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.

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 80 percent.

(c) *Uses and restrictions.* The color additive Ext. D&C Violet No. 2 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 Ext. D&C Violet No. 2 shall be certified in accordance with regulations in Subpart A of this Part.

§ 9.411 [Revoked]

2. Part 9 is amended by revoking § 9.411.

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.76-34523 Filed 11-22-76;8:45 am]

[Docket No. 76C-0442]

PART 8—COLOR ADDITIVES

PART 9—COLOR CERTIFICATION

Listing of D&C Red No. 31 for Use In Externally Applied Drugs and Cosmetics

The Food and Drug Administration (FDA) is "permanently" listing D&C Red No. 31 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 August 6, 1973 (38 FR 21199) stated that a petition (CAP 5C0032) for the "permanent" listing of D&C Red No. 31 as a color additive for use in externally applied drugs and cosmetics had been filed by the Cosmetic, Toiletry and Fragrance Association (1133 15th St. NW., Washington, D.C. 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 Red No. 31 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. 31 for use in externally applied drugs and cosmetics under new §§ 8.4125 and 8.7192 (21 CFR 8.4125 and 8.7192). The provisional listing of D&C Red No. 31 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. 31 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. D&C Red No. 31 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) (21 CFR 8.501(b)).

This order establishes specifications for the certification of batches of D&C Red No. 31 that are more restrictive than those currently prescribed under § 9.176 (21 CFR 9.176). 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 § 9.176 become obsolete upon the effective date of new §§ 8.4125 and 8.7192. However, it is necessary to maintain § 9.176 to provide for the use of the color additive in lakes. Accordingly, § 9.176 is revised to reference the identity nomenclature and specifications prescribed by § 8.4125.

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 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 Red No. 31 for us in externally applied drugs and cosmetics is deleted.

b. In Subpart E, new § 8.4125 is added to read as follows:

§ 8.4125 D&C Red No. 31.

(a) *Identity.* (1) The color additive D&C Red No. 31 is principally the calcium salt of 3-hydroxy - 4-(phenylazo) - 2-naphthalenecarboxylic acid.

(2) Color additive mixtures for drug use made with D&C Red No. 31 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. 31 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 10 percent.

Aniline, not more than 0.2 percent.

3-Hydroxy-2-naphthoic acid, calcium salt, not more than 0.4 percent.

Subsidiary colors, not more than 1 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 90 percent.

(c) *Uses and restrictions.* D&C Red No. 31 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 D&C Red No. 31 shall be certified in accordance with regulations in Subpart A of this Part.

c. In Subpart G, new § 8.7192 is added to read as follows:

§ 8.7192 D&C Red No. 31.

(a) *Identity and specifications.* The color additive D&C Red No. 31 shall conform in identity and specifications to the requirements of § 8.4125 (a)(1) and (b).

(b) *Uses and restrictions.* D&C Red No. 31 may be safely used for coloring ex-

ternally 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. 31 shall be certified in accordance with regulations in Subpart A of this part.

2. Part 9 is amended by revising § 9.176 to read as follows:

§ 9.176 D&C Red No. 31.

The color additive D&C Red No. 31 shall conform in identity and specifications to the requirements of § 8.4125 (a) (1) and (b) of this chapter. D&C Red No. 31 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.

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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. 401–407 (21 U.S.C. 376 note).)

Dated: November 17, 1976.

JOSEPH P. HILE,
Associate Commissioner for Compliance.

[FR Doc.76-34528 Filed 11-22-76;8:45 am]

SUBCHAPTER D—DRUGS FOR HUMAN USE

PART 452—MACROLIDE ANTIBIOTIC DRUGS

Erythromycin Ethylsuccinate

The Food and Drug Administration (FDA) is amending the macrolide antibiotic drug regulations to provide for certification of two new tablet forms of erythromycin and ethylsuccinate, to clarify the nomenclature used in the provisions for chewable tablets, and to delete provisions for one strength of erythromycin ethylsuccinate chewable tablets that is no longer marketed; effective November 23, 1976.

The Commissioner of Food and Drugs has evaluated data submitted in accordance with regulations promulgated under section 507 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 357), as amended, with respect to providing for certification of erythromycin ethylsuccinate plain coated and uncoated tablets.

The Commissioner has concluded that data supplied by the manufacturer concerning the subject antibiotic drug products are adequate to establish their safety and efficacy when used as directed in the labeling and that the regulations should be amended to provide for certification of these drug products. A new § 452.125d (21 CFR 452.125d) is being established for this purpose.

Section 452.125a (21 CFR 452.125a) provides only for erythromycin ethylsuccinate tablets that are intended to be chewed. The Commissioner finds it appropriate to amend § 452.125a by adding "chewable" to the section heading and by revising the paragraph that provides for labeling to clarify that "chewable" is not part of the established name. The policy of FDA is to include the word "chewable" in the heading of sections that provide for chewable tablets but not to include it as part of the established or nonproprietary name of the drug.

In addition, provisions for the 100-milligram chewable tablet are being deleted because the tablet is no longer being marketed.

(Sec. 507, 59 Stat. 463, as amended (21 U.S.C. 357)) 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 452 is amended as follows:

1. In § 452.125a, by revising the section heading, amending paragraph (a) (1) by revising the first two sentences therein and by revising paragraph (a) (2) to read as follows:

§ 452.125a Erythromycin ethylsuccinate chewable tablets.

(a) *Requirements for certification—*(1) *Standards of identity, strength, quality, and purity.* Erythromycin ethylsuccinate chewable tablets are composed of erythromycin ethylsuccinate and suitable and harmless diluents, binders, buffers, colorings, and flavorings. Each tablet contains erythromycin ethylsuccinate equivalent to 200 milligrams of erythromycin. * * *

(2) *Labeling.* In addition to the labeling requirements prescribed by § 432.5 of this chapter, this drug shall be labeled "erythromycin ethylsuccinate tablets".

* * * * *

2. By adding new § 452.125d, to read as follows:

§ 452.125d Erythromycin ethylsuccinate tablets.

(a) *Requirements for certification—*(1) *Standards of identity, strength, quality, and purity.* Erythromycin ethylsuccinate tablets are composed of erythromycin ethylsuccinate and suitable and harmless diluents, binders, buffers, and colorings. Each tablet contains erythromycin ethylsuccinate equivalent to 400 milligrams of erythromycin. Its potency is satisfactory if it is not less than 90 percent and not more than 120 percent of the number of milligrams of erythromycin that it is represented to contain. The loss on drying is not more than 4.0 percent. The tablets shall disintegrate within 40 minutes. The erythromycin ethylsuccinate used conforms to the standards prescribed by § 452.25 (a) (1).

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 432.5 of this chapter.

(3) *Requests for certification; samples.* In addition to complying with the requirements of § 431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The erythromycin ethylsuccinate used in making the batch for potency, safety, moisture, pH, residue on ignition, identity, and crystallinity.

(*b*) The batch for potency, loss on drying, and disintegration time.

(ii) Samples required:

(*a*) The erythromycin ethylsuccinate used in making the batch: 10 packages, each containing approximately 500 milligrams.

(*b*) The batch: A minimum of 36 tablets.

(b) *Tests and methods of assay—*(1) *Potency.* Proceed as directed in § 436.105 of this chapter, preparing the sample for assay as follows: Place a representative number of tablets into a high-speed glass blender jar containing 200 milliliters of methyl alcohol. Blend for 2 to 3 minutes. Add 300 milliliters of 0.1*M* potassium phosphate buffer, pH 8.0 (solution 3), and blend again for 2 to 3 minutes. Further dilute an aliquot with solution 3 to the reference concentration of 1.0 microgram of erythromycin base per milliliter (estimated).

(2) *Loss on drying.* Proceed as directed in § 436.200(a) of this chapter.

(3) *Disintegration time—*(i) *If the tablet is uncoated.* Proceed as directed in § 436.212 of this chapter, using the procedure described in paragraph (e) (1) of that section.

(ii) *If the tablet is plain-coated.* Proceed as directed in § 436.212 of this chapter, using the procedure described in paragraph (e) (2) of that section.

Since the conditions prerequisite to providing for certification of the subject antibiotic drug have been complied with, interested persons have been consulted, and there are no significant points of controversy, notice, public procedure, and delayed effective date are unnecessary pursuant to 5 U.S.C. 553 (b) and (d).

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

(Sec. 507, 59 Stat. 463, as amended (21 U.S.C. 357).)

Dated: November 16, 1976.

MARY A. MCENIRY,
Assistant Director for Regulatory Affairs, Bureau of Drugs.

[FR Doc.76-34342 Filed 11-22-76;8:45 am]

Title 24—Housing and Urban Development

CHAPTER X—FEDERAL INSURANCE ADMINISTRATION, DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

SUBCHAPTER B—NATIONAL FLOOD INSURANCE PROGRAM

[Docket No. FI 2450]

PART 1914—COMMUNITIES ELIGIBLE FOR THE SALE OF INSURANCE

Status of Participating Communities

The purpose of this notice is to list those communities wherein the sale of flood insurance is authorized under the National Flood Insurance Program (42 U.S.C. 4001-4128).

Insurance policies can be obtained from any licensed property insurance agent or broker serving the eligible community, or from the National Flood Insurers Association servicing company for the state (addresses are published at § 1912.5, 24 CFR Part 1912).

The Flood Disaster Protection Act of 1973 (Pub. L. 93-234) requires the purchase of flood insurance as a condition of receiving any form of Federal or Federally related financial assistance for acquisition or construction purposes in a flood plain area having special hazards within any community identified for at least one year by the Secretary of Housing and Urban Development. The requirement applies to all identified special flood hazard areas within the United States, and no such financial assistance can legally be provided for acquisition or construction except as authorized by section 202(b) or the Act, as amended, unless the community has entered the program. Accordingly, for communities listed under this Part no such restriction exists, although insurance, if required, must be purchased.

The Federal Insurance Administrator finds that delayed effective dates would be contrary to the public interest. The Administrator also finds that notice and public procedure under 5 U.S.C. 553(b) are impracticable and unnecessary.

Section 1914.6 of Part 1914 of Subchapter B of Chapter X of Title 24 of the Code of Federal Regulations is amended by adding in alphabetical sequence new entries to the table. In each entry, a complete chronology of effective dates appears for each listed community. The date that appears in the fourth column of the table is provided in order to designate the effective date of the authorization of the sale of flood insurance in the area under the emergency or the regular flood insurance program. These dates serve notice only for the purposes of granting relief, and not for the application of sanctions, within the meaning of 5 U.S.C. 551. The entry reads as follows:

§ 1914.6 List of eligible communities.

State	County	Location	Effective date of authorization of sale of flood insurance for area	Hazard area identified	Community No.
•	•	•	•	•	•
Georgia	Fannin	Mineral Bluff, city of	Nov. 15, 1976, emergency	July 2, 1976	130251
Iowa	Iowa	Williamsburg, city of	do		190427
Oklahoma	Pittsburg	Crowder, town of	do	Apr. 2, 1976	400283
Utah	Cache	Newton, town of	do	July 11, 1975	490022
New Jersey	Union	Linden, city of	Nov. 20, 1970, emergency; Nov. 24, 1976, regular.	July 16, 1976	340467 A
Pennsylvania	Dauphin	Middletown, borough of	Oct. 13, 1972, emergency; Dec. 28, 1976, regular.	Feb. 20, 1973	420388 A
Do	Clinton	Renovo, borough of	Feb. 9, 1973, emergency; Dec. 28, 1976, regular.	Oct. 5, 1973	420334A
•	•	•	•	•	•
Minnesota	Swift	Murdock, city of	Nov. 16, 1976, emergency	Aug. 23, 1974	270473A
Ohio	Summit	Boston Heights, village of	do	July 25, 1975	390749
Oklahoma	Kiowa	Lone Wolf, town of	do	May 3, 1974	400085A
Do	Jackson	Olustee, town of	do	Apr. 9, 1976	400430
•	•	•	•	•	•
Georgia	Fannin	Morganton, town of	Nov. 17, 1976, emergency	June 18, 1976	130449
Maine	Hancock	Sorrento, town of	do	Jan. 24, 1975	230292
Wisconsin	Barron	Almena, village of	do	Sept. 6, 1974 May 14, 1976	550009A
•	•	•	•	•	•
Arkansas	Woodruff	Unincorporated areas	November 18, 1976, emergency	May 28, 1976	050468
Kansas	Rice	Raymond, city of	do	Dec. 27, 1974	200296
Missouri	Taney	Branson, city of	Dec. 10, 1971, emergency; Oct. 26, 1976, regular.	July 7, 1974 May 28, 1976	290436B
Pennsylvania	Bucks	Chalfont, borough of	Feb. 25, 1972, emerbency; Dec. 28, 1976, regular.	Mar. 16 1973	420184
Do	Montgomery	Cheltenham, township of	Oct. 1, 1974, emergency; Nov. 22, 1976, regular.	June 28, 1974 Apr. 11, 1975	420696B

(National Flood Insurance Act of 1968 (title XIII of the Housing and Urban Development Act of 1968); effective Jan. 28, 1969 (33 FR 17804, Nov. 28, 1968), as amended, 42 U.S.C. 4001-4128; and Secretary's delegation of authority to Federal Insurance Administrator, 34 FR 2680, Feb. 27, 1969)) as amended 39 FR 2787, Jan. 24, 1974.)

Issued: November 12 1976.

J. ROBERT HUNTER,
Federal Insurance Administrator.

[FR Doc.76-34354 Filed 11-22-76;8:45 am]

[Docket No. FI 2451]

PART 1914—COMMUNITIES ELIGIBLE FOR THE SALE OF INSURANCE

Suspension of Community Eligibility

The purpose of this notice is to list communities wherein the sale of flood insurance as authorized under the National Flood Insurance Program (42 U.S.C. 4001-4128) will be suspended because of noncompliance with the program regulations (24 CFR Part 1909 et seq.)

The Flood Disaster Protection Act of 1973 requires the purchase of flood insurance as a condition of receiving any form of Federal or Federally related financial assistance for acquisition or construction purposes in a flood plain area having special hazards within any community identified by the Secretary of Housing and Urban Development.

The requirement applies to all identified special flood hazard areas within the United States, and no such financial assistance can legally be provided for acquisition or construction in these areas unless the community has entered the program and insurance is purchased. Accordingly, for communities listed under this Part such restriction exists as of the effective date of suspension because insurance, which is required, cannot be purchased.

Section 1315 of the National Flood Insurance Act of 1968, as amended (42 U.S.C. 4022) prohibits flood insurance coverage unless an appropriate public body shall have adopted adequate flood plain management measures with effective enforcement measures. The communities suspended in this notice no longer meet that statutory requirement. Accordingly, the communities are sus-