

and the effect of those changes on consumers, and a decrease in the time required to process producer applications.

Several of the parties that filed comments on the proposed rulemaking requested a conference with the Staff to discuss the proposed form. Because of the elimination of Schedule 506 as it appeared in the Notice, the fact that the form collects information that is now being filed with the Commission on existing forms, and the modifications to the instructions and format made at the suggestion of the respondents, a conference would not serve any useful purpose. Therefore, the requests for a conference are denied.

Pursuant to the requirements of 44 U.S.C. 3512, Form No. 108 was submitted to the Comptroller General for clearance on August 19, 1976. By letter dated October 5, 1976, the Commission received conditional acceptance of the form. We have reviewed the comments of the General Accounting Office (GAO) and we have amended our procedures to conform thereto. Therefore, we now consider the GAO clearance to be unconditional.

The Commission finds: (1) The notice and opportunity to participate in this proceeding with respect to the matter presently before the Commission through the submissions in writing are consistent and in accordance with all procedural requirements as prescribed in Section 553, Title 5 of the United States Code.

(2) The amendments to Part 260 of the Commission's Statements and Reports to add amended § 260.6, to Part 154 of the Commission's Rate Schedules and Tariffs to add new § 154.92(e), and to Part 3 of the Commission's Organization; operation; information and requests; miscellaneous charges; ethical standards to substitute for the present § 3.170(a)(17) a revised version are necessary and appropriate for the administration of the Natural Gas Act.

(3) Sections 154.94(f), 154.91(b)(3), 157.24, 250.5, and 260.5 shall be amended pursuant to the provisions of the instant order.

The Commission orders: (A) The Commission, acting pursuant to the provisions of the Natural Gas Act, as amended, particularly Sections 8, 10, 14, 15, and 16 thereof (52 Stat. 825, 826, 828, 829, 830; 15 U.S.C. 717g, 717i, 717m, 717n, 717o) hereby orders the following amendments to its Rules and Regulations, effective January 1, 1977:

(a) Subparts (a) and (b) of § 260.6 of Part 260, Statements and Reports are deleted in their entirety. Substituted therefor is a new § 260.6, which would read as set forth below:

PART 3—ORGANIZATIONS; OPERATION; INFORMATION AND REQUESTS; MISCELLANEOUS CHARGES; ETHICAL STANDARDS

(1) Part 3, Organization; operation information and requests; miscellaneous charges; ethical standards; Subchapter A, Chapter I, Title 18 of the Code of Federal Regulations is amended by deleting in its entirety § 3.170(a)(17) and substituting therefor:

§ 3.170(a)(17) Form No. 108³, rate schedule analysis on a continuing current basis.

(B) As of January 1, 1977, the following sections of the Commission's Regulations are amended as noted:

PART 154—RATE SCHEDULES AND TARIFFS

(2) Part 154, Rate Schedules and Tariffs in § 154.92—Filings of rate schedules by independent producer, Chapter I, Title 18 of the Code of Federal Regulations is amended by adding a new subsection (e), which would read as follows:

§ 154.92 Filing of rate schedules by independent producer.

(e) Any jurisdictional natural gas company that maintains a rate schedule on file with the Commission or makes application to have a rate schedule approved by this Commission or modifies any existing or proposed rate schedule must, in addition to the requirements of this or any other section, complete and submit Form No. 108, or applicable schedules thereof, pursuant to the direction of § 260.6 of this chapter.

(13) FPC Form 280, an alternative to § 154.94(f), is no longer in effect. Section 154.94(f) is amended as follows:

§ 154.94 Changes in rate schedules.

(f) Notice of change in rate level. (1) An independent producer who is proposing a contractual change in rates, charges, etc., shall file the information called for in Schedule 507 of Form No. 108.

§ 154.91 [Removed]

(4) Section 154.91(b)(3) is deleted in its entirety.

PART 157—APPLICATIONS FOR CERTIFICATES OF PUBLIC CONVENIENCE AND NECESSITY AND FOR ORDERS PERMITTING AND APPROVING ABANDONMENT UNDER SECTION 7 OF THE NATURAL GAS ACT

§ 157.24 [Amended]

(5) Section 157.24(a) is amended as follows:

(a) Every application for a certificate of public convenience and necessity required under § 157.23 shall be filed with the Commission. If the application is filed by an assignee seeking authority, as successor in interest, only to render service previously authorized by the Commission or to initiate service resulting from a farmout agreement, he shall describe the service to be continued (1) under the original F.P.C. Docket No(s), granting authorization to the assignor and (2) the proposed disposition of the assignor's F.P.C. Gas Rate Schedule(s), and, if applicable, in addition to the refund obligations required by § 154.92 (d)(3) indicate if the assignor intends to file bond or undertaking to assure

³ Form No. 108 is filed as a part of the original document.

total refund from the date increased rate of assignor becomes effective subject to refund or from date operation commenced under assignor's temporary certificate containing a refund condition, as the case may be. In addition, the application shall set forth in the order indicated the following:

PART 250—FARMS

§ 250.5 [Removed]

(6) Section 250.5 is deleted in its entirety.

PART 260—STATEMENTS AND REPORTS (SCHEDULES)

§ 260.5 [Removed]

(7) Section 260.5 is deleted in its entirety.

Subparts (a) and (b) of § 260.6 are deleted in their entirety. Substituted therefor is a new § 260.6, which reads as follows:

§ 260.6 Rate schedule analysis on a continuing current basis.

(a) The form of Rate Schedule Analysis Report as FPC Form No. 108 is prescribed for natural gas companies commencing January 1, 1977.

(b) Each person found by the Commission to be a natural gas company as defined by the Natural Gas Act, as amended, 52 Stat. 821, that is required to submit a rate schedule to the Commission pursuant to § 154.92 of the Regulations shall prepare and file with the Commission an original and 3 copies of the Rate Schedule Analysis Report, FPC Form No. 108, or the applicable schedules thereof, each and every time a rate schedule is either submitted to the Commission for the first time or a rate schedule presently on file with the Commission is proposed to be amended.

By the Commission.

KENNETH F. PLUMB,
Secretary.

[FR Doc.76-35071 Filed 11-29-76;8:45 am]

Title 21—Food and Drugs

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

SUBCHAPTER A—GENERAL

[Docket No. 76C-0464]

PART 8—COLOR ADDITIVES

Listing of Guaiazulene for Use in Externally Applied Cosmetics

The Food and Drug Administration (FDA) is "permanently" listing guai-azulene for use in externally applied cosmetics; effective January 3, 1977, objections by December 30, 1976.

A notice published in the FEDERAL REGISTER of August 6, 1973 (38 FR 21200) stated that a petition (CAP 8C0070) for the "permanent" listing of azulene as a color additive for use in externally applied cosmetics had been filed by the Cosmetic, Toiletry and Fragrance Association (CTFA) (1133 15th St. NW., Washington, DC 20005), c/o Hazleton Labora-

tories, Inc., PO 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 the color additive is safe under the conditions set forth below for use in coloring externally applied cosmetics and that certification is not necessary for the protection of the public health. This order "permanently" lists the color additive as guaiazulene, the nomenclature that more properly identifies the color additive that was the subject of the petition, for use in externally applied cosmetics under new § 8.8010 (21 CFR 8.8010). The provisional listing of azulene for use in externally applied cosmetics under § 8.501 (g) (21 CFR 8.501(g)), 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 January 3, 1977 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.

Cosmetic labeling is required, under § 701.3 (21 CFR 701.3), to list the name of each color additive present as an ingredient in the finished cosmetic. Cosmetic labeling listing the color additive guaiazulene under its formerly accepted name "azulene" may be used until current supplies are exhausted or until January 3, 1978. In a separate action published in the FEDERAL REGISTER of September 23, 1976 (41 FR 41855) terminating provisional listing for 10 color additives, the Commissioner concluded that 1 year would be sufficient time to permit the depletion of cosmetic labeling improperly identifying the substances as color additives. The Commissioner concludes that 1 year should also be sufficient time for depletion of existing stocks of labels declaring guaiazulene as "azulene."

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)), Part 8 of Chapter I of Title 21 of the Code of Federal Regulations is amended as follows:

§ 8.501 [Amended]

1. In paragraph (g) of § 8.501 *Provisional lists of color additives*, the entry for azulene for use in externally applied cosmetics is deleted.

2. In Subpart H, new § 8.8010 is added to read as follows:

§ 8.8010 Guaiazulene.

(a) *Identity.* (1) The color additive, guaiazulene, is principally 1,4-dimethyl-7-isopropyl-azulene.

(2) Color additive mixtures of guaiazulene for cosmetic use may contain the following diluent:

Polyethylene glycol-40 castor oil (PEG-40 castor oil).

Saponification No., 60 to 70.

Hydroxyl No., 63 to 78.

Acid No., <3.

Specific gravity, 1.05 to 1.07.

(b) *Specifications.* Guaiazulene 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.

Melting point, 30.5° C to 31.5° C.

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 99 percent.

(c) *Uses and restrictions.* Guaiazulene may be safely used in externally applied cosmetics 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) *Exemption from certification.* Certification of this color additive for the prescribed use is not necessary for the protection of the public health and therefore batches thereof are exempt from the certification requirements of section 706(c) of the act.

Any person who will be adversely affected by the foregoing order may at any time on or before December 30, 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 January 3, 1977, 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 23, 1976.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner
for Compliance.

[FR Doc.76-35126 Filed 11-29-76;8:45 am]

[Docket No. 76C-0044]

PART 8—COLOR ADDITIVES

PART 9—COLOR CERTIFICATION

Listing of D&C Blue No. 4 for Use in Externally Applied Drugs and Cosmetics

The Food and Drug Administration (FDA) is "permanently" listing D&C Blue No. 4 for use in externally applied drugs and cosmetics; effective January 3, 1977; objections by December 30, 1976.

A notice published in the FEDERAL REGISTER of March 5, 1976 (41 FR 9584) stated that a petition (CAP 9C0095) for the "permanent" listing of D&C Blue No. 4 as a color additive for use in externally applied drugs and cosmetics had been filed by the Cosmetic, Toiletry and Fragrance Association, Inc. (1133 15th St. NW., Washington, DC 20005), c/o Hazleton Laboratories, Inc., PO 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 Blue No. 4 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 Blue No. 4 for use in externally applied drugs and cosmetics under new §§ 8.4023 and 8.7034 (21 CFR 8.4023 and 8.7034). The provisional listing of D&C Blue No. 4 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 January 3, 1977, 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 Blue No. 4 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 Blue No. 4 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 Blue No. 4 that are more restrictive than those currently prescribed under § 9.240 (21 CFR 9.240). 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 § 9.240 become obsolete upon the effective date of new §§ 8.4023 and 8.7034. However, it is necessary to retain § 9.240 to provide for the use of the color additive in lakes. Accordingly, § 9.240 is revised to reference the identity nomenclature and specifications prescribed by § 8.4023.

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 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 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 Blue No. 4 for use in externally applied drugs and cosmetics is deleted.

b. In Subpart E, new § 8.4023 is added to read as follows:

§ 8.4023 D&C Blue No. 4.

(a) *Identity*. (1) The color additive D&C Blue No. 4 is principally the diammonium salt of ethyl[4-[p[ethyl(m-sulfobenzyl)amino] - α - (o-sulfophenyl)benzylidene] - 2,5 - cyclohexadien - 1 - ylidene] (m-sulfobenzyl) ammonium hydroxide inner salt with smaller amounts of the isomeric diammonium salts of ethyl [4-[p[ethyl(p-sulfobenzyl) amino]-α-(o-sulfophenyl)benzylidene]-2,5-cyclohexadien - 1 - ylidene] (p-sulfobenzyl) ammonium hydroxide inner salt and ethyl[4-[p[ethyl(o-sulfobenzyl) amino] - α - (o-sulfophenyl)benzylidene] - 2,5 - cyclohexadien - 1 - ylidene] (o-sulfobenzyl) ammonium hydroxide inner salt.

(2) Color additive mixtures for use in externally applied drugs made with D&C Blue No. 4 may contain only those diluents that are suitable and that are listed in Subpart F of this part for use in color additive mixtures for coloring externally applied drugs.

(b) *Specifications*. D&C Blue No. 4 shall conform to the following specifications and shall be free from impurities other than those named to the extent that such impurities may be avoided by good manufacturing practice:

Sum of volatile matter (at 135° C) and chlorides and sulfates (calculated as sodium salts), not more than 15 percent.

Water-insoluble matter, not more than 0.2 percent.

Leuco base, not more than 5 percent.

Sum of o-, m, and p-sulfobenzaldehydes, ammonium salt, not more than 1.5 percent.
N-ethyl-N-(m-sulfobenzyl) sulfanilic acid, ammonium salt, not more than 0.3 percent.
Subsidiary colors, not more than 6 percent.
Chromium (as Cr), not more than 50 parts per million.
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*. D&C Blue No. 4 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 Blue No. 4 shall be certified in accordance with regulations in Subpart A of this part.

c. In Subpart G, new § 8.7034 is added to read as follows:

§ 8.7034 D&C Blue No. 4.

(a) *Identity and specifications*. The color additive D&C Blue No. 4 shall conform in identity and specifications to the requirements of § 8.4023(a)(1) and (b).

(b) *Uses and restrictions*. D&C Blue No. 4 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 Blue No. 4 shall be certified in accordance with regulations in Subpart A of this part.

2. Part 9 is amended by revising § 9.240 to read as follows:

§ 9.240 D&C Blue No. 4.

The color additive D&C Blue No. 4 shall conform in identity and specifications to the requirements of § 8.4023(a)(1) and (b) of this chapter. D&C Blue No. 4 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 30, 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 January 3, 1977, 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 23, 1976.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner
for Compliance.

[FR Doc.76-35127 Filed 11-29-76;8:45 am]

[Docket No. 76C-0468]

PART 8—COLOR ADDITIVES

Listing of Iron Oxides for Use in Cosmetics

The Food and Drug Administration (FDA) is "permanently" listing iron oxides for use in cosmetics, generally, including those intended for use in the area of the eye; effective January 3, 1977; objections by December 30, 1976.

A notice published in the FEDERAL REGISTER of August 6, 1973 (38 FR 21200) stated that a petition (CAP 9C0088) for the "permanent" listing of iron oxides as color additives for use in externally applied cosmetics, including lipsticks and those for use in the area of the eye, had been filed by the Cosmetic, Toiletry and Fragrance Association, Inc. (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). A notice published in the FEDERAL REGISTER of March 5, 1976 (41 FR 9534) amended the filing of this petition to include the additional use of iron oxides in all types of cosmetics subject to ingestion.

The Commissioner has evaluated the data in the petition and concludes that iron oxides are safe under the conditions set forth below for use in coloring cosmetics generally, including those intended for use in the area of the eye, and that certification is not necessary for the protection of the public health. This order "permanently" lists iron oxides for use in cosmetics, including those for use in the area of the eye, under new § 8.8009 (21 CFR 8.8009). The provisional listing of iron oxides (including hydrated iron oxides) for use in cosmetics under § 8.501(g) (21 CFR 8.501(g)), 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 January 3, 1977, unless this order is stayed by the timely filing of ob-