public participation and 30-day effective date requirements are inapplicable.

The following regulations contained in Title 7 CFR are deleted:

## PART 728—WHEAT

**§§ 728.310 through 728.526 [Deleted]**

1. In Part 728—Wheat, Subpart—Regulations Pertaining to Farm Acreage Allotments, Yields and Wheat Certificate Program for 1968 and Subsequent Crop Years and Wheat Diversion Program for Crop Years 1969–70 (728.310 through 728.526) is deleted.

**§§ 728.1141 through 728.1186 [Deleted]**

Subpart—Wheat Marketing Quota Regulations for 1961 and Subsequent Crop Years (Sections 728.1141 through 728.1186), is deleted.

## PART 730—RICE

**§§ 730.33 through 730.87 and 730.1507 and 730.1508 [Deleted]**

2. In Part 730—Rice, §§ 730.33 through 730.87 and 730.1507 and 730.1508 are deleted.

## PART 751—LAND USE ADJUSTMENT PROGRAM [DELETED]

3. Part 751—Land Use Adjustment Program, is deleted.

## PART 777—PROCESSOR WHEAT MARKETING CERTIFICATE REGULATIONS [DELETED]

4. Part 777—Processor Wheat Marketing Certificate Regulations, is deleted.

Signed at Washington, D.C., on December 5, 1977.

STEWART N. SMITH,
*Acting Administrator, Agricultural Stabilization and Conservation Service.*

[FR Doc.77-35375 Filed 12-12-77;8:45 am]

[ 3410-02 ]

# CHAPTER IX—AGRICULTURAL MARKETING SERVICE (MARKETING AGREEMENTS AND ORDERS; FRUITS, VEGETABLES, NUTS), DEPARTMENT OF AGRICULTURE

[Orange, Grapefruit, Tangerines, and Tangelo Regulation 1, Amdt. 5]

## PART 905—ORANGES, GRAPEFRUIT, TANGERINES, AND TANGELOS GROWN IN FLORIDA

### Amendment of Tangerine and Tangelo Size Requirements

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Amendment to final rule.

SUMMARY: This amendment, applicable to domestic fresh shipments of Florida tangerines, permits each handler to ship during the week December 5–11, 1977, a quantity of tangerines, not smaller than 2 4/16 inches in diameter (size 210), equal to 45 percent of the volume of tangerines the handler shipped in the most recent previous week of the current fiscal period and to ship unlimited quantities of size 210 tangerines during the period December 12, 1977, through September 24, 1978. Currently, any handler may handle only 30 percent of size 210 fruit during the week December 5–11 and no quantity of size 210 tangerines after such week. This amendment also lowers the minimum diameter requirement applicable to domestic fresh shipments of Florida tangelos from 2 9/16 inches to 2 8/16 inches effective December 12, 1977, through September 24, 1978. Specification of minimum size requirements for Florida tangerines and tangelos is necessary because of current and prospective supply and demand for the fruit, and to maintain orderly marketing conditions in the interest of producers and consumers.

DATES: This amendment is effective during the periods December 5 through 11, 1977, and December 12, 1977, through September 24, 1978.

FOR FURTHER INFORMATION CONTACT:

Charles R. Brader, 202-447-3545.

SUPPLEMENTARY INFORMATION: *Findings.* (1) Pursuant to the marketing agreement and Order No. 905, both as amended (7 CFR Part 905), regulating the handling of oranges, grapefruit, tangerines and tangelos grown in Florida, effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674), and upon the basis of the recommendations of the committees established under the marketing agreement and order, and upon other information, it is found that the regulation of shipments of tangerines and tangelos, as hereinafter provided, will tend to effectuate the declared policy of the act.

(2) The amendment reflects the Department's appraisal of the current and prospective supply and market demand conditions for Florida tangerines and tangelos. It is designed to assure an ample supply of aceptable size fruit to consumers consistent with the quality and size composition of the crops. For the season through December 4, 1977, fresh shipments of Florida tangerines and tangelos totaled 1,876 carlots and 1,338 carlots, respectively.

(3) It is further found that it is impracticable and contrary to the public interest to give preliminary notice, engage in public rulemaking, and postpone the effective date until January 12, 1978 (5 U.S.C. 553), because of insufficient time between the date when information became available upon which this amendment is based and the effective date necessary to effectuate the declared policy of the act; and this amendment relieves restrictions on the handling of tangerines and tangelos.

Accordingly, it is found that the provisions of § 905.301 (42 FR 57947, 59367, 59955, 60918, 61590) should be and hereby are amended by revising in Table I of paragraph (a) the minimum size applicable to tangerines and tangelos and by revising paragraph (d), so that after the revisions the portion of Table I which is effective December 12, 1977, and paragraph (d) read as follows:

**§ 905.301 Orange, Grapefruit, Tangerine, and Tangelo Regulation 1.**

(a) * * *

* * * * *

TABLE I

| Variety (1) | Regulation period (2) | Minimum grade (3) | Minimum diameter (inch) (4) |
|---|---|---|---|
| Tangerines: Dancy and similar, including Robinson | Dec. 12, 1977 to Sept. 24, 1978. | U.S. No. 1 | 2 4/16 |
| Tangelos | do | do | 2 8/16 |

(d) Notwithstanding the provisions of this section, during the period December 5 through December 11, 1977, no handler shall handle tangerines smaller than 2 4/16 inches in diameter, except that a quantity of tangerines smaller than such minimum size may be handled if (1) the volume of such smaller tangerines does not exceed 45 percent of the total volume of tangerines shipped by such handler during the last previous week, within the current fiscal period in which the handler shipped tangerines; and (2) such smaller tangerines are of a size not smaller than 2 4/16 inches in diameter, except that a diameter tolerance for such smaller tangerines is permitted as specified in paragraph (c) of this section.

* * * * *

(Secs. 1–19, 48 Stat. 31, as amended; 7 U.S.C. 601–674.)

Dated: December 7, 1977.

FLOYD F. HEDLUND,
*Director, Fruit and Vegetable Division, Agricultural Marketing Service.*

[FR Doc.77-35491 Filed 12-12-77;8:45 am]

[7590-01]

Title 10—Energy

CHAPTER I—NUCLEAR REGULATORY COMMISSION

PART 9—PUBLIC RECORDS

Release of Transcripts of Closed Commission Meetings

AGENCY: U.S. Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Commission is amending its regulations to remove the requirement that counsel attend all closed Commission meetings to advise the Commission on possible withholding of transcripts of those meetings. It is no longer necessary for counsel to attend all closed Commission meeting due to Commission experience in operation under the Sunshine Act. Determination as to which, if any portions of transcripts are to be withheld from the public may now be made by the Commission or by the Commission's Secretary.

EFFECTIVE DATE: December 13, 1977.

FOR FURTHER INFORMATION CONTACT:

Stephen Ostrach, 202-254-8017.

SUPPLEMENTARY INFORMATION: Experience in operation under the Government in the Sunshine Act, 5 U.S.C. 552b, has shown that it is no longer necessary for counsel to attend all closed Commission meetings. Determination of which, if any, portions of transcripts or other items of information may be withheld pursuant to 10 CFR 9.104, may now be made by the Commission's Secretary, based upon prior Commission policy guidance, the advice of the Office of the General Counsel, and consultation with the Commission. The Commission has therefore decided to amend 10 CFR 9.108(c). This action is not intended to have any substantive effect on Commission policies under the Sunshine Act.

Accordingly, and because this amendment relates to matters of agency organization and practice, general notice of proposed rulemaking is unnecessary.

Pursuant to section 161 of the Atomic Energy Act of 1954, as amended, 5 U.S.C. 552(g) and 5 U.S.C. 553, 10 CFR 9.108(c) is amended to read as follows:

§ 9.108 Certification, transcripts, recordings, and minutes.

* * * * *

(c) In the case of any meeting closed pursuant to § 9.104, as the last item of business, the Commission shall determine which, if any, portions of the electronic recording, transcript or minutes and which, if any, items of information withheld pursuant to § 9.105(c) contain information which should be withheld pursuant to § 9.104; provided however, that should the Commission, upon the advice of the Office of the General Counsel and after consulting with the Commission, shall make such determinations.

* * * * *

Dated at Washington, D.C., this 6th day of December 1977.

For the Commision.

SAMUEL J. CHILK,
*Secretary of the Commission.*

[FR Doc.77-35286 Filed 12-12-77;8:45 am]

[4510-27]

Title 20—Employees' Benefits

CHAPTER IV—EMPLOYEES' COMPENSATION APPEALS BOARD, DEPARTMENT OF LABOR

PART 501—RULES OF PROCEDURE

Miscellaneous Amendments

AGENCY: Department of Labor.

ACTION: Final rules.

SUMMARY: The name of the Bureau of Employees' Compensation has been changed to the Office of Workers' Compensation Programs. This document is issued to conform the Rules of Procedure in Part 501 to the current terminology. At present the Director of the Office of Workers' Compensation Programs is required to submit the record of the case on appeal and accompanying pleadings to the Employees' Compensation Appeals Board within 30 days of service. In practice, this is insufficient time and there are many requests for extensions of time. Accordingly, the 30 days is changed to 60 days.

EFFECTIVE DATE: December 13, 1977.

FOR FURTHER INFORMATION CONTACT:

E. Gerald Lamboley, Acting Chairman, Employees' Compensation Appeals Board, 200 Constitution Avenue, NW., Washington, D.C. 20210, Telephone: 202-653-5031.

SUPPLEMENTARY INFORMATION: The "Rules of Procedure" of the Employees' Compensation Appeals Board do not now reflect the current structure of the agency responsible for administering the Federal Employees' Compensation Act (5 U.S.C. 8101 et seq.) (FECA). This agency is now called the Office of Workers' Compensation Programs, Employment Standards Administration, U.S. Department of Labor (OWCP). The present Board rules refer to the former name of the agency which was the Bureau of Employees' Compensation. The amendment is necessary to correctly reflect the name of the administering agency throughout the Rules.

Experience has demonstrated that a period of 60 rather than 30 days is requested for the Director of the Office to transmit the administrative record of an appeal and the appropriate accompanying pleading for consideration of the case to the Appeals Board. The 30-day requirement was promulgated in 1946 at the inception of the Employees' Compensation Appeals Board. At that time the administering agency had only limited field activity. During the intervening years the administering agency has expanded its operations nationwide and the volume of FECA appeals has significantly increased. A recent review of the Board's operations by a management engineering survey team of the Division of Management Assistance and Manpower Utilization of the Assistant Secretary for Administration and Management concluded that the changes here recommended are required. This 30-day requirement is no longer sufficient to afford administrative due process for such cases.

Because this amendment is a statement of policy and consists of rules of agency organization, procedure, and practice, the rulemaking procedure prescribed by 5 U.S.C. 553 is not required.

This document was prepared in the Office of the Solicitor under the direction of Laurie M. Streeter, Associate Solicitor for Employee Benefits, in consultation with E. Gerald Lamboley, Acting Chairman, Employees' Compensation Appeals Board.

Accordingly, 20 CFR Part 501 is amended in the following respect:

1. The nomenclature of the Rules of the Employees' Compensation Appeals Board is revised by substitution of the terms "Office of Workers' Compensation Programs" and "Office" respectively wherever the terms "Bureau of Employees' Compensation" and "Bureau" now appear.

2. Section 501.4 is revised to read as follows:

§ 501.4 Transmittal of Record.

(a) The Board shall serve upon the Director a copy of each application for review and any brief or supporting statement accompanying it. Within 60 days from the date of such service, the Director, through his legal representative, the Solicitor of Labor, shall transmit to the Board the record of the proceeding to which the application refers and a statement in support of his decision, or other pleading, as appropriate, signed on his behalf by his legal representative.

(b) On application of the Director, the Board may in its discretion extend the 60 day time for submittal to the Board of the record of proceedings and accompanying statement or pleading.

Signed at Washington, D.C., this 5th day of December, 1977.

ROBERT J. BROWN,
*Under Secretary of Labor.*

[FR Doc.77-35331 Filed 12-12-77;8:45 am]

[4110-03]

Title 21—Food and Drugs

CHAPTER I—FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

SUBCHAPTER A—GENERAL

[Docket No. 77C-0381]

D&C BLUE NO. 6

Listing For Use in Surgical Sutures

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: This document "permanently" lists D&C Blue No. 6 for safe use in coloring polyethylene terephthalate nonabsorbable sutures, plain or chromic collagen absorbable sutures and polypropylene nonabsorbable sutures for use in general or ophthalmic surgery. Davis and Geck Division, American Cyanamid Co.; Ethicon, Inc.; ASR Division, Cenco Medical Industries, Inc.; and the Toilet Goods Association, Inc., the Pharmaceutical Manufacturers Association, and the Certified Color Industry Committee, c/o Hazleton Laboratories, Inc., filed petitions for such use.

DATES: Effective date, January 13, 1978; objections by January 12, 1978.

ADDRESS: Written objections to the Hearing Clerk (HFC–20), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, Md. 20857.

FOR FURTHER INFORMATION CONTACT:

Gerad L. McCowin, Bureau of Foods (HFF–334), Food and Drug Administration, Department of Health, Education, and Welfare, 200 C St. SW., Washington, D.C. 20204, 202–472–5740.

SUPPLEMENTARY INFORMATION: A notice published in the FEDERAL REGISTER of April 11, 1973 (38 FR 9176) stated that a petition (CAP 6C0046) for the "permanent" listing of D&C Blue No. 6 as a color additive for coloring polyethylene terephthalate sutures for use in general surgery had been filed by Davis and Geck Division, American Cyanamid Co., Danbury, CT 06813 (now Pearl River, NY. 10965). A second notice published in the FEDERAL REGISTER of April 11, 1973 (38 FR 9176) stated that a petition (CAP 7C0048) for the "permanent" listing of D&C Blue No. 6 as a color additive for coloring plain or chromic collagen absorbable sutures for use in general and ophthalmic surgery had been filed by Ethicon, Inc., Somerville, N.J. 08876. A third notice published in the FEDERAL REGISTER of April 11, 1973 (38 FR 9176) stated that a petition (CAP 8C0054) for the "permanent" listing of D&C Blue No. 6 as a color additive for coloring polypropylene sutures for use in general surgery had been filed by Cenco Medical Industries, Inc., 4401 W. 26th St., Chicago, Ill. 60623 (now 4150 Laclede Ave., St. Louis, Mo.). A notice published in the FEDERAL REGISTER of November 20, 1968 (33 FR 17205) stated that a petition (CAP 57) for the "permanent" listing of D&C Blue No. 6 as a color additive for coloring externally applied drugs and cosmetics, sutures for use in general surgery, and ingested drugs and cosmetics has been filed by the Toilet Goods Association (now the Cosmetic, Toiletry, and Fragrance Association, Inc., 1133 15th St. N.W., Washington, D.C. 20005), the Pharmaceutical Manufacturers Association (1155 15th St. NW., Washington, D.C. 20005), and the Certified Color Industry Committee (now the Certified Color Manufacturers Association, 900 17th St. NW., Washington, D.C. 20006), c/o Hazelton Laboratories, Inc., Falls Church, Va. 22046. The petitions were filed pursuant to section 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 376).

The Commissioner of Food and Drugs, having evaluated the data in the petition and other relevant material, concludes that D&C Blue No. 6 is safe and suitable for use, under the conditions prescribed in this order, in coloring polyethylene terephthalate sutures for use in general surgery; plain or chromic collagen absorbable sutures for use in general and ophthalmic surgery; polypropylene sutures for use in general surgery; and that certification is necessary for the protection of the public health.

New § 74.1106, promulgated by this regulation, establishes specifications for the certification of batches of D&C Blue No. 6 that are more restrictive than those currently prescribed under § 82.1106 (21 CFR 82–1106). Additionally, the identity of the color has been revised to be consistent with current chemical nomenclature.

The identity nomenclature and the specifications currently prescribed in § 82.1106 become obsolete upon the effective date of new § 74.1106, and therefore § 82.1106 is being revoked.

When this regulation becomes effective, the provisional entry for "D&C Blue No. 6" in § 81.1(b) (21 CFR 81.1(b)) will no longer be considered to include drug use in dyeing surgical sutures. The regulation removes D&C Blue No. 6 from the provisional list.

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))) and 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 (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 § 74.1106 to Subpart B, to read as follows:

### § 74.1106 D&C Blue No. 6.

(a) *Identity.* (1) The color additive D&C Blue No. 6 is principally [Δ2.2′-biindoline]-3,3′-dione.

(b) *Specifications.* D&C Blue No. 6 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:

Volatile matter (at 135°C), not more than 3 percent.

Matter insoluble in *N,N*-dimethylformamide, not more than 1 percent.

Isatin, not more than 0.3 percent.

Anthranilic acid, not more than 0.3 percent.

Indirubbin, not more than 1 percent.

Lead (as Pb), not more than 10 parts per million.

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

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

Pure color, not less than 95 percent.

(c) *Use and restriction.* (1) D&C Blue No. 6 may be safely used at a level, (i) not to exceed 0.2 percent by weight of the suture material for coloring polyethylene terephthalate surgical sutures for general surgical use; (ii) not to exceed 0.25 percent by weight of the suture material for coloring plain or chromic collagen absorbable sutures for general surgical use; (iii) not to exceed 0.5 percent by weight of the suture material for coloring plain or chromic collagen absorbable sutures for ophthalmic surgical use; and (iv) not to exceed 0.5 percent by weight of the suture material for coloring polypropylene surgical sutures for general surgical use.

(2) When the sutures are used for the purposes specified in their labeling, there is no migration of the color additive to the surrounding tissue.

(3) If the suture is a new drug, an approved new drug application, pursuant to section 505 of the act, is in effect for it.

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

(e) *Certification.* All batches of D&C Blue No. 6 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

### § 81.1 [Amended]

2. Part 81 is amended in paragraph (b) of § 81.1 *Provisional lists of color additives*, by deleting the entry for D&C Blue No. 6 in the table.

## PART 82—LISTING OF CERTIFIED PROVISIONALLY LISTED COLORS AND SPECIFICATIONS

### § 82.1106 [Revoked]

3. Part 82 is amended by revoking § 82.1106 *D&C Blue No. 6.*

Any person who will be adversely affected by the foregoing regulation may at any time on or before January 12, 1978, file with the Hearing Clerk (HFC–20), Food and Drug Administration, Rm. 4–65, 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 § 71.30 (21 CFR 71.30). If a hearing is requested, the objection shall state the issues for the hearing, be supported by grounds factually and legally sufficient to justify the relief sought, and 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 identified with the Hearing Clerk docket

number found in brackets in the hearing of this regulation. Received objections may be seen in the office of the Hearing Clerk, between 9 a.m. and 4 p.m., Monday through Friday.

Effective date: This regulation shall become effective January 13, 1978, except as to any provisions that may be stayed by the filing of proper objections. 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))) and (Title II, Pub. L. 86–618; sec. 203, 74 Stat. 404–407, U.S.C. 376 note).)

Dated: December 5, 1977.

WILLIAM F. RANDOLPH,
*Acting Associate Commissioner for Compliance.*

[FR Doc.77-35326 Filed 12-7-77;2:28 pm]

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[4110-03]

[Docket No. 77C-0383]

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

### Provisional Listing of D&C Blue No. 6; Termination of Closing Date

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: This document terminates the closing date for the provisional listing, and hence the approval, of the color additive D&C Blue No. 6 for coloring drugs and cosmetics. This action is taken because of the failure to comply with the conditions for continued provisional listing of the color for use in drugs and cosmetics. Provisional listing of D&C Blue No. 6 will be continued until January 31, 1978, for its use in coloring general and ophthalmic surgical sutures only. Color additive certifications for D&C Blue No. 6 will continue to be issued for its use in sutures.

EFFECTIVE DATE: December 13, 1977.

FOR FURTHER INFORMATION CONTACT:

Gerad L. McCowin, Bureau of Foods (HFF-334), Food and Drug Administration, Department of Health, Education, and Welfare, 200 C St. SW., Washington, D.C. 20204, 202–472–5740.

SUPPLEMENTARY INFORMATION: Section 81.1 (21 CFR 81.1) of the color additive regulations designates those color additives that are provisionally listed under section 203(b) of 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)) on an interim basis pending completion of scientific investigations needed for determinations about "permanent listing" in accordance with section 706 of the Federal Food, Drug, and Cosmetic Act (sec. 706, 74 Stat. 399–403 (21 U.S.C. 376)).

The color additive D&C Blue No. 6 has been in use for many years. D&C Blue No. 6 was approved for drug and cosmetic use as a permitted "coal-tar" color after enactment of the Federal Food, Drug, and Cosmetic Act in 1938 by regulation published in the FEDERAL REGISTER of May 9, 1939 (4 FR 1922).

Under the Color Additive Amendments of 1960, a color additive may be approved only if data establish that it is safe under its permitted conditions of use. The transitional provisions of those amendments provide, however, for provisional listing of color additives in use in 1960 for a period of time necessary to complete the scientific investigations needed to establish their safety. Under this procedure, D&C Blue No. 6 was previously listed for use in drugs and cosmetics on July 12, 1960, and appeared officially on the provisional list published in the FEDERAL REGISTER of October 12, 1960 (25 FR 9759). D&C Blue No. 6 is currently provisionally listed for use in drugs, cosmetics, and sutures with a closing date of January 31, 1981. The establishment of January 31, 1981 as the closing date for this color originated with a proposal published in the FEDERAL REGISTER of September 23, 1976 (41 FR 41860). The final regulations in response to that proposal were issued in the FEDERAL REGISTER of February 4, 1977 (42 FR 6992). The continued provisional listing of the color was conditioned on submission of final reports of chemistry data and analytical methods by August 3, 1977 and chronic toxicity feeding studies by August 4, 1980.

D&C Blue No. 6 is the subject of a petition (CAP 57) submitted by the Toilet Goods Association, Inc. (now the Cosmetic, Toiletry and Fragrance Association, 1133 15th St. NW., Washington, D.C. 20005); the Pharmaceutical Manufacturers Association (1155 15th St. NW., Washington, D.C. 20005); and the Certified Color Industry Committee (now the Certified Color Manufacturers Association, 900 17th St. NW., Washington, D.C. 20006), c/o Hazelton Laboratories, Inc., Falls Church, Va. 22046. This petition was filed for the use of D&C Blue No. 6 for coloring ingested drugs, surgical sutures, lipsticks, and externally applied drugs and cosmetics by a notice in the FEDERAL REGISTER of November 20, 1968 (33 FR 17205). This filing notice was amended by a notice published in the FEDERAL REGISTER of March 5, 1976 (41 FR 9584) to include use of the color in area of the eye. The D&C Blue No. 6 is also the subject of petitions for coloring surgical sutures. These petitions were submitted by the Davis and Geck Division, American Cyanamid Co., Pearl River, N.Y. 10965 (CAP 6C0046); by Ethicon, Inc., Somerville, N.J. 08876 (CAP 7C0048); and by ASR Division, Cenco Medical Industries, Inc., 4150 Laclede Ave., St. Louis, Mo. 63108 (CAP 8C0054), filed by notices in the FEDERAL REGISTER of April 11, 1973 (38 FR 9176). All petitions were filed under the provisions of section 706 of the Federal Food, Drug, and Cosmetic Act, as amended by the Color Additive Amendments of 1960.

D&C Blue No. 6 is a color additive that has been subject to the requirements of batch certification as provided by section 706(c) of the act. The Commissioner has concluded that batch certification of the color would continue to be necessary if the color were to be listed. The conditions for the continued provisional listing of the color were defined in the FEDERAL REGISTER of Feburary 4, 1977 under § 81.27(c) (21 CFR 81.27(c)). Adequate analytical methods were required for the development of specifications for batch certification and the definition of purity of the color used for toxicological testing. These data and analytical methods were to be submitted to FDA by August 3, 1977.

The petitioner agreed under the requirements of § 81.27(c)(2) (21 CFR 81.27(c)(2)) to provide the information necessary for the certification and the "permanent" listing for D&C Blue No. 6. In response to the regulation, the petitioner submitted data for analytical procedures for the identification of subsidiary colors. The agency has reviewed these submissions and finds that the data are inadequate to resolve the chemistry deficiencies for the color.

The analytical methods used to determine intermediates in D&C Blue No. 6 show the presence of unidentified substances when it is extracted with methanol, *N,N*-dimethylformamide, or tergitol TMN in water, followed by examination using thin layer chromatography. Continued provisional listing of the color has been conditioned upon the submission of satisfactory methods for the determination of these unidentified substances, as well as sufficient analytical data on commercial and pharmacological samples of D&C Blue No. 6. Approximately 3 percent of the color consists of unidentified substances that are insoluble in methanol, in *N,N*-dimethylformamide, or in tergitol TMN in water; but it is uncertain whether the same or different unknowns are found by the different extraction systems.

Identification of the unknown substances continues to be necessary for listing of the color in drugs and cosmetics. The petitioners have requested that FDA consider listing of the color for use in sutures on the basis of the available data and the minimal exposure represented by sutures. The Commissioner of Food and Drugs has concluded that the data are sufficient to support listing of D&C Blue No. 6 in sutures. Published elsewhere in this issue of the FEDERAL REGISTER is a regulation listing D&C Blue No. 6 for use in sutures. The use of D&C Blue No. 6 for coloring drugs and cosmetics was provisionally listed until October 31, 1977, pending resolution of chemistry questions concerning unidentified substances. The chemistry questions are not expected to be answered in the near future. Without a satisfactory analytical procedure to compare different batches of D&C Blue No. 6, it will be impossible to certify the color.

In addition to the chemistry questions, the petitioners were also requested to conduct new chronic feeding studies with the color. The petitioners have recently advised FDA that they do not plan to conduct chronic feeding studies with the color.

ACTION

The purpose of the transitional provisions of the Color Additive Amendments of 1960, (section 203) as noted above, "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." This provisional listing of previously marketed colors was to expire on a date, also referred to as the closing date, 2½ years after the effective date of the Amendments.

Section 203 of the Amendments further provides, however, that the closing date for the provisional listing may be postponed to a later date as considered "necessary to carry out the purpose of this section, if in the Secretary'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, or such specified use or uses thereof, under section 706 of the basic Act."

Under the transitional provision of the Amendments (section 203(a)(2)), the Commissioner may "terminate a postponement of the closing date at any time if he finds that such postponement should not have been granted, or that by reason of change in circumstances the basis for such postponement no longer exists, or that there has been a failure to comply with a requirement for submission of progress reports or with other conditions attached to such postponement." Based on the available information, the Commissioner concludes that the petitioners for D&C Blue No. 6 have not successfully answered all questions concerning the unknown substances in D&C Blue No. 6, nor are they expected to do so in the near future. The Commissioner further concludes that the provisional listing of D&C Blue No. 6 for coloring drugs and cosmetics should be terminated because of the failure to comply with the conditions for continued provisional listing of submission of chemistry data and analytical methods and the conduct of new chronic feeding studies. The closing date for D&C Blue No. 6 is being continued until January 31, 1978 for its use in surgical sutures to provide time for the issuance of listing regulations for that use.

Batches of D&C Blue No. 6 will continue to be certified for coloring sutures only. All other certificates heretofore issued for batches of D&C Blue No. 6 are revoked except for use of the color in the color to any drugs or cosmetics will surgical sutures, and the addition of cause such product to be adulterated within the meaning of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) and subject to regulatory action. This prohibition applies to the use of the straight color, its lakes, and mixtures of D&C Blue No. 6 and its lakes. The Commissioner concludes that the protection of the public health does not require the recall from the market of drugs and cosmetics containing the color additive, or the destruction of drugs or cosmetics in preparations to which the color additive has already been added.

Manufacturers of new drugs and new animal drugs (including certifiable antibiotics for animal use) that contain D&C Blue No. 6 may either delete the color additive 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. The applicant shall submit data providing the new composition and showing that the change in composition does not interfere with any assay or other control procedures used in manufacturing the drug, or that the assay and control procedures have been revised to make them adequate. The applicant shall also submit data available to 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 a 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 specifications for the drug.

The Commissioner 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 Blue No. 6 may continue to be used with the uncolored product or products containing alternative colors during the time necessary to obtain supplies of revised labeling or until December 13, 1978, whichever occurs first.

The Commissioner has carefully considered the environmental effects of this action, and because the action will not significantly affect the quality of the human environment, has concluded that an environmental impact statement is not required. A copy of the FDA environmental assessment, together with copies of the other documents mentioned above, are on file with the Hearing Clerk (HFC–20), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, Md. 20857.

Therefore, under 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 (21 CFR 5.1), Part 81 is amended as follows:

1. In § 81.1 by revising the table entry for D&C Blue No. 6 in paragraph (b) to read as follows:

**§ 81.1 Provisional lists of color additives.**

* * * * *

(b) * * *

| Color additive | Closing date | Restrictions |
|---|---|---|
| * * * | * * * | * * * |
| D. & C. Blue No. 6.. | Jan. 31, 1978 | Surgical suture use only. |
| * * * | * * * | * * * |

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

**§ 81.10 Termination of provisional listings of color additives.**

* * * * *

(n) *D&C Blue No. 6.* The Commissioner of Food and Drugs, having concluded that unresolved questions remain concerning the chemistry of unidentified minor components, hereby terminates the provisional listing of D&C Blue No. 6 for use in drugs and cosmetics.

**§ 81.27 [Amended]**

3. In § 81.27 *Conditions of provisional listing of additives,* by deleting the entry for D&C Blue No. 6 in pargaraphs (c) and (d).

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

**§ 81.30 Cancellation of certificates.**

* * * * *

(o)(1) Certificates issued for D&C Blue No. 6 and all mixtures containing this color additive are cancelled insofar as its use in drugs and cosmetics is concerned and have no effect after December 13, 1977, and use of the color additive in the manufacture of drugs or cosmetics after this date will result in adulteration. The color will continue to be certified for use in the coloring of surgical sutures.

(2) The Commissioner finds, on the basis of the scientific evidence before him, that no action has to be taken to remove from the market drugs andcosmetics containing the color additive.

Notice and public procedure are not necessary prerequisites to the promulgation of this regulation because section 203(d)(2) of Pub. L. 86–618 so provides.

Because this action is final (not proposed), an economic impact evaluation is not required by Executive Order 11821 (3A CFR, 1975 Compilation, p. 203).

Effective date: This regulation shall be effective December 13, 1977.

(Sec. 203, 74 Stat. 404–407 (21 U.S.C. 376 note))

Dated: December 5, 1977.

WILLIAM F. RANDOLPH,
*Acting Associate Commissioner for Compliance.*

[FR Doc.77–35325 Filed 12–7–77;2:28 pm]

[4110–03]

[Docket No. 77C–0382]

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

## PART 82—LISTING OF CERTIFIED PROVISIONALLY LISTED COLORS AND SPECIFICATIONS

### Termination of Provisional Listing and Certification of D&C Red No. 10, D&C Red No. 11, D&C Red No. 12, and D&C Red No. 13

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: This document terminates the closing date for the provisional listing, and hence the approval, of the color additives D&C Red No. 10, D&C Red No. 11, D&C Red No. 12, and D&C Red No. 13 for coloring drugs and cosmetics. All color additive certificates for each of these colors are being cancelled. The closing date is being terminated because the color additive petition for these colors has been withdrawn, and there no longer exists a basis for their continued provisional listing. This action is effective immediately because data raise concerns about the safety of these colors. D&C Red No. 10, D&C Red No. 11, D&C Red No. 12, and D&C Red No. 13 may not be added to drugs and cosmetics after December 13, 1977.

EFFECTIVE DATE: December 13, 1977.

FOR FURTHER INFORMATION CONTACT:

Gerad L. McCowin, Bureau of Foods (HFF–334), Food and Drug Administration, Department of Health, Education, and Welfare, 200 C St. SW., Washington, D.C. 20204, 202–472–5740.

SUPPLEMENTARY INFORMATION: Under section 706 of the act (21 U.S.C. 376), the Color Additive Amendments of 1960, a color additive may be approved only if data establish that it is safe under its intended conditions of use (sec. 706, 74 Stat. 399–403 (21 U.S.C. 376)). The transitional provisions of the Color Additive Amendments, however, "make possible, on an interim basis for a reasonable period, through provisional listing, 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." (Title II, Pub. L. 86–618; sec. 203, 74 Stat. 404–407 (21 U.S.C. 376 note).) This provisional listing of previously marketed colors was to expire on the date, also referred to as the closing date, 2½ years after the effective date of the amendments.

Section 203 of the Amendments further provides, however, that the closing date for the provisional listing can be postponed to a later date as considered "necessary to carry out the purpose of this section, if in the Secretary'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, or such specified use or uses thereof, under section 706 of the basic Act." Section 81.1 (21 CFR 81.1) of the color additive regulations designates those color additives that are provisionally listed.

A notice published in the FEDERAL REGISTER of August 6, 1973 (38 FR 21199) stated that a petition (CAP 5C0029) for the "permanent" listing of D&C Red No. 10, D&C Red No. 11, D&C Red No. 12, and D&C Red No. 13 had been filed by the Cosmetic, Toiletry and Fragrance Association, Inc. (CTFA), 1133 15th St. NW., Washington, D.C. 20005, %Hazleton Laboratories, Inc., P.O. Box 30, Falls Church, Va. 22046. The petition was filed pursuant to section 706 of the act.

On October 21, 1977, CTFA wrote to FDA requesting that the color additive petition for D&C Red No. 10, D&C Red No. 11, D&C Red No. 12, and D&C Red No. 13 be withdrawn without prejudice to future filing. On October 5, 1977, CTFA had advised FDA that it did not intend to conduct new chronic feeding studies with these colors as required by § 81.27 (d) (21 CFR 81.27(d)). Published elsewhere in this issue of the FEDERAL REGISTER is a notice announcing the withdrawal of the petition for D&C Red Nos. 10 through 13, while the regulations set forth below terminate the provisional listing of these four colors for use as color additives in drugs and cosmetics effective December 13, 1977, because there are no pending color additive petitions or progress reports for them as required by § 81.1. In addition, as will be discussed, the Commissioner is concerned that the continued use of these four colors in drugs and cosmetics may pose a hazard to the public health.

The colors D&C Red Nos. 10, 11, 12, and 13 have been used as color additives for many years. D&C Red Nos. 10, 11, 12, and 13 were approved for certification for drug and cosmetic use as permitted "coal-tar" colors after enactment of the Federal Food, Drug, and Cosmetic Act of 1938 by order published in the FEDERAL REGISTER of May 9, 1939 (4 FR 1922). Under the Color Additive Amendments, D&C Red No. 10, D&C Red No. 11, D&C Red No. 12, and D&C Red No. 13 were provisionally listed for use in drugs and cosmetics on July 12, 1960, and appeared officially on the provisional list published in the FEDERAL REGISTER of October 12, 1960 (25 FR 9759). Since then, D&C Red Nos. 10, 11, 12, and 13 have been provisionally listed for use in drugs and cosmetics, with a present closing date of January 31, 1981. The establishment of January 31, 1981 as the closing date for these four colors pending submission of a final report on new chronic feeding studies originated with a proposal published in the FEDERAL REGISTER of September 23, 1976 (41 FR 41860). The final regulations in response to that proposal were issued in the FEDERAL REGISTER of February 4, 1977 (42 FR 6992).

On November 23, 1976, FDA received a comment to the proposal of September 23, 1976, which cited a reference from "Occupational and Environmental Cancers of the Urinary System," stating that according to the author, Dr. Hueper, there is reason to believe that azo dyes contain various carcinogenic amines, including β-naphthylamine. The comment objected to the listing of azo dyes. β-naphthylamine has long been known to be a carcinogen, causing bladder cancer in humans as well as test animals. Two colors, Ext. D&C Yellow No. 9 and Ext. D&C Yellow No. 10, which were synthesized from β-naphthylamine, were prohibited by FDA from use in externally applied drugs and cosmetics because of a finding that they might contain β-naphthylamine. Accordingly, the Commissioner has viewed with concern the possibility that any color additive for food, drug, or cosmetic use might contain β-naphthylamine.

β-Naphthylamine is an intermediate that is used in producing diazotized compounds for industrial use. These compounds are not, however, used in the production of color additives intended for use in food, drugs, or cosmetics. Therefore, β-naphthylamine would not be expected to be present in color additives, except as a contaminant.

Upon review of the data on each of the azo dyes, the Commissioner concluded that there were five colors that could possibly contain low levels of β-naphthylamine as impurities—four provisionally listed colors, D&C Red No. 10, D&C Red No. 11, D&C Red No. 12, and D&C Red No. 13, and a "permanently" listed color, D&C Red No. 34. These colors are synthesized from 2-amino-1-naphthalenesulfonic acid which, according to some information, might contain β-naphthylamine.

To resolve the questions raised by the comment, the Commissioner requested that the petitioner promptly provide to FDA data about the possible contamination of 2-amino-1-naphthalenesulfonic acid and each of the five colors with β-naphthylamine. In addition, FDA began some laboratory investigations of its own, including analysis of samples of each of the five colors and 2-amino-1-naphthalenesulfonic acid for the presence of β-naphthylamine. Copies of correspondence between the petitioners and FDA and memoranda of meetings and telephone conversations concerning this matter are on public display at the office of the Hearing Clerk (HFC–20), Food and Drug Administration, Room 4–65, 5600 Fishers Lane, Rockville, Md. 20857.

The liscussion and regulations stated in this document concern the Commissioner's conclusions on the provisionally listed color additives D&C Red No. 10, D&C Red No. 11, D&C Red No. 12, and D&C Red No. 13. The status of the "permanently" listed color additive D&C Red No. 34 is being considered separately and will be the subject of a future FEDERAL REGISTER document.

D&C Red No. 10 is an azo compound that is formed by the diazotization of 2-amino-1-naphthalenesulfonic acid (Tobias acid) and subsequent coupling with β-naphthol. D&C Red No. 10 is the monosodium salt of 2-(2-hydroxy-1-naphthylazo)-1-naphthalenesulfonic acid. D&C Red No. 11, D&C Red No. 12, and D&C Red No. 13 are the calcium, barium, and strontium salts, respectively, of 2-(2-hydroxy-1-naphthylazo)-1-naphthalenesulfonic acid.

The data for Tobias acid show that it contains small amounts of β-naphthylamine. The β-naphthylamine is considered to be present primarily as a result of incomplete reactions in the manufacture of Tobias acid. Tobias acid is manufactured in two steps. First, β-naphthol is sulfonated by reacting with sulfuric acid to form 2-hydroxy-1-naphthalenesulfonic acid. Second, the 2-hydroxy-1-naphthalenesulfonic acid is aminated by reacting with ammonia or ammonium bisulfite to form 2-amino-1-naphthalenesulfonic acid (Tobias acid).

The sulfonation step in the production of the Tobias acid never results in 100-percent conversion of β-naphthol to 2-hydroxy-1-naphthalenesulfonic acid. As a result, there is always some free β-naphthol present in the 2-hydroxy-1-naphthalenesulfonic acid during the subsequent amination step of the process. Because β-naphthol can be aminated to form β-naphthylamine, any β-naphthol that might be present would be expected to react during the amination step of the process for Tobias acid to produce β-naphthylamine.

Three samples of Tobias acid, one each from three color manufacturers, were analyzed by the Division of Color Technology, Food and Drug Administration. β-Naphthylamine was found in each of the three samples. In addition, analytical data on many batches of Tobias acid have been submitted by the producers, the Sherwin-Williams Co. and the American Cyanamid Co., and the data show the presence of β-naphthylamine.

The data submitted by the manufacturers show that levels of β-naphthylamine commonly detected in production lots of Tobias acid are between 100 and 500 parts per million (ppm). The current data sheets for the Tobias acid products by those two companies contain a specification of less than 0.1 percent (1,000 parts per million (ppm)) for β-naphthylamine. These levels were confirmed by FDA analyses showing levels of β-naphthylamine of 300, 400, and 1,100 ppm.

In addition, Sherwin-Williams reported that there is an apparent hydrolysis of Tobias acid to form β-napthylamine. They had extracted a solution of the sodium salt of Tobias acid with water until there was no extractable β-naphthylamine. This water solution of the Tobias acid was then permitted to stand overnight. Reanalysis of this solution on the following day disclosed 33 ppm β-naphthylamine. The firm's scientists concluded that Tobias acid dissolved in water as the sodium salt slowly hydrolyzes to form β-naphthylamine and estimated that the amount of hydrolysis was approximately 0.001 to 0.002 percent. A similar study was conducted using ethanol as the solvent. The firm's scientists concluded from this study that contact with ethanol causes Tobias acid to hydrolyze to β-naphthylamine at a greater rate.

Free Tobias acid in these four colors would be expected to hydrolyze much in the same way as for the pure Tobias acid, as discussed above, yielding free β-naphthylamine. The specifications used in the certification of these four colors contain a limitation of "not more than 0.2 percent" for 2-amino-1-naphthalenesulfonic acid (Tobias acid). Using analytical methodology sensitive to 0.05 percent, samples of these colors submitted for certification are generally found to contain less than 0.05 percent Tobias acid (nondetectable); however, as much as 0.13 percent Tobias acid has been found in some lots. If, as suggested by scientists from Sherwin-Williams, 0.001 to 0.002 percent of this Tobias acid were to hydrolyze to yield free β-naphthylamine, as much as 0.026 ppm free β-naphthylamine might be expected to be found in these colors as a result of the hydrolysis.

Analysis for free β-naphthylamine in each of the four colors by FDA's laboratories was hampered by difficulties with the analytical methods and has not shown free β-naphthylamine. The primary difficulty is one of separating β-naphthylamine from the color.

During a meeting with representatives of the Cosmetic, Toiletry, and Fragrance Association, agency personnel were advised that American Cyanamid had reported finding 1.8 to 3.6 ppm β-naphthylamine in their technical-grade lithol red. This color is not used for drugs and cosmetics, but is used in industry, e.g., as a component of paints and printing inks. Although the exact identity of the lithol reds tested by American Cyanamid is unknown, lithol reds are generally sufficiently similar to the four colors, D&C Red Nos. 10, 11, 12, and 13, to permit a conclusion that the latter colors would also contain free β-naphthylamine. The agency received a letter of June 16, 1977, from the petitioner, transmitting the results of analysis of two laboratory batches of D&C Red No. 10. One batch was found to contain 7.0 and 5.8 ppm β-naphthylamine in duplicate analyses of the batch; no β-naphthylamine was found in the second batch.

Theoretically, free β-naphthylamine in Tobias acid would be expected to diazotize to some extent and couple with β-naphthol to form a subsidiary color. The FDA Division of Color Technology conducted experiments to determine whether any subsidiary colors formed from β-naphthylamine might be present in these four colors. Samples of the subsidiary color formed from β-naphthylamine and β-napthol were prepared by FDA chemists and used as standards for the analysis of previously certified batches of each of the four colors—D&C Red Nos. 10 through 13. These analyses revealed the presence of the subsidiary color at levels ranging from 25 to 276 ppm. The identity of the β-naphthylamine subsidiary color was confirmed by comparison with the infrared spectra, the visible spectra, and the thin-layer chromatographic $R_f$ (retardation factor) value of authentic samples previously prepared by the Division of Color Technology, Food and Drug Administration. The presence of subsidiary colors produced from β-napthylamine raises concern about the safety of these four colors because their metabolism after ingestion or other degradation would yield free β-naphthylamine. The data for metabolism of azo dyes establish that the azo bond is broken during metabolism yielding the constituent amine.

The toxicity of β-naphthylamine is well known—it has been considered a carcinogen for many years. In its evaluation of the data on β-naphthylamine, the International Agency for Research on Cancer stated that 2-naphthylamine, another name for β-naphthylamine, is carcinogenic in the mouse, hamster, dog, and monkey. In addition, there are considerable epidemiological data that establish that β-naphthylamine is a bladder carcinogen in humans (IRAC Monographs, Vol. 4, 1974).

The Commisioner finds that the use of D&C Red No. 10, D&C Red No. 11, D&C Red No. 12, and D&C Red No. 13 as color additives could result in exposure of the consumer to β-naphthylamine. There is free β-naphthylamine at appreciable levels (up to 1,100 ppm) in the intermediate used to produce the color. There is a possibility that the intermediate Tobias acid, which can be present in the finished colors at levels as great as 2,000 ppm, may hydrolyze to form free β-naphthylamine. β-Naphthylamine was found in a laboratory sample of D&C Red No. 10. The chemistry data establish that D&C Red Nos. 10 through 13 contain a subsidiary color produced from β-naphthylamine that would be expected to yield β-naphthylamine when metabolized or degraded. The evidence of the presence of this subsidiary color supports a conclusion that each of the four colors does contain some free β-naphthylamine, particularly in view of the finding of β-naphthylamine in D&C Red No. 10.

Under the transitional provisions of the Color Additive Amendments (section 203(a)(2)), the Commissioner may "terminate the postponement of the closing date at any time if he finds that such postponement should not have been granted, or that by reason of change in circumstances the basis for such postponement no longer exists, or that there has been a failure to comply with a requirement for submission of progress reports or with other conditions attached to such postponement." In view of the petitioner's withdrawal of the petition for these four colors and its statement that it does not intend to conduct chronic feeding studies with D&C Red No. 10 through 13 as required by § 81.27 (d) as a condition of continued provi-

sional listing, the Commissioner concludes that there no longer exists a basis for the provisional listing of these four colors.

The transitional provisions of the Amendments (section 203(d)(1)(E)) "provide for the termination of a provisional listing or deemed provisional listing of a color additive or particular use thereof forthwith whenever" such action is necessary to protect the public health. On the basis of the available data, the Commissioner concludes that the colors D&C Red No. 10, D&C Red No. 11, D&C Red No. 12, and D&C Red No. 13 would be expected to contain β-naphthylamine, a known carcinogen, or to yield β-naphthylamine when ingested. Accordingly, under section 203 (d)(1)(E)) of the Amendments, the Commissioner concludes that the provisional listing of D&C Red No. 10, D&C Red No. 11, D&C Red No. 12, and D&C Red No. 13 for use in drugs and cosmetics should be terminated immediately because such action is necessary to protect the public health.

All certificates heretofore issued for batches of D&C Red No. 10, D&C Red No. 11, D&C Red No. 12, and D&C Red No. 13 are revoked, and the addition of these colors to any drugs or cosmetics after December 13, 1977, will cause such product to be adulterated within the meaning of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) and subject to regulatory action. This prohibition applies to the use of the straight colors, their lakes, and mixtures of one or more of these colors: D&C Red No. 10, D&C Red No. 11, D&C Red No. 12, and D&C Red No. 13, or their lakes. The Commissioner concludes that the protection of the public health does not require the recall from the market of drugs and cosmetics containing the color additives, or the destruction of drugs or cosmetics in preparation to which the color additives have already been added.

Manufacturers of new drugs and new animal drugs (including certifiable antibiotics for animal use) that contain D&C Red No. 10, D&C Red No. 11, D&C Red No. 12, or D&C Red No. 13 may either delete 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. The applicant shall submit data providing the new composition and showing that the change in composition does not interfere with any assay or other control procedures used in manufacturing the drug, or that the assay and control procedures have been revised to make them adequate. The applicant shall also submit data available to 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 a 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 specifications for the drug.

The Commissioner is aware that the 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 Red No. 10, D&C Red No. 11, D&C Red No. 12, or D&C Red No. 13 may continue to be used with the uncolored product or products containing alternative colors during the time necessary to obtain supplies of revised labeling or until December 13, 1978, whichever occurs first.

The Commissioner has carefully considered the environmental effects of this action, and because the action will not significantly affect the quality of the human environment, has concluded that an environmental impact statement is not required. A copy of the FDA environmental assessment, together with copies of the other documents mentioned above, are on file with the Hearing Clerk (HFC–20), Food and Drug Administration, Room 4–65, 5600 Fishers Lane, Rockville, Md. 20857.

Therefore, under 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 (21 CFR 5.1), Parts 81 and 82 are amended as follows:

1. Part 81 is amended:

**§ 81.1 [Amended]**

a. In § 81.1 *Provisional lists of color additives,* in paragraph (b), by deleting the table entries for D&C Red No. 10, D&C Red No. 11, D&C Red No. 12, and D&C Red No. 13.

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

**§ 81.10 Termination of provisional listing of color additives.**

* * * * *

(h) *D&C Red Nos. 10, 11, 12, and 13.* The petition for these color additives was withdrawn so that there no longer exists a basis for their continued provisional listing. In addition, the Commissioner has learned of the possible contamination of D&C Red No. 10, D&C Red No. 11, D&C Red No. 12, and D&C Red No. 13 with β-naphthylamine. The Commissioner concludes that these colors cannot be produced with any reasonable assurance that they will not contain β-naphthylamine as an impurity or not yield β-naphthylamine from the metabolism of subsidiary colors present in them. β-Naphthylamine is a known carcinogen; therefore, there is no scientific evidence that will support a safe tolerance for these colors in drugs or cosmetics. The Commissioner of Food and Drugs, upon withdrawal of the petition for their use and in order to protect the public health, hereby terminates the provisional listing of D&C Red No. 10, D&C Red No. 11, D&C Red No. 12, and D&C Red No. 13 for use in drugs and cosmetics, effective December 13, 1977.

**§ 81.25 [Amended]**

c. In § 81.25 *Temporary tolerances,* paragraph (a) is amended by deleting the table entries for D&C Red No. 10, D&C Red No. 11, D&C Red No. 12, and D&C Red No. 13; and paragraph (b)(1) is amended by deleting the tabular entry for D&C Red No. 12.

**§ 81.27 [Amended]**

d. In § 81.27 *Conditions of provisional listing,* paragraph (d) is amended by deleting the entries for D&C Red No. 10, D&C Red No. 11, D&C Red No. 12, and D&C Red No. 13 from the introductory text.

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

**§ 81.30 Cancellation of certificates.**

* * * * *

(k) (1) Certificates issued for D&C Red No. 10, D&C Red No. 11, D&C Red No. 12, and D&C Red No. 13, their lakes and all mixtures containing these color additives or their lakes are cancelled and have no effect after December 13, 1977, and use of these color additives in the manufacture of drugs or cosmetics after this date will result in adulteration.

(2) The Commissioner finds, on the basis of the scientific evidence before him, that no action has to be taken to remove from the market, drug and cosmetic products containing the color additives.

2. Part 82 is amended:

**§ 82.1310 [Revoked]**

a. By revoking § 82.1310 *D&C Red No. 10.*

**§ 82.1311 [Revoked]**

b. By revoking § 82.1311 *D&C Red No. 11.*

**§ 82.1312 [Revoked]**

c. By revoking § 82.1312 *D&C Red No. 12.*

**§ 82.1313 [Revoked]**

d. By revoking § 82.1313 *D&C Red No. 13.*

Notice and public procedure are not necessary prerequisities to the promulgation of these regulations because section 203(d)(2) of Pub. L. 86–618 so provides.

NOTE.—Because this action is final (not proposed), an economic impact evaluation is not required under Executive Orders 11821 and 11949 and OMB Circular A–107.

*Effective date.* These regulations shall be effective on December 13, 1977.

(Sec. 203, 74 Stat. 404–407 (21 U.S.C. 376 note).)

Dated: December 5, 1977.

WILLIAM F. RANDOLPH,
*Acting Associate Commissioner for Compliance.*

[FR Doc.77–35324 Filed 12–7–77;2:28 pm]