[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]

[Docket No. 76C-0441]

PART 8—COLOR ADDITIVES

PART 9—COLOR CERTIFICATION

D&C Brown No. 1; Confirmation of Effective Date

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration is confirming the effective date of December 27, 1976 of an order concerning the use of D&C Brown No. 1 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 51593) that amended Part 8 by adding § 8.7061 (21 CFR 8.7061) to provide for safe use of D&C Brown No. 1 in externally applied cosmetics and amended Part 9 by revoking § 9.230 (21 CFR 9.230). It also amended § 8.501 (21 CFR 8.501) by deleting D&C Brown No. 1 from the provisionally listed colors in paragraph (b).

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.77-6492 Filed 3-3-77;8:45 am]

[Docket No. 76C-0427]

PART 8—COLOR ADDITIVES

PART 9—COLOR CERTIFICATION

D&C Green No. 8; 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 Green No. 8 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, DC 20204, (202) 472-5740.

SUPPLEMENTARY INFORMATION: An order was published in the FEDERAL REGISTER of November 19, 1976 (41 FR 51006) that added §§ 8.4072 and 8.7102 (21 CFR 8.4072 and 8.7102) to provide for the safe use of D&C Green No. 8 in externally applied drugs and cosmetics and amended § 8.501 (21 CFR 8.501) by deleting D&C Green No. 8 from the provisionally listed colors in paragraph (b). The order also amended Part 9 by revoking § 9.106 (21 CFR 9.106).

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

1. Two letters were received objecting to the identity and specifications for D&C Green No. 8 in the order of November 19, 1976. The objectors stated that the proposal was in error in that § 8.4072 (a) and (b) were not descriptive or applicable for identity and specifications for D&C Green No. 8. One of the objectors requested a correction document for these items; the other objector recommended republication of a corrected proposal and extension of the comment period for the corrected proposal.

After evaluation, the Commissioner concurred that the cited identity and specifications were wrong. Accordingly, a correction was published in the FEDERAL REGISTER of December 21, 1976 (41 FR 55509) to provide the proper identity and specifications for D&C Green No. 8. The Commissioner regarded the request for republication of the proposal and additional time for comment as an invalid objection—a letter, dated December 17, 1976, from the primary manufacturer stated that the corrected regulation, with an exception, appeared to be adequate.

2. An objection received in response to the correction document requested amendment of the specifications under § 8.4072(b) to include the phrase "subsidiary colors other than those named, not more than 2.0 percent." An additional objection was raised by this letter, to the effect that no extension to the original December 20, 1976 effective date was included in the correction document to allow an additional comment period.

The Commissioner disagrees that it is necessary to include the phrase concerning subsidiary colors as a specification in the regulation. The specifications as stated in the correction are currently used for certification of batches of D&C Green No. 8, and certified batches of the color meet the specifications as corrected.

Further, the Commissioner is unaware of any data demonstrating the presence of subsidiary colors other than those identified within the specifications, and accordingly he cannot reasonably incorporate the recommended change. Therefore, the Commissioner concludes that the specifications for the color as stated in the correction are the appropriate specifications.

If the need for the requested addition to the specifications—"subsidiary colors other than those named, not more than 2.0 percent"—can be demonstrated, then a petition should be submitted containing data identifying the subsidiary colors and providing appropriate chemical and toxicological data.

The Commissioner concludes that further formal extension of the December 20, 1976 effective date to receive comments is not warranted. The Commissioner notes that although objectors have had adequate time—since the December 21, 1976 correction until publication of this order—to submit any additional comments, none have been submitted. The letter of December 17, 1976 supports the confirmation of effective date because it states that the corrected specifications appear to be in order. In view of the above information and because batches of D&C Green No. 8 presently submitted for certification comply with the stated specifications, the Commissioner concludes that there is no further need to extend the comment period.

(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 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.77-6493 Filed 3-3-77;8:45 am]

SUBCHAPTER C—DRUGS: GENERAL

[Docket No. 75N-0056]

PART 210—CURRENT GOOD MANUFACTURING PRACTICES IN MANUFACTURING, PROCESSING, PACKING, OR HOLDING OF DRUGS: GENERAL

PART 225—CURRENT GOOD MANUFACTURING PRACTICE FOR MEDICATED FEEDS

Medicated Feeds: Current Good Manufacturing Practice; Correction

In FR Doc. 76-34796 appearing on page 52612 in the FEDERAL REGISTER of Tuesday, November 30, 1976 (41 FR 52612), the Food and Drug Administration issued revised regulations regarding current good manufacturing practice in the production of medicated feeds. The last sentence of item 3 in the preamble stated that § 225.10(b)(2) was being deleted. The section as published inadvertently deleted § 225.10(b)(3)—paragraph (b)(3) was to have been redesignated as paragraph (b)(2). Therefore, § 225.10 is corrected by revising paragraph (b)(2) to read as follows:

§ 225.10 Personnel.

* * * * *

(b)(1) * * *

(2) The manufacturer shall provide an on-going program of evaluation and