rules and regulations

[6325–01]

Title 5—Administrative Personnel

CHAPTER I—CIVIL SERVICE COMMISSION

PART 213—EXCEPTED SERVICE

Department of Agriculture

AGENCY: Civil Service Commission.

ACTION: Final rule.

SUMMARY: One additional position of Confidential Assistant to the General Counsel is excepted under Schedule C because it is confidential in nature.

EFFECTIVE DATE: December 13, 1977.

FOR FURTHER INFORMATION CONTACT:

William Bohling, Chief, 202–632–4533.

Accordingly, 5 CFR 213.3313(d)(4) is amended as set out below:

§ 213.3313 Department of Agriculture.

* * * * *

(d) *Office of the General Counsel.* * * *

(4) Two Confidential Assistants to the General Counsel.

(5 U.S.C. 3301, 3302; EO 10577, 3 CFR 1954–1958 Comp., p. 218.)

UNITED STATES CIVIL SERVICE COMMISSION,
JAMES C. SPRY,
Executive Assistant to the Commissioners.

[FR Doc.77–35390 Filed 12–12–77;8:45 am]

[6325–01]

PART 213—EXCEPTED SERVICE

Department of Health, Education, and Welfare

AGENCY: Civil Service Commission.

ACTION: Final rule.

SUMMARY: This amendment excepts from the competitive service under Schedule A 30 positions at GS–15 and below for employment not to exceed September 30, 1980, on the staff of the White House Conference on Families. These positions are excepted under Schedule A because it is not practicable to hold an examination for them.

EFFECTIVE DATE: December 13, 1977.

FOR FURTHER INFORMATION CONTACT:

William Bohling, 202–632–4533.

Accordingly, 5 CFR 213.3116(k) is added as set out below:

§ 213.3116 Department of Health, Education, and Welfare.

* * * * *

(k) *Office of Human Development Services.* (1) Thirty positions at GS–15 and below for employment not to exceed September 30, 1980, on the staff of the White House Conference on Families.

(5 U.S.C. 3301, 3302; EO 10577, 3 CFR 1954–1958 Comp., p. 218.)

UNITED STATES CIVIL SERVICE COMMISSION,
JAMES C. SPRY,
Executive Assistant to the Commissioners.

[FR Doc.77–35571 Filed 12–12–77;8:45 am]

[6325–01]

PART 213—EXCEPTED SERVICE

Department of Defense

AGENCY: Civil Service Commission.

ACTION: Final rule.

SUMMARY: This amendment excepts from the competitive service under Schedule C one position of Adviser to the Secretary and Deputy Secretary of Defense for NATO Affairs, Office of the Secretary, Department of Defense because the position is confidential in nature.

EFFECTIVE DATE: December 13, 1977.

FOR FURTHER INFORMATION:

On Position Authority Contact:

Thomas H. Meyer, Civil Service Commission, 202–632–4695.

On Position Content Contact:

Karl F. Becker, Director of Personnel and Security, Department of Defense, 202–697–4211.

Accordingly, 5 CFR 213.3306(a)(96) is added as set out below:

§ 213.3306 Department of Defense.

(a) *Office of the Secretary.* * * *

(96) Adviser to the Secretary and Deputy Secretary of Defense for NATO Affairs.

* * * * *

(5 U.S.C. 3301, 3302; E.O. 10577, 3 CFR 1954–1958 Comp., p. 218.)

UNITED STATES CIVIL SERVICE COMMISSION,
JAMES C. SPRY,
Executive Assistant to the Commissioners.

[FR Doc.77–35611 Filed 12–12–77;8:45 am]

[6325–01]

PART 213—EXCEPTED SERVICE

U.S. Information Agency

AGENCY: Civil Service Commission.

ACTION: Final rule.

SUMMARY: This addition excepts from the competitive service under Schedule one position of Special Assistance to the C one position of Special Assistant to the Assistant Director (Broadcasting) because the position is confidential in nature.

EFFECTIVE DATE: December 13, 1977.

FOR FURTHER INFORMATION CONTACT:

William Bohling, Chief, 202–632–4533.

Accordingly, 5 CFR 213.3328(m) is amended as follows:

§ 213.3328 U.S. Information Agency.

* * * * *

(m) One Special Assistant and one Secretarial Assistant to the Assistant Director (Broadcasting).

(5 U.S.C. 3301, 3302; EO 10577, 3 CFR 1954–1958 Comp., p. 218.)

UNITED STATES CIVIL SERVICE COMMISSISON,
JAMES C. SPRY,
Executive Assistant to the Commissioners.

[FR Doc.77–35684 Filed 12–12–77;8:45 am]

[3410–05]

Title 7—Agriculture

CHAPTER VII—AGRICULTURAL STABILIZATION AND CONSERVATION SERVICE (AGRICULTURAL ADJUSTMENT), DEPARTMENT OF AGRICULTURE

Miscellaneous Deletions

AGENCY: Agricultural Stabilization and Conservation Service, USDA.

ACTION: Final rule.

SUMMARY: The purpose of this document is to delete from the Code of Federal Regulations several regulations which are obsolete. Certain operating provisions concerning wheat and rice programs are no longer required. The terms of the Cropland Adjustment Program for 1966 Through 1969 have expired. The Processor Wheat Marketing Certificate Regulations are no longer in effect. Any obligation or liability incurred, or any rights received or accrued under these regulations are not affected by their deletion.

EFFECTIVE DATE: December 13, 1977.

FOR FURTHER INFORMATION CONTACT:

Adrian Crawford, Box 2415, Washington, D.C.. 20013, 202–447–2341.

SUPPLEMENTARY INFORMATION: Because this document merely deletes obsolete regulations, the relevant provisions of the Administrative Procedure Act (5 U.S.C. 553) providing for notice of proposed rulemaking, opportunity for

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]

[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.