property.

(3) Furnish copies of all documents such as title documents, operating permits and easements needed to support representations made in the registration statement.

* * * * *

Item 15. Financial Statements and Instructions

(f) With respect to companies engaged or to be engaged in the mining business, attention is directed to the instruction to Item 7A(a)(4) concerning the appropriate classification of issuers engaged in the exploratory, development and production stage of mining.

* * * * *

PART 230—GENERAL RULES AND REGULATIONS, SECURITIES ACT OF 1933

1. By revising paragraph (a)(5)(ii) of § 230.242 to read as follows:

§ 230.242 Exemption of limited offers and sales by qualified issuers.

* * * * *

(a) * * *

(5) * * *

(ii) Does not engage or intend to engage in oil and gas related operations which exceed the criteria for exemption specified in § 210.4–10(k) of Regulation S–X.

* * * * *

Statutory Authority

The Commission hereby adopts the amendments to Form S–18 pursuant to Sections 6, 7, 8, 10, and 19(a) of the Securities Act of 1933.

(Secs. 6, 7, 8, 10, 19(A), 48 Stat. 78, 79, 81, 85; secs. 205, 209, 48 Stat. 906, 908; sec. 301, 54 Stat. 857; sec. 8, 68 Stat. 685; sec. 1, 79 Stat. 1051; sec. 308(a)(2), 90 Stat. 57; 15 U.S.C. 77f, 77g, 77h, 77j, 77s(a))

With respect to the technical amendments to Form S–18 and Rule 242 under the Securities Act the Commission believes that it is appropriate to adopt these technical amendments in order to clarify potentially confusing language therein. Accordingly, the Commission pursuant to Section 553(b) of the Administrative Procedure Act ("APA") (5 U.S.C. 553(b)) for good cause finds that notice and opportunity for public comment at this time is impracticable, unnecessary and contrary to the public interest.

By the Commission.

George A. Fitzsimmons,

Secretary.

March 18, 1981.

[FR Doc. 81-9001 Filed 3-26-81; 8:45 am]

BILLING CODE 8010-01-M

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

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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.