taining a place of business within the United States.

(2) Applications, including subsequent amendments and supplements for the products listed in paragraph (a) of this section shall be submitted to the Director, Bureau of Biologics, 8800 Rockville Pike, Bethesda, MD 20014 instead of to the address shown in paragraph (c) of this section. In reading this Part 314, applicants of such listed products should substitute "Bureau of Biologics" for "Bureau of Drugs" wherever it appears. The products are as follows:

(i) Ingredients packaged together with containers intended for the collection, processing, or storage of blood and blood components.

(ii) Urokinase products.

* * * * *

Pursuant to the Administrative Procedure Act (5 U.S.C. 553 (b) and (d)), the Commissioner finds that notice, public procedure, and delayed effective date are unnecessary for the promulgation of this order because it does not impose a duty or burden on any person, but merely provides notice of internal administrative designation of responsibility.

Effective date: This regulation is effective on November 23, 1976.

(Secs. 505, 701(a), 52 Stat. 1052-1053 as amended, 1055 (21 U.S.C. 355, 371(a)); sec. 351, 58 Stat. 702 as amended (42 U.S.C. 262))

Dated: November 17, 1976.

JOSEPH P. HILE,
Associate Commissioner for Compliance.

[FR Doc.76-34524 Filed 11-22-76;8:45 am]

SUBCHAPTER A—GENERAL

PART 5—DELEGATIONS OF AUTHORITY AND ORGANIZATION

Subpart B—Redelegations of Authority From the Commissioner of Food and Drugs

Grants and Service Fellowships

The Food and Drug Administration (FDA) is amending the regulation setting forth its delegation of authority concerning the awarding of service fellowships; effective November 23, 1976.

By memorandum dated May 24, 1976, the Executive Officer, Public Health Service (PHS), delegated to the Commissioner of Food and Drugs the authority to award service fellowships under section 207(g) of the Public Health Service Act (42 U.S.C. 209(g)). The delegation is effective upon approval of a Service Fellowship Program by an authorized PHS official. On July 27, 1976, the Director, Office of Administrative Management, PHS, approved the establishment of the FDA staff Fellowship Program. This amendment revises and corrects the Commissioner's delegation of service fellowship authority.

Further redelegation of the authority delegated by this amendment is not authorized. Authority delegated by this amendment to a position by title may be exercised by a person officially designated to serve in such position in an acting capacity or on a temporary basis, unless prohibited by a restriction written into the document designating him as "acting," or unless it is not legally permissible.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 701(a), 52 Stat. 1055 (21 U.S.C. 371(a))) and under authority delegated to the Commissioner (21 CFR 5.1) (recodification published in the FEDERAL REGISTER of June 15, 1976 (41 FR 24262)), Part 5 is amended by revising § 5.36 and adding new § 5.53 to read as follows:

§ 5.36 Delegations regarding grants.

(a) The Associate and Deputy Associate Commissioner for Science are authorized to approve or disapprove all applications for grants under secs. 301, 307, 311, and 356 of the Public Health Service Act, and to select officials to serve as program managers to exercise scientific oversight and to monitor grantee progress.

(b) The Associate and Deputy Associate Commissioner for Administration and the Director and Deputy Director of the Division of Contracts and Grants Management of the Office of Administration are authorized to execute grant awards upon approval by the Associate or Deputy Associate Commissioner for Science, and to notify grantees of officials who will serve as the Food and Drug Administration program manager for their grant.

§ 5.53 Delegations regarding service fellowships.

The Associate and Assistant Commissioners, the Directors of Bureaus, the Director, National Center for Toxicological Research, and the Executive Director of Regional Operations are authorized to designate persons to receive service fellowships in the Food and Drug Administration Staff Fellowship Program under sec. 207(g) of the Public Health Service Act.

Effective date: This amendment shall be effective on November 23, 1976.

(Sec. 701(a), 52 Stat. 1055 (21 U.S.C. 371(a)).)

Dated: November 17, 1976.

JOSEPH P. HILE,
Associate Commissioner for Compliance.

[FR Doc.76-34520 Filed 11-22-76;8:45 am]

[Docket No. 76C-0432]

PART 8—COLOR ADDITIVES

PART 9—COLOR CERTIFICATION

Listing of Ext. D&C Yellow No. 7 for Use in Externally Applied Drugs and Cosmetics

The Food and Drug Administration (FDA) is "permanently" listing Ext. D&C Yellow No. 7 for use in externally applied drugs and cosmetics; effective on December 27, 1976; objections on or before December 23, 1976.

A notice published in the FEDERAL REGISTER of November 20, 1968 (33 FR 17205) stated that a petition (CAP 26) for the "permanent" listing of Ext. D&C Yellow No. 7 as a color additive for use in drugs and cosmetics that are applied externally had been filed 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 Hazleton Laboratories, Inc., P.O. Box 30, Falls Church, VA 22046. The petition was filed pursuant to section 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 376).

The Commissioner has evaluated the data in the petition and concludes that Ext. D&C Yellow No. 7 is safe under the conditions set forth below for use in coloring externally applied drugs and cosmetics and that certification is necessary for the protection of the public health. This order "permanently" lists Ext. D&C Yellow No. 7 for use in externally applied drugs and cosmetics under new §§ 8.4178 and 8.7258 (21 CFR 8.4178 and 8.7258). The provisional listing of Ext. D&C Yellow No. 7 for use in externally applied drugs and cosmetics under § 8.501(c) (21 CFR 8.501(c)), which was etxended to December 31, 1976 by regulation published in the FEDERAL REGISTER of September 23, 1976 (41 FR 41856), will be deleted when this order becomes effective on December 27, 1976, unless this order is stayed by the timely filing of objections, in which case the provisional listing will continue until December 31, 1976 unless terminated or extended by regulation.

This order does not list Ext. D&C Yellow No. 7 for use in lakes as requested in the petition. The Commissioner notes that proposed regulations related to the use of color additives in lakes were published in the FEDERAL REGISTER of May 11, 1965 (31 FR 6490). The Commissioner advises that new proposed regulations governing the use of color additives in lakes will be published in the FEDERAL REGISTER in the near future and concludes that the listing of colors for use in lakes can best be implemented by general regulations. Ext. D&C Yellow No. 7 will, therefore, continue to be approved for use in lakes for coloring externally applied drugs and cosmetics under the general provisional listing for "Lakes (Ext. D&C)" under § 8.501(c).

This order establishes specifications for the certification of batches of Ext. D&C Yellow No. 7 that are more restrictive than those currently prescribed under § 9.307 (21 CFR 9.307). Additionally, the identity of the color has been revised to be consistent with current chemical nomenclature. The identity nomenclature and the specification currently prescribed in § 9.307 become obsolete upon the effective date of new §§ 8.4178 and 8.7258. However, it is necessary to maintain § 9.307 to provide for the use of the color additive in lakes. Accordingly,

§ 9.307 is revised to reference the identity nomenclature and specifications prescribed by § 8.4178.

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) (recodification published in the FEDERAL REGISTER of June 15, 1976 (41 FR 24262)), Parts 8 and 9 of Chapter I of Title 21 of the Code of Federal Regulations are amended as follows:

1. Part 8 is amended:

§ 8.501 [Amended]

a. In paragraph (c) of § 8.501 Provisional lists of color additives, the entry for Ext. D&C Yellow No. 7 for use in externally applied drugs and cosmetics is deleted.

b. In Subpart E, new § 8.4178 is added to read as follows:

§ 8.4178 Ext. D&C Yellow No. 7.

(a) *Identity.* (1) The color additive Ext. D&C Yellow No. 7 is principally the disodium salt of 8-hydroxy-5,7-dinitro-2-naphthalenesulfonic acid.

(2) Color additive mixtures for drug use made with Ext. D&C Yellow No. 7 may contain only those diluents that are suitable and that are listed in Subpart F of this part as safe for use in color additive mixtures for coloring externally applied drugs.

(b) *Specifications.* Ext. D&C Yellow No. 7 shall conform to the following specifications and shall be free from impurities, other than those named, to the extent that such other impurities may be avoided by good manufacturing practice:

Sum of violatile matter (at 135° C) and chlorides and sulfates (calculated as sodium salts), not more than 15 percent.
Water-insoluble matter, not more than 0.2 percent.
1-Naphthol, not more than 0.2 percent.
2,4-Dinitro-1-naphthol, not more than 0.03 percent.
Lead (as Pb), not more than 20 parts per million.
Arsenic (as As), not more than 3 parts per million.
Mercury (as Hg), not more than 1 part per million.
Total color, not less than 85 percent.

(c) *Uses and restrictions.* Ext. D&C Yellow No. 7 may be safely used in externally applied drugs in amounts consistent with good manufacturing practice.

(d) *Labeling.* The label of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 8.32.

(e) *Certification.* All batches of Ext. D&C Yellow No. 7 shall be certified in accordance with regulations in Subpart A of this Part.

3. In Subpart G, new § 8.7258 is added to read as follows:

§ 8.7258 Ext. D&C Yellow No. 7.

(a) *Identity and specifications.* The color additive Ext. D&C Yellow No. 7 shall conform in identity and specifications to the requirements of § 8.4178(a) (1) and (b).

(b) *Uses and restrictions.* Ext. D&C Yellow No. 7 may be safely used for coloring externally applied cosmetics in amounts consistent with good manufacturing practice.

(c) *Labeling.* The label of the color additive shall conform to the requirements of § 8.32.

(d) *Certification.* All batches of Ext. D&C Yellow No. 7 shall be certified in accordance with regulations in Subpart A of this Part.

4. Part 9 is amended by revising § 9.307 to read as follows:

§ 9.307 Ext. D&C Yellow No. 7.

The color additive Ext. D&C Yellow No. 7 shall conform in identity and specifications to the requirements of § 8.4178(a) (1) and (b) of this chapter. Ext. D&C Yellow No. 7 is restricted to use in externally applied drugs and cosmetics.

Any person who will be adversely affected by the foregoing order may at any time on or before December 23, 1976, file with the Hearing Clerk, 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 order, specify with particularity the provisions of the order deemed objectionable, and state the grounds for the objections. Objections shall be filed in accordance with the requirements of § 8.19 (21 CFR 8.19). If a hearing is requested, the objections shall state the issues for the hearing, shall be supported by grounds factually and legally sufficient to justify the relief sought, and shall include a detailed description and analysis of the factual information intended to be presented in support of the objections in the event that a hearing is held. Five copies of all documents shall be filed and should be identified with the Hearing Clerk docket number found in brackets in the heading of this order. Received objections may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Effective date: This order shall become effective on December 27, 1976, 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)); Title II, Pub. L. 86–618, sec. 203, 74 Stat. 404–407 (21 USC. 376 note).)

Dated: November 17, 1976.

JOSEPH P. HILE,
Associate,
Commissioner for Compliance.

[FR Doc.76-34518 Filed 11-22-76;8:45 am]

[Docket No. 76C-0425]

PART 8—COLOR ADDITIVES
PART 9—COLOR CERTIFICATION

Listing of D&C Red No. 34 for Use in Externally Applied Drugs and Cosmetics

The Food and Drug Administration (FDA) is "permanently" listing D&C Red No. 34 for use in externally applied drugs and cosmetics; effective on December 27, 1976; objections on or before December 23, 1976.

A notice published in the FEDERAL REGISTER of November 20, 1968 (33 FR 17205) stated that a petition (CAP 38) for the "permanent" listing of D&C Red No. 34 as a color additive for use in drugs and cosmetics that are applied externally had been filed 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., P.O. Box 30, Falls Church, Va. 22046. The petition was filed pursuant to section 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 376).

The Commissioner has evaluated the data in the petition and concludes that D&C Red No. 34 is safe under the conditions set forth below for use in coloring externally applied drugs and cosmetics and that certification is necessary for the protection of the public health. This order "permanently" lists D&C Red No. 34 for use in externally applied drugs and cosmetics under new §§ 8.4128 and 8.7195 (21 CFR 8.4128 and 8.7195). The provisional listing of D&C Red No. 34 for use in externally applied drugs and cosmetics under § 8.501(b) (21 CFR 8.501(b)), which was extended to December 31, 1976 by regulation published in the FEDERAL REGISTER of September 23, 1976 (41 FR 41856), will be deleted when this order becomes effective on December 27, 1976, unless this order is stayed by the timely filing of objections, in which case the provisional listing will continue until December 31, 1976 unless terminated or extended by regulation.

This order does not list D&C Red No. 34 for use in lakes as requested in the petition. The Commissioner notes that proposed regulations related to the use of color additives in lakes were published in the FEDERAL REGISTER of May 11, 1965 (30 FR 6490). The Commissioner advises that new proposed regulations governing the use of color additives in lakes will be published in the FEDERAL REGISTER in the near future and concludes that the listing of colors for use in lakes can best be implemented by general regulations. D&C Red No. 34 will, therefore, continue to be approved for use in lakes for coloring externally applied drugs and cosmetics under the general provisional listing for "Lakes (D&C)" under § 8.501(b).

This order establishes specifications for the certification of batches of D&C Red

No. 34 that are more restrictive than those currently prescribed under § 9.179 (21 CFR 9.179). 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 § 9.179 become obsolete upon the effective date of new §§ 8.4128 and 8.7195. However, it is necessary to maintain § 9.179 to provide for the use of the color additive in lakes. Accordingly, § 9.179 is revised to reference the identity nomenclature and specifications prescribed by § 8.4128.

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), (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)) and under authority delegated to the Commissioner (21 CFR 5.1) (recodification published in the FEDERAL REGISTER of June 15, 1976 (41 FR 24262)), Parts 8 and 9 of Chapter I of Title 21 of the Code of Federal Regulations are amended as follows:

1. Part 8 is amended:

§ 8.501 [Amended]

a. In paragraph (b) of § 8.501 Provisional lists of color additives, the entry for D&C Red No. 34 for use in externally applied drugs and cosmetics is deleted.

b. In subpart E, new § 8.4128 is added to read as follows:

§ 8.4128 D&C Red No. 34.

(a) *Identity.* (1) The color additive D&C Red No. 34 is principally the calcium salt of 3-hydroxy-4-[(1-sulfo-2-naphthalenyl)azol - 2 - naphthalenecarboxylic acid.

(2) Color additive mixtures for drug use made with D&C Red No. 34 may contain only those diluents that are suitable and that are listed in Subpart F of this Part as safe for use in color additive mixtures for coloring externally applied drugs.

(b) *Specifications.* D&C Red No. 34 shall conform to the following specifications and shall be free from impurities, other than those named, to the extent that such other impurities may be avoided by good manufacturing practice:

Sum of volatile matter (at 135° C) and chlorides and sulfates (calculated at sodium salts), not more than 15 percent.
2-Amino-1-naphthalensulfonic acid, calcium salt, not more than 0.2 percent.
3-Hydroxy-2-naphthoic acid, not more than 0.4 percent.
Subsidiary colors, nor more than 4 percent.
Lead (as Pb), not more than 20 parts per million.
Arsenic (as As), nor more than 3 parts per million.
Mercury (as Hg), not more than 1 part per million.
Total color not less than 85 percent.

(c) *Uses and restrictions.* The color additive D&C Red No. 34 may be safely used for coloring externally applied drugs in amounts consistent with good manufacturing practice.

(d) *Labeling.* The label of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 8.32.

(e) *Certification.* All batches of D&C Red No. 34 shall be certified in accordance with regulations in Subpart A of this Part.

c. In Subpart G, new § 8.7195 is added to read as follows:

§ 8.7195 D&C Red No. 34.

(a) *Identity and specifications.* The color additive D&C Red No. 34 shall conform in identity and specifications to the requirements of § 8.4128(a)(1) and (b).

(b) *Uses and restrictions.* D&C Red No. 34 may be safely used for coloring externally applied cosmetics in amounts consistent with good manufacturing practice.

(c) *Labeling.* The label of the color additive shall conform to the requirements of § 8.32.

(d) *Certification.* All batches of D&C Red No. 34 shall be certified in accordance with regulations in Subpart A of this part.

2. Part 9 is amended by revising § 9.179 to read as follows:

§ 9.179 D&C Red No. 34.

The color additive D&C Red No. 34 shall conform in identity and specifications to the requirements of § 8.4128(a)(1) and (b) of this chapter. D&C Red No. 34 is restricted to use in externally applied drugs and cosmetics.

Any person who will be adversely affected by the foregoing order may at any time on or before December 23, 1976, file with the Hearing Clerk, Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20852, written objections thereto. Objections shall show wherein the person filing will be adversely affected by the order, specify with particularity the provisions of the order deemed objectionable, and state the grounds for the objections. Objections shall be filed in accordance with the requirements of § 8.19 (21 CFR 8.19). If a hearing is requested, the objections shall state the issues for the hearing, shall be supported by grounds factually and legally sufficient to justify the relief sought, and shall include a detailed description and analysis of the factual information intended to be presented in support of the objections in the event that a hearing is held. Five copies of all documents shall be filed and should be identified with the Hearing Clerk docket number found in brackets in the heading of this order. Received objections may be seen in the above office during working hours, Monday through Friday.

Effective date: This order shall become effective December 27, 1976, 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)); Title II, Pub. L. 86–618, sec. 203, 74 Stat. 404–407 (21 U.S.C. 376 note).)

Dated: November 17, 1976.

JOSEPH P. HILE,
Associate Commissioner for Compliance.

[FR Doc.78-34519 Filed 11-22-76;8:45 am]

[Docket No. 76C-0441]

PART 8—COLOR ADDITIVES

PART 9—COLOR CERTIFICATION

Listing of D&C Brown No. 1 for Use in Externally Applied Cosmetics

The Food and Drug Administration (FDA) is "permanently" listing D&C Brown No. 1 for use in externally applied cosmetics; effective December 27, 1976; objections on or before December 23, 1976.

A notice published in the FEDERAL REGISTER of August 6, 1973 (38 FR 21199) stated that a petition (CAP 8C0087) for the "permanent" listing of D&C Brown No. 1 as a color additive for use in externally applied cosmetics had been filed by the Cosmetic Toiletry and Fragrance Association (1133 15th St. NW., Washington, DC 20005), c/o Hazleton Laboratories, Inc., P.O. Box 30, Falls Church, VA 22046. The petition was filed pursuant to section 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 376).

The Commissioner has evaluated the data in the petition and concludes that D&C Brown No. 1 is safe under the conditions set forth below for use in coloring externally applied cosmetics and that certification is necessary for the protection of the public health. This order "permanently" lists D&C Brown No. 1 for use in externally applied cosmetics under new § 8.7061 (21 CFR 8.7061). The provisional listing of D&C Brown No. 1 for use in externally applied cosmetics under § 8.501(b) (21 CFR 8.501(b)), which was extended to December 31, 1976 by regulation published in the FEDERAL REGISTER of September 23, 1976 (41 FR 41856), and the corresponding § 9.230 *D&C Brown No. 1* (21 CFR 9.230), which prescribes specifications for the color additive while provisionally listed, will be deleted when this order becomes effective on December 27, 1976, unless this order is stayed by the timely filing of objections, in which case the provisional listing and § 9.230 will continue in effect until December 31, 1976 unless terminated or extended by regulation.

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 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) (recodification published in the FEDERAL REGISTER of June 15, 1976 (41 FR 24262)), Parts 8 and 9 of Chapter I

of Title 21 of the Code of Federal Regulations are amended as follows:

1. Part 8 is amended:

§ 8.501 [Amended]

a. In paragraph (b) of § 8.501 *Provisional lists of color additives*, the entry for D&C Brown No. 1 for use in externally applied cosmetics is deleted.

b. In Subpart G, new § 8.7061 is added to read as follows:

§ 8.7061 D&C Brown No. 1.

(a) *Identity.* The color additive D&C Brown No. 1 is a mixture of the sodium salts of 4[[5-[(dialkylphenyl)azo]-2,4-dihydroxyphenyl]azo] - benzenesulfonic acid. The alkyl group is principally the methyl group.

(b) *Specifications.* D&C Brown No. 1 shall conform to the following specifications and shall be free from impurities other than those named to the extent that such other impurities may be avoided by good manufacturing practice:

Sum of volatile matter (at 135° C) and chlorides and sulfates (calculated as sodium salts), not more than 16 percent.

Water-insoluble matter, not more than 0.2 percent.

Sulfanilic acid, sodium salt, not more than 0.2 percent.

Resorcinol, not more than 0.2 percent.

Xylidines, not more than 0.2 percent.

Disodium salt of 4[[5-[(4-sulfophenyl)-azo]-2,4-dihydroxyphenyl]azo] benzenesulfonic acid, not more than 3 percent.

Monosodium salt of 4[[5-[(2,4-dimethylphenyl)azo]-2,4-dihydroxyphenyl]azo] benzenesulfonic acid, not less than 29 percent and not more than 39 percent.

Monosodium salt of 4[[5-[(2,5-dimethylphenyl)azo]-2,4-dihydroxyphenyl]azo] benzenesulfonic acid, not les than 12 percent and not more than 17 percent.

Monosodium salt of 4[[5-[(2,3-dimethylphenyl)azo]-2,4-dihydroxyphenyl]-azo] benzenesulfonic acid, not less than 6 percent and not more than 13 percent.

Monosodium salt of 4[[5-[(2-ethylphenyl)-azo]-2,4-dihydroxyphenyl]-azo] benzenesulfonic acid not less than 5 percent and not more than 12 percent.

Monosodium salt of 4[[5-[(3,4-dimethylphenyl)azo]-2,4-dihydroxyphenyl]-azo] benzenesulfonic acid, not less than 3 percent and not more than 9 percent.

Monosodium salt of 4[[5-[(2,6,-dimethylphenyl)azo]-2,4-dihydroxyphenyl]azo] benzenesulfonic acid, not less than 3 percent and not more than 8 percent.

Monosodium salt of 4[[5-[(4-ethylphenyl)azo]-2,4-dihydroxyphenyl]-azo] benzenesulfonic acid, not less than 2 percent and not more than 8 percent.

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

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

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

Total color, not less than 84 percent.

(c) *Uses and restrictions.* D&C Brown No. 1 may be safely used for coloring externally applied cosmetics in amounts consistent with good manufacturing practice.

(d) *Labeling.* The label of the color additive shall conform to the requirements of § 8.32.

(e) *Certification.* All batches of D&C Brown No. 1 shall be certified in accordance with regulations in Subpart A of this part.

§ 9.230 [Revoked]

2. Part 9 is amended by revoking § 9.230.

Any person who will be adversely affected by the foregoing order may at any time on or before December 23, 1976, file with the Hearing Clerk, 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 order, specify with particularity the provisions of the order deemed objectionable, and state the grounds for the objections. Objections shall be filed in accordance with the requirements of § 8.19 (21 CFR 8.19). If a hearing is requested, the objections shall state the issues for the hearing, shall be supported by grounds factually and legally sufficient to justify the relief sought, and shall include a detailed description and analysis of the factual information intended to be presented in support of the objections in the event that a hearing is held. Five copies of all documents shall be filed and should be identified with the Hearing Clerk docket number found in brackets in the heading of this order. Received objections may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Effective date: This order shall become effective on December 27, 1976, 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)); Title II, Pub. L. 86-618, sec. 203, 74 Stat. 404-407 (21 U.S.C. 376 note))

Dated: November 17, 1976.

JOSEPH P. HILE,
Associate Commissioner for Compliance.

[FR Doc.76-34522 Filed 11-22-76;8:45 am]

[Docket No. 76C-0433]

PART 8—COLOR ADDITIVES

PART 9—COLOR CERTIFICATION

Listing of Ext. D&C Violet No. 2 for Use in Externally Applied Cosmetics

The Food and Drug Administration (FDA) is "permanently" listing Ext. D&C Violet No. 2 for use in externally applied cosmetics; effective on December 27, 1976; objections on or before December 23, 1976.

A notice published in the FEDERAL REGISTER of September 3, 1971 (36 FR 17669) stated that a petition (CAP 8C0072) for the "permanent" listing of Ext. D&C Violet No. 2 as a color additive for use in externally applied cosmetics had been filed by the Cosmetic, Toiletry and Fragrance Association (1133 15th St. NW., Washington, DC 20005), c/o Hazleton Laboratories, Inc., P.O. Box 30, Falls Church, VA 22046. The petition was filed pursuant to section 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 376).

The Commissioner has evaluated the data in the petition and concludes that Ext. D&C Violet No. 2 is safe under the conditions set forth below for use in coloring externally applied cosmetics and that certification is necessary for the protection of the public health. This order "permanently" lists Ext. D&C Violet No. 2 for use in externally applied cosmetics under new § 8.7223 (21 CFR 8.7223). The provisional listing of Ext. D&C Violet No. 2 for use in externally applied cosmetics under § 8.501 (c) (21 CFR 8.501(c)), which was extended to December 31, 1976 by regulation published in the FEDERAL REGISTER of September 23, 1976 (41 FR 41856) and the corresponding regulation, § 9.411 (21 CFR 9.411), in Part 9 that prescribes specifications for the certification of Ext. D&C Violet No. 2 will be deleted when this order becomes effective on December 27, 1976, unless this order is stayed by the timely filing of objections, in which case the provisional listing and § 9.411 will continue in effect until December 31, 1976 unless terminated or extended by regulation.

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) (recodification published in the FEDERAL REGISTER of June 15, 1976 (41 FR 24262)), Parts 8 and 9 of Chapter I of Title 21 of the Code of Federal Regulations are amended as follows:

1. Part 8 is amended:

§ 8.501 [Amended]

a. In paragraph (c) of § 8.501 *Provisional lists of color additives*, the entry for Ext. D&C Violet No. 2 for use in externally applied cosmetics is deleted.

b. In Subpart E, new § 8.7223 is added to read as follows:

§ 8.7223 Ext. D&C Violet No. 2.

(a) *Identity.* (1) The color additive Ext. D&C Violet No. 2 is principally the monosodium salt of 2-[(9,10-dihydro-4-hydroxy - 9,10 - dioxo - 1 - anthracenyl) amino]-5-methly-benzenesulfonic acid.

(b) *Specifications.* Ext. D&C Violet No. 2 shall conform to the following specifications and shall be free from impurities, other than those named, to the extent that such other impurities may be avoided by good manufacturing practice:

Sum of volatile matter (at 135° C) and chlorides and sulfates (calculated as sodium salts), not more than 18 percent.

Water-insoluble matter, not more than 0.4 percent.

1-Hydroxy-9,10-anthracenedione, not more than 0.2 percent.

1,4-Dihydroxy-9,10-anthracenedione, not more than 0.2 percent.

p-Toluidine, not more than 0.1 percent.

p-Toluidine sulfonic acids, sodium salts, not more than 0.2 percent.

Subsidiary colors, not more than 1 percent.

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