Title 18—Conservation of Power and Water Resources

CHAPTER I—FEDERAL POWER COMMISSION

PART 295—EMERGENCY REGULATIONS

Order No. 4–A

Subparagraph (c) of Paragraph No. (2) of Order No. 4 is amended by substituting for "Mcf" in the first line the term "MMBtu".

Paragraph No. (2) of Order No. 4 is hereby amended by redesignating subparagraph (g) as subparagraph (h) and inserting a new subparagraph (g) as follows:

* * * * *

(g) The amount and method of determination of any broker's fees, commissions, or finder's fees paid in relation to the transaction;

* * * * *

RICHARD L. DUNHAM,
Administrator.

MARCH 1, 1977.

[FR Doc.77-6655 Filed 3-3-77;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. 76N-0414]

PART 2—ADMINISTRATIVE PRACTICES AND PROCEDURES

Subpart D—Public Hearing Before a Public Advisory Committee; Clarification of Device Committee Names

The Food and Drug Administration (FDA) issued final procedures for holding a public hearing before a public advisory committee, published in the FEDERAL REGISTER of November 26, 1976 (41 FR 52148).

Section 2.340 (21 CFR 2.340) lists all FDA standing advisory committees, including statements of function and the date the committee was established where appropriate. The panel names for medical device panels listed under § 2.340 (d) are not consistent with the names under which the panels were chartered. Therefore, the Commissioner has decided that it is reasonable to revise § 2.340(d) to change the names of the medical device panels listed to coincide with the original panel charters where appropriate.

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), Part 2 is amended by revising § 2.340(d)(1) (i) through (xix) to read as follows:

§ 2.340 **List of standing advisory committees.**

* * * * *

(d) *Bureau of Medical Devices and Diagnostic Products.* (1) Advisory review panels for medical devices, and dates established.

(i) *Anesthesiology Device Classification Panel.* Established August 9, 1976.

(ii) *Cardiovascular Device Classification Panel.* Established August 9, 1976.

(iii) *Clinical Chemistry Device Classification Panel.* Established August 10, 1976.

(iv) *Clinical Toxicology Device Classification Panel.* Established August 10, 1976.

(v) *Dental Device Classification Panel.* Established August 9, 1976.

(vi) *Ear, Nose, and Throat Device Classification Panel.* Established August 9, 1976.

(vii) *Gastroenterological and Urological Device Classification Panel.* Established August 9, 1976.

(viii) *General and Plastic Surgery Device Classification Panel.* Established August 9, 1976.

(ix) *General Hospital and Personal Use Device Classification Panel.* Established August 9, 1976.

(x) *Hematology Device Classification Panel.* Established August 10, 1976.

(xi) *Immunology Device Classification Panel.* Established August 10, 1976.

(xii) *Microbiology Device Classification Panel.* Established August 10, 1976.

(xiii) *Neurological Device Classification Panel.* Established August 9, 1976.

(xiv) *Obstetrical and Gynecological Device Classification Panel.* Established August 9, 1976.

(xv) *Ophthalmic Device Classification Panel.* Established August 9, 1976.

(xvi) *Orthopedic Device Classification Panel.* Established August 9, 1976.

(xvii) *Pathology Device Classification Panel.* Established August 10, 1976.

(xviii) *Physical Medicine Device Classification Panel.* Established August 9, 1976.

(xix) *Radiological Device Classification Panel.* Established August 9, 1976.

* * * * *

Since this amendment merely sets forth the advisory committee names as they were formally chartered, notice and public procedure and delayed effective date are unnecessary for its promulgation.

Effective date. This amendment shall be effective March 4, 1977.

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

Dated: March 1, 1977.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Compliance.

[FR Doc.77-6711 Filed 3-3-77;8:45 am]

[Docket No. 76C-0434]

PART 8—COLOR ADDITIVES

PART 9—COLOR CERTIFICATION

D&C Yellow No. 11; Confirmation of Effective Date

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration confirms the effective date of December 20, 1976 of an order concerning the use of D&C Yellow No. 11 in externally applied drugs and cosmetics.

DATE: Effective date confirmed: December 20, 1976.

FOR FURTHER INFORMATION CONTACT:

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

SUPPLEMENTARY INFORMATION: An order was published in the FEDERAL REGISTER of November 19, 1976 (41 FR 51008) that added §§ 8.4182 and 8.7262 (21 CFR 8.4182 and 8.7262) to provide for safe use of D&C Yellow No. 11 in externally applied drugs and cosmetics and amended § 8.501 (21 CFR 8.501) by deleting D&C Yellow No. 11 for the provisionally listed colors in paragraph (b). The order also amended Part 9 by revoking § 9.134 (21 CFR 9.134).

An objection was filed in response to the order. (No person requested a formal evidentiary hearing.) A letter was received from a copetitioner for the color additive, objecting to the specifications of D&C Yellow No. 11 that restricted the level of lead to 10 parts per million (ppm). The copetitioners requested that the specification for lead for D&C Yellow No. 11 be restricted to 20 ppm to be consistent with levels imposed on other D&C colors and noncertified colors intended for use in externally applied drugs or cosmetics.

After evaluating the objection and reviewing the matter, the Commissioner notes that the level of 10 ppm appeared in the listing regulation for D&C Yellow No. 11 by error and should have been 20 ppm as stated in the copetitioner's letter. Accordingly, the Commissioner concludes that the regulation should be corrected as stated in the objection. Published elsewhere in this issue of the FEDERAL REGISTER is a document changing the limitation for lead to 20 parts per million.

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 authority delegated to the Commissioner (21 CFR 5.1), notice is given that there being no other objections or any requests for hearing in response to the order of November 19, 1976, the amendments promulgated thereby became effective on December 20, 1976.

Dated: February 28, 1977.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Compliance.

[FR Doc.77-6486 Filed 3-3-77;8:45 am]

[Docket No. 76C-0433]

PART 8—COLOR ADDITIVES

PART 9—COLOR CERTIFICATION

Ext. D&C Violet No. 2; Confirmation of Effective Date

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration confirms the effective date of December 27, 1976, of an order concerning the use of Ext. D&C Violet No. 2 in externally applied cosmetics.

DATE: Effective date confirmed: December 27, 1976.

FOR FURTHER INFORMATION CONTACT:

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

SUPPLEMENTARY INFORMATION: An order was published in the FEDERAL REGISTER of November 23, 1976 (41 FR 51594) that amended Part 8 by adding § 8.7223 (21 CFR 8.7223) to provide for safe use of Ext. D&C Violet No. 2 in externally applied cosmetics and amended Part 9 by revoking § 9.411 (21 CFR 9.411). It also amended § 8.501 (21 CFR 8.501) by deleting Ext. D&C Violet No. 2 from the provisionally listed colors in paragraph (c).

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 authority delegated to the Commissioner (21 CFR 5.1), notice is given that no objections or requests for hearing were filed in response to the order of November 23, 1976. Accordingly, the amendments promulgated thereby became effective on December 27, 1976.

Dated: February 28, 1977.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Compliance.

[FR Doc.77-6488 Filed 3-3-77;8:45 am]

[Docket No. 76C-0434]

PART 8—COLOR ADDITIVES

PART 9—COLOR CERTIFICATION

Listing of D&C Yellow No. 11 for Use in Externally Applied Drugs and Cosmetics; Correction

In FR Doc. 76-33996 appearing at page 51008 in the FEDERAL REGISTER of Friday, November 19, 1976, the following change is made:

On page 51008, the specifications of D&C Yellow No. 11 in paragraph (b) of § 8.4182 D&C Yellow No. 11 is corrected by revising the limitation for "Lead (as Pb)" to read as follows: "Lead (as Pb), not more than 20 parts per million."

Dated: February 28, 1977.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Compliance.

[FR Doc.77-6487 Filed 3-3-77;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; Stay of Effectiveness

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) stays the effectiveness of an order published in the FEDERAL REGISTER of November 23, 1976 (41 FR 51592) concerning the use of D&C Red No. 34 in externally applied drugs and provides for its continued use under provisional listing.

EFFECTIVE DATE: March 4, 1977.

FOR FURTHER INFORMATION CONTACT:

Gerad L. McCowin, Division of Food and Color Additives (HFF-334), Food and Drug Administration, Department of Health, Education, and Welfare, 200 C St. SW., Washington, DC 20204. (202-472-5740).

SUPPLEMENTARY INFORMATION: In the FEDERAL REGISTER of November 23, 1976 (41 FR 51592), the Commissioner of Food and Drugs issued an order listing 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 order also deleted the color from provisional listing in § 8.501(b) and revised the specifications prescribed in § 9.179 for D&C Red No. 34 to reference the new § 8.4128.

A comment was filed in response to the proposal, published in the FEDERAL REGISTER of September 23, 1976 (41 FR 41860), concerning the extension of the closing date for the provisionally listed color additives. The comment objected to the listing of azo dyes of which D&C Red No. 34 is one. Citing a reference from "Occupational and Environmental Cancers of the Urinary System," the comment stated that according to Dr. Hueper, there is reason to believe that azo dyes contain various carcinogenic amines, including β-naphthylamine.

The Commissioner discussed this possibility in the preamble to the regulation, published in the FEDERAL REGISTER of February 4, 1977 (42 FR 6992), finalizing the September 23, 1976 proposal:

The Commissioner concurs with the comment's statement that β-naphthylamine is considered to be a carcinogen. Two colors, Ext. D&C Yellow No. 9 and Ext. D&C Yellow No. 10, which were synthesized from β-naphthylamine, were prohibited by FDA from use in drugs and cosmetics because of a finding that they might contain β-naphthylamine. Accordingly, the Commissioner views with concern the possibility that any color additive for food, drug, or cosmetic use might contain the impurity.

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

However, upon further review of the data on each of the azo dyes, the Commissioner concludes that there are five colors that could possibly contain low levels of β-naphthylamine as impurities—D&C Red No. 10, D&C Red No. 11, D&C Red No. 12, D&C Red No. 13, and D&C Red No. 34. These colors are synthesized from 2-amino-1-naphthalenesulfonic acid, which may contain β-naphthylamine.

To resolve the questions raised by this comment, the Commissioner has requested that the petitioners promptly provide to FDA data about the possible contamination of 2-amino-1-naphthalenesulfonic acid and each of the five colors with β-naphthylamine.

Furthermore, in view of the concern that β-naphthylamine may be present in the color additives, FDA has initiated immediate action to investigate the possibility. It will promptly conduct analyses of samples of each of the five colors and 2-amino-1-naphthalenesulfonic acid using very sensitive methods. The Commissioner is continuing the provisional listing for D&C Red No. 10, D&C Red No. 11, D&C Red No. 12, and D&C Red No. 13 because the short period of time required to resolve this question will not present a hazard to the public health. If data become available, either from investigation by FDA or from the petitioners, that indicate that β-naphthylamine may be present in any of the color additives, the Commissioner will take immediate action to protect the public health.

As concerns the listing of D&C Red No. 34, the Commissioner concludes that it would be inappropriate, pending resolution of the questions concerning β-naphthylamine, to confirm the effectiveness of the order "permanently" listing D&C No. 34 for use in externally applied drugs and cosmetics.

Although the comment concerning β-naphthylamine was directed at the proposal concerning extension of the closing date for the provisional list, the Commissioner concludes that it also constitutes a valid objection to the listing order for D&C Red No. 34. This is appropriate in view of the criticism of azo

dyes, the timeliness of the objection, and because the comment raises genuine questions of fact. The filing of this objection automatically served to stay the effectiveness of the order of November 23, 1976 because the objection challenges its primary finding, i.e., that there are safe conditions of use for D&C Red No. 34.

An order was published in the FEDERAL REGISTER of February 4, 1977, (42 FR 6992), extending the closing dates for the provisionally listed color additives. The stay of effectiveness of the order listing D&C Red No. 34 results in its being retained on the provisional list under § 8.501 (21 CFR 8.501). The Commissioner is extending the closing date for provisional listing of D&C Red No. 34 until July 1, 1977, unless action is taken to terminate the provisional listing before then. The identity and specifications that were to be established in the new § 8.4128 have been incorporated into § 9.179 to provide specifications for the certification of the color. The Commissioner advises that the question concerning β-naphthylamine will be resolved by July 1, 1977 and concludes that the provisional listing of D&C Red No. 34 for this short period will not present a hazard to the public health. The Commissioner will take immediate action to protect the public health if the data indicate that D&C Red No. 34 might contain β-naphthylamine.

In accordance with 5 U.S.C. 553(d)(1) and (d)(3), the amendments set forth below are effective on March 4, 1977 to permit the uninterrupted use of the affected color additives.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 701(e), 706 (b), (c), and (d), 70 Stat. 919 as amended, 74 Stat. 399-403 (21 U.S.C. 371(e), 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), notice is given that the effective date of December 27, 1977 for the order amending Part 8 by adding new §§ 8.4128 and 8.7195 listing D&C Red No. 34 for use in externally applied drugs and cosmetics and by deleting D&C Red No. 34 from the list in § 8.501 and amending Part 9 by revising § 9.179 is stayed by the filing of timely and valid objections. Further, Parts 8 and 9 of Chapter I of Title 21 of the Code of Federal Regulations are amended as follows:

§ 8.501 [Amended]

1. Part 8 is amended in paragraph (b) of § 8.501 *Provisional lists of color additives*, by inserting alphabetically an entry for D&C Red No. 34 with a closing date of "July 1, 1977" and restriction of "External use only."

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

§ 9.179 D&C Red No. 34.

Calcium salt of 3-hydroxy-4-[(1-sulfo-2-naphthalenyl)azo]-2-naphthalenecarboxylic acid.

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

2-Amino-1-naphthalenesulfonic acid, calcium salt, not more than 0.2 percent.

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

Subsidiary colors, not more than 4 percent.

Total color not less than 85 percent.

Effective date: This regulation is effective March 4, 1977.

(Secs. 701(e), 706, 70 Stat. 919 as amended, 74 Stat. 399-403 (21 U.S.C. 371(e), 376 (b), (c), and (d)); Title II, Pub. L. 86-618, sec. 203, 74 Stat. 404-407 (21 U.S.C. 376 note).)

Dated: February 28, 1977.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Compliance.

[FR Doc.77-6485 Filed 3-3-77;8:45 am]

[Docket No. 76C-0468]

PART 8—COLOR ADDITIVES

Iron Oxides; Confirmation of Effective Date

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration confirms the effective date of January 3, 1977, of an order concerning use of iron oxides in cosmetics generally, including those intended for use in the area of the eye.

DATE: Effective date confirmed: January 3, 1977.

FOR FURTHER INFORMATION CONTACT:

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

SUPPLEMENTAL INFORMATION: An order was published in the FEDERAL REGISTER of November 30, 1976 (41 FR 52445) that added § 8.8009 (21 CFR 8.8009) to provide for safe use of iron oxides in cosmetics, generally, including those intended for use in the area of the eye. The order also amended § 8.501 (21 CFR 8.501) by deleting iron oxides from the provisionally listed colors in paragraph (g).

Two objections were filed in response to the order. (No person requested a formal evidentiary hearing). The objections received and the Commissioner's final action upon the objections are discussed below.

1. Both letters objected to the limitations placed on the level of lead in iron oxides and stated that it should be 20 parts per million (ppm) instead of 10 ppm. The objections stated that, historically, industry guidelines have allowed lead to be present at 20 ppm and that this level is consistent with existing regulations for other colors.

The Commissioner concludes that no basis has been presented for changing the limitation on the level of lead to 20 ppm. He would agree that 20 ppm would be an appropriate limit on the level of lead if the product were to be used only in externally applied cosmetics. The objectors, apparently, do not realize that the order permits the use of the color additive in cosmetics that may be ingested. The petition was amended, as cited in the filing notice, published in the FEDERAL REGISTER of March 5, 1976 (41 FR 9584), to request listing of the color additive for use in all ingested cosmetics. Accordingly, the order of November 30, 1976, in response to this petition, as amended, listed the color additive for use in cosmetics generally, which includes those cosmetics that might be subject to ingestion, and incorporated the limit for lead of 10 ppm that was proposed by the petitioner. The Commissioner points out that the limit of 10 ppm for lead in cosmetics that may be ingested is consistent with the limit prescribed for synthetic iron oxides under § 8.6001 (21 CFR 8.6001) for use in ingested or topically applied drugs.

2. One of the letters objected to the identity of the order under § 8.8009(a), which states that the color "is free from admixture with other substances." The objector stated that this phrase should be deleted since the color is normally supplied as a mixture with talc (5 to 75 percent) or other ingredients that are regulated by FDA as cosmetic ingredients.

The Commissioner disagrees with this objection, noting that the objector has apparently misunderstood the purpose of § 8.8009(a). This paragraph was used to describe specifically the identity of the particular color that is the subject of the regulation, i.e., iron oxides. It was not intended to identify those particular substances that might be used as diluents along with the color additive to prepare color additive mixtures, as would be suggested by the objector. Proposed regulations are being prepared concerning the use of diluents in color additive mixtures for cosmetic use and will include a request for public comment on the use of various diluents in color additive mixtures for coloring cosmetics.

The Commissioner concludes that neither of the objections presents sufficient cause for revising or staying the effective date of the provisions of the order listing iron oxides.

(Sec. 706 (b), (c), and (d), 74 Stat. 399-403 (21 U.S.C. 376 (b), (c), and (d)) and under authority delegated to the Commissioner (21 CFR 5.1).)

There being no other objections or any request for a hearing in response to the order of November 30, 1976, the amendments promulgated thereby became effective on January 3, 1977.

Dated: February 28, 1977.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Compliance.

[FR Doc.77-6494 Filed 3-3-77;8:45 am]