The Commission has ordered the issuance of the complaint in the form contemplated by the agreement, made its jurisdictional findings and entered its order to cease and desist, as set forth in the proposed consent agreement, in disposition of this proceeding.

The prohibited trade practices and/or affirmative corrective actions, as codified under 16 CFR 13, are as follows:

Subpart—Coercing and Intimidating: § 13.358 Distributors. Subpart—Corrective Actions and/or Requirements: § 13.533 Corrective actions and/or requirements; 13.533–5 Arbitration; 13.533–20 Disclosures; 13.533–65 Renegotiation and/or amendment of contracts. Subpart—Cutting off Access to Customers or Market: § 13.535 Contracts restricting customers' handling of competing products; § 13.560 Interfering with distributive outlets. Subpart—Dealing on Exclusive and Tying Basis: § 13.670 Dealing on exclusive and tying basis; 13.670–20 Federal Trade Commission Act.

(Sec. 6, 38 Stat. 721; 15 U.S.C. 46. Interprets or applies sec. 5, 38 Stat. 719, as amended; 15 U.S.C. 45.)

CAROL M. THOMAS,
Secretary.

[FR Doc.77-34215 Filed 11-28-77;8:45 am]

[8010-01]

Title 17—Commodity and Securities Exchanges

CHAPTER II—SECURITIES AND EXCHANGE COMMISSION

[Release Nos. 34-14184, IC-10014; File No. S7-654]

PART 240—GENERAL RULES AND REGULATIONS, SECURITIES EXCHANGE ACT OF 1934

Securities Confirmations; Postponement of Effective Date

AGENCY: Securities and Exchange Commission.

ACTION: Rule amendment; postponement of effective date of rule.

SUMMARY: The Commission has postponed until April 1, 1978, the effective date of its rule prescribing delivery and disclosure requirements for confirmations sent to customers by brokers and dealers. The confirmation rule was adopted by the Commission on May 5, 1977, to become effective on January 1, 1978, with the exception of certain paragraphs which became effective on June 1, 1977. Because the Commission desires to coordinate implementation of the new rule with the possible adoption of amendments to that rule currently under consideration, it has postponed until April 1, 1978, the effective date of the rule. This postponement of the effective date has also required a technical amendment to the text of the rule.

EFFECTIVE DATE: November 17, 1977.

FOR FURTHER INFORMATION CONTACT:

Richard Chase, Office of Chief Counsel, Division of Market Regulation, Securities and Exchange Commission, Washington, D.C. 20549, 202–755–7621.

SUPPLEMENTARY INFORMATION: The Commission today announced the postponement of the effective date of Rule 10b–10 (17 CFR 240.10b–10) until April 1, 1978, with the exception of the several paragraphs of the rule which became effective on June 1, 1977. The Commission adopted Rule 10b–10 on May 5, 1977,[1] and, with the exception of those paragraphs which became effective on June 1, 1977, the rule was to become effective on January 1, 1978. The Commission also announced when it adopted Rule 10b–10 that it intended to propose amendments to Rule 10b–10, which it subsequently did on June 23, 1977.[2] The Commission currently is considering those proposed amendments, and the postponement of the January 1, 1978, effective date will permit the Commission additional time to consider those amendments and will allow both Rule 10b–10 and any of the amendments adopted to become effective at one time. A single effective date for the rule as adopted and any amendments adopted in the near future will minimize any burden on brokers and dealers who must revise printed confirmation forms, computer programs, and internal procedures in order to comply with the new confirmation requirements. Rule 15c1–4 (17 CFR 240.15c1–4), which currently prescribes confirmation delivery and disclosure requirements, will remain in effect until April 1, 1978.

AMENDMENTS TO RULE 10b–10

This change in the effective date also requires a technical amendment to Rule 10b–10, to reflect the fact that Rule 15c1–4 will remain effective until April 1, 1978. Paragraph (b) of Rule 10b–10 currently provides that brokers and dealers effecting transactions pursuant to qualified "periodic" plans may send to customers quarterly statements in lieu of the "written notification" described in paragraph (a) of Rule 15c1–4 (until January 1, 1978) and paragraph (a) of Rule 10b–10 (after that date). When Rule 10b–10 was originally adopted, it was anticipated that Rule 15c1–4 could be rescinded on January 1, 1978. By postponing the effective date of Rule 10b–10 until April 1, 1978, it has become necessary to amend the January 1, 1978, date that appears in paragraph (b) of the rule. This amendment is only technical in nature and imposes no new requirements upon brokers and dealers.

For the reasons stated above and pursuant to the Administrative Procedure Act (5 U.S.C. 551 et seq.), the Commission finds for good cause that notice and public procedure on this amendment to Rule 10b–10 is both impracticable and unnecessary and that this technical amendment to the rule should become effective immediately. The Commission also finds that adoption of this amendment to Rule 10b–10 does not impose any burdens on competition that are not necessary or appropriate in furtherance of the purposes of the Act.

STATUTORY BASIS

The Securities and Exchange Commission, acting pursuant to the Act, and particularly sections 3, 9, 10, 11, 15, 17 and 23 thereof (15 U.S.C. 78c, 78i, 78j, 78k, 78o, 78q, and 78w) hereby postpones until April 1, 1978, the effective date of paragraph (a) of section 240.10b–10 of the Code of Federal Regulations and amends paragraph (b) of Section 240.10b–10 of Title 17 of the Code of Federal Regulations to reflect that delay in the effective date.

17 CFR Part 240.10b–10(e) is amended to read as follows:

§ 240.10b–10 Confirmations of transactions.

* * * * *

(b) A broker or dealer may effect transactions for or with the account of a customer without giving or sending to such customer the written notification described in paragraph (a) of this section (until April 1, 1978, § 240.15c1–4(a)) if * * *

* * * * *

By the Commission.

GEORGE A. FITZSIMMONS,
Secretary.

NOVEMBER 17, 1977.

[FR Doc.77-34226 Filed 11-28-77;8:45 am]

---

[1] *See* Securities Exchange Act Release No. 13508 (May 5, 1977), 41 FR 25318 (May 17, 1977).

[2] *See* Securities Exchange Act Release No. 13661 (June 23, 1977), 42 FR 33348 (June 30, 1977).

[4110-03]

Title 21—Food and Drugs

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

SUBCHAPTER A—GENERAL

[Docket No. 77c-0362]

PART 81—GENERAL SPECIFICATIONS AND GENERAL RESTRICTIONS FOR PROVISIONAL COLOR ADDITIVES FOR USE IN FOODS, DRUGS, AND COSMETICS

Provisional Listing of Graphite; Termination of Closing Date

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: This document terminates the closing date for the provisional listing, and hence the approval, of the color additive graphite for use in externally applied cosmetics, including those intended for use in the area of the eye. The closing date is being terminated because graphite contains polynuclear aromatics, some of which are known to be carcinogens. Graphite may not be added to externally applied cosmetics, including those used in the area of the eye, after November 29, 1977.

DATE: Effective November 29, 1977.

FOR FURTHER INFORMATION CONTACT:

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

SUPPLEMENTARY INFORMATION: The Color Additive Amendments of 1960 provide that a color additive may be approved only if data establish that it is safe under its permitted conditions of use. Section 203(b) of 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)) provides, however, for the provisional listing of color additives in use in 1960 on an interim basis pending completion of scientific investigations needed for determinations about "permanent listing" in accordance with section 706 of the Federal Food, Drug, and Cosmetic Act (sec. 706, 74 Stat. 399-403 (21 U.S.C. 376)). Section 81.1 (21 CFR 81.1) of the color additive regulations designates those color additives that are provisionally listed.

The color additive graphite has been in use for many years in externally applied cosmetics. Graphite had been provisionally listed for use in externally applied cosmetics on January 11, 1963 (28 FR 317). Graphite is currently provisionally listed for use in externally applied cosmetics, with a closing date of October 31, 1977. The establishment of October 31, 1977 as the closing date for this color originated with a proposal published in the FEDERAL REGISTER of September 23, 1976 (41 FR 41860). The final regulations in response to that proposal were issued in the FEDERAL REGISTER of February 4, 1977 (42 FR 6992).

In response to a comment regarding the proposal to extend the provisional list published in the FEDERAL REGISTER of September 23, 1976 (41 FR 41860), the Commissioner indicated that the main question about the use of graphite in cosmetics is whether extractable polynuclear aromatic hydrocarbons (PNA's) are contained in the color additive. The need for additional data to resolve this question was also discussed in the preamble to the final regulation, published in the FEDERAL REGISTER of February 4, 1977 (42 FR 6996).

The PNA's comprise a large family of chemicals where two to seven benzene rings have fused in an angular arrangement to form the PNA molecule. The particular PNA's that have raised the greatest concern are those containing three to six benzene rings in their molecular structure. A number of literature references indicate that certain types of graphite may contain PNA's. Accordingly, the petitioner was requested to supply data to demonstrate whether graphite contains PNA's. At the time of the February 4, 1977 regulation the petitioner had submitted an analysis of one batch of graphite which showed that no PNA's were present to a claimed sensitivity of 2 parts per billion (ppb). These data, however, were determined to be inadequate because there were serious deficiencies in the analytical method, and the results of the analysis were from only one sample of graphite. Because there were no conclusive data at that time that indicated whether graphite contained PNA's, the Commissioner concluded that its provisional listing could safely continue for the short time necessary to develop and submit the additional data.

Since that time the petitioner has submitted data from the analysis of six additional batches of graphite mined from two different countries. All these batches of graphite were shown to contain PNA's of various types and in variable amounts. All samples contained pyrene in amounts ranging from 15 to 90 ppb and fluoranthene in the range of 3 to 85 ppb. Benzo(a)pyrene (BaP) and benzo(b)fluoranthene (BbF), which are known carcinogens (ACS Monograph No. 173 Chemical Carcinogens), have been found at the level of 3 ppb for BaP and 9 to 11 ppb for BbF in samples of graphite that were mined in Korea. Chrysene, which may be a carcinogen, has been found at the level of 12 to 32 ppb in the Korean samples. In addition, all the analyses were characterized by the presence of unidentified components. These reports are on public display in the office of the Hearing Clerk (HFC-20), Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, Md. 20857.

Although some of the samples contained only PNA's that have not been shown to be carcinogens, such as pyrene and fluoranthene, the presence of these PNA's in all samples analyzed, coupled with the presence of unidentified components in these extracts of the graphite samples, portends the presence of carcinogenic PNA's. The Commissioner concludes, therefore, that the data submitted by the petitioner are inadequate to support safe conditions of use for graphite in coloring drugs and cosmetics.

Pursuant to the regulation published in the FEDERAL REGISTER of February 4, 1977, the petitioner agreed to the requirement of developing adequate analytical procedures for the demonstration of the presence or absence of PNA's and to submit data from the analysis of several batches of graphite from various sources to FDA by the deadline of August 3, 1977. The continued provisional listing of the color was dependent upon the satisfactory completion of these requirements.

Under the transitional provision of the Amendments (section 203(d)(1)(E)), the Commissioner may "provide for the termination of a provisional listing (or deemed provisional listing) of a color additive or particular use thereof forthwith whenever in his judgment such action is necessary to protect the public health." On the basis of the available data, the Commissioner concludes that the color additive graphite may be expected to contain PNA's, some of which are known carcinogens. The possible presence of PNA's raises serious questions about the safety of the color additive under intended conditions of use. The data presented by the petitioner generally confirm the presence of PNA's in the graphite samples; but the data are not adequate to demonstrate unequivocally the absence of PNA's known to be carcinogenic. Accordingly, under section 203(d)(1)(E) of the Amendments, the Commissioner concludes that the provisional listing of graphite for use in externally applied cosmetics should be terminated because such action is necessary to protect the public health.

Graphite is the subject of a petition (CAP 8C0080) submitted by the Toilet Goods Association, Inc. (now the Cosmetic, Toiletry, and Fragrance Association, 1133 15th Street NW., Washington, D.C. 20005). This petition for the permanent listing of graphite for use in coloring externally applied cosmetics, including those intended for use in the area of the eye, was filed by a notice published in the FEDERAL REGISTER of August 6, 1973 (38 FR 21200), under the provisions of section 706 of the Federal Food, Drug, and Cosmetic Act. A subsequent notice published in the FEDERAL REGISTER of June 17, 1977 (42 FR 30893) amended the filing of this petition to include the additional use of the color additive in externally applied drugs, including those intended for use in the area of the eye. The Commissioner finds that the possible presence of extractable PNA's precludes him from approving the petition requesting the "permanent" listing of graphite (CAP 8C0080). Published elsewhere in this issue of the FEDERAL REGISTER is a notice denying the petition to list the color additive for use in externally applied drugs and cosmetics, including drugs and cosmetics intended for use in the area of the eye.

The Commissioner concludes that the protection of the public health does not require the recall from the market of cosmetics containing the color additive, or the destruction of cosmetics in preparation to which the color additive has already been added.

The Commissioner is aware that supplies of alternative cosmetic labeling may be difficult to obtain immediately. Consequently, cosmetic labeling listing graphite among the ingredients may continue to be used with the uncolored product or products containing an alternative color during the time necessary to obtain supplies of revised labeling or until November 29, 1978, whichever occurs first.

The Commissioner has carefully considered the environmental effects of this action, and because the action will not significantly affect the quality of the human environment, has concluded that an environmental impact statement is not required. A copy of the FDA environmental assessment, together with copies of the other documents mentioned above, are on file with the Hearing Clerk (HFC-20), Food and Drug Administration,

Room 4–65, 5600 Fishers Lane, Rockville, Md. 20857.

Therefore, 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), Part 81 is amended as follows:

§ 81.1 [Amended]

1. In § 81.1 *Provisional lists of color additives,* in paragraph (g), by deleting the table entry for Graphite.

2. In § 81.10 by adding new paragraph (j), to read as follows:

§ 81.10 Termination of provisional listing of color additives.

* * * * *

(j) *Graphite.* Data have been developed that show the contamination of graphite with polynuclear aromatic hydrocarbons (PNA's). There is no reasonable assurance this color can be produced so that it will not contain PNA's as an impurity. The presence of certain PNA's in graphite would indicate that PNA's known to be carcinogenic to animals and humans may also be present. Therefore, there is no scientific evidence that will support a safe tolerance for this color in drugs or cosmetics. The Commissioner of Food and Drugs, in order to protect the public health, hereby terminates the provisional listing of graphite for use in externally applied cosmetics, effective November 29, 1977.

* * * * *

Effective date: November 29, 1977.

(Sec. 203, 74 Stat. 404–407 (21 U.S.C. 376 note).)

Dated: November 23, 1977.

JOSEPH P. HILE,
Associate Commissioner for Compliance.

[FR Doc.77–34253 Filed 11–28–77;8:45 am]

[4110–03]

[Docket No. 77C–0365]

PART 81—GENERAL SPECIFICATIONS AND GENERAL RESTRICTIONS FOR PROVISIONAL COLOR ADDITIVES FOR USE IN FOODS, DRUGS, AND COSMETICS

PART 82—LISTING OF CERTIFIED PROVISIONALLY LISTED COLORS AND SPECIFICATIONS

Provisional Listing of Ext. D&C Green No. 1; Termination of Closing Date

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: This document terminates the closing date for the provisional listing, and hence the approval, of the color additive Ext. D&C Green No. 1 for use in externally applied drugs and cosmetics. All color additive certificates for the color are being cancelled. The closing date is being terminated because of the absence of methodology necessary for the certification of the color. Ext. D&C Green No. 1 may not be added to externally applied drugs and cosmetics after November 29, 1977.

EFFECTIVE DATE: November 29, 1977.

FOR FURTHER INFORMATION CONTACT:

Gerad L. 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: The Color Additive Amendments of 1960 provide that a color additive may be approved only if data established that it is safe under its permitted conditions of use. Section 203(b) of 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)) provides, however, for provisional listing of color additives in use in 1960 on an interim basis pending completion of scientific investigations needed for determinations about "permanent listing" in accordance with section 706 of the Federal Food, Drug, and Cosmetic Act (sec. 706, 74 Stat. 399–403 (21 U.S.C. 376)). Section 81.1 (21 CFR 81.1) of the color additive regulations designates those color additives that are provisionally listed.

The color additive Ext. D&C Green No. 1 has been in use for many years. Ext. D&C Green No. 1 was approved for externally applied drug and cosmetic use as a permitted "coal-tar" color after enactment of the Federal Food, Drug, and Cosmetic Act in 1938 by order published in the FEDERAL REGISTER of May 9, 1939 (4 FR 1922). Ext. D&C Green No. 1 was provisionally listed for use in externally applied drugs and cosmetics on July 12, 1960, and appeared officially on the provisional list published in the FEDERAL REGISTER of October 12, 1960 (25 FR 9759). Ext. D&C Green No. 1 is currently provisionally listed for use in externally applied drugs and cosmetics, with a closing date of October 31, 1977. The establishment of October 31, 1977 as the closing date for this color originated with a proposal published in the FEDERAL REGISTER of September 23, 1976 (41 FR 41860). The final regulations in response to that proposal were issued in the FEDERAL REGISTER of February 4, 1977 (42 FR 6992). The color additive regulation published in the FEDERAL REGISTER of February 4, 1977 extended the closing date for Ext. D&C Green No. 1 until October 31, 1977 to provide time for the submission of required chemistry data to support the "permanent" listing of the color.

Ext. D&C Green No. 1 is the subject of a petition (CAP 7C0055) submitted by the Cosmetic, Toiletry, and Fragrance Association, Inc., 1133 15th St. NW., Washington, D.C. 20005. The petition was filed by notice in the FEDERAL REGISTER of August 6, 1973 (38 FR 21199), under the provisions of section 706 of the act, as amended by the Color Additive Amendments of 1960. The petition for Ext. D&C Green No. 1 seeks listing for use in externally applied drug and cosmetic products.

Ext. D&C Green No. 1 is a color additive that has been subject to the requirements of batch certification as provided by section 706(c) of the act. The Commissioner has concluded that batch certification of the color would continue to be necessary if the color were to be listed. The conditions for the continued provisional listing of the color were defined in the FEDERAL REGISTER regulation of February 4, 1977 under § 81.27(c) (21 CFR 81.27(c)). Adequate analytical methods were required for the development of specifications for batch certification and the definition of purity of the color used for toxicological testing. These data and analytical methods were to be submitted to FDA by August 3, 1977.

The petitioner agreed under the requirements of § 81.27(c)(2) (21 CFR 81.27(c)(2) to provide that information necessary for the certification and the "permanent" listing for Ext. D&C Green No. 1. In response to the regulation the petitioner submitted data for a regulatory analytical method and analytical procedures for the identification of subsidiary colors.

The agency reviewed these submissions and found that the data were not adequate to resolve the chemistry deficiencies for the color. The petitioner was notified by letter on June 30, 1977 that the deficiencies in the chemistry data required submission of additional data to support the "permanent" listing. Additional information necessary to resolve the deficiencies in the chemistry data was not submitted prior to the expiration of the deadline date of August 3, 1977 as required under § 81.27(c)(2).

The purpose of the transitional provisions of the Color Additive Amendments of 1960, (section 203) as noted above, "is to make possible, on an interim basis for a reasonable period, through provisional listings, the use of commercially established color additives to the extent consistent with the public health, pending the completion of the scientific investigations needed as a basis for making determinations as to listing of such additives." This provisional listing of previously marketed color additives was to expire on the date, also referred to as the closing date, 2½ years after the effective date of the Amendments.

Section 203 of the Amendments further provided, however, that the closing date for the provisional listing could be postponed to a later date as considered "necessary to carry out the purpose of this section, if in the Secretary's judgment such action is consistent with the objective of carrying to completion in good faith, as soon as reasonably practicable, the scientific investigations necessary for making a determination as to listing such additive, or such specified use or uses thereof, under section 706 of the basic Act."

Under the transitional provision of the Amendments (section 203(a)(2)), the Commissioner may "terminate the postponement of the closing date at any time if he finds that such postponement should not have been granted, or that by reason of change in circumstances the basis for such postponement no longer exists, or that there has been a failure to comply with a requirement for submission of progress reports or with other conditions attached to such postponement."

The Commissioner finds that there has been a failure to comply with the conditions attached to the postponement of the closing date and hereby terminates the postponement of the closing date for the provisional listing of Ext. D&C Green No. 1 for use in externally applied drugs and cosmetics in accordance with section 203(a)(2) of the transitional provisions of the Color Additive Amendments of 1960. It is not possible to certify batches of the color without adequate analytical methods and data. Because the petitioner has not complied with the requirements of § 81.27(c)(2) (21 CFR 81.27(c)(2)) and in the absence of the required data that are considered to be necessary for certification of the color, the Commissioner concludes that the provisional listing of Ext. D&C Green No. 1 shall be terminated on November 29, 1977. Published elsewhere in this issue of the FEDERAL REGISTER is a notice denying the petition to list the color additive for use in externally applied drugs and cosmetics.

All certificates heretofore issued for batches of Ext. D&C Green No. 1 are revoked and the addition of the color to externally applied drugs or cosmetics after November 29, 1977 will cause such product to be adulterated within the meaning of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) and subject to regulatory action. This prohibition applies to the use of the straight color, its lakes, and mixtures of Ext. D&C Green No. 1 or its lake. The Commissioner concludes that the protection of the public health does not require the recall from the market of drugs and cosmetics containing the color additive, or the destruction of drugs or cosmetics in preparation to which the color additive has already been added.

Manufacturers of new drugs and new animal drugs (including certifiable antibiotics for animal use) that contain Ext. D&C Green No. 1 may either delete the color additive or substitute a different color in accordance with the provisions of § 314.8 (d)(3) and (e) or § 514.8 (d)(3) and (e) (21 CFR 314.8 (d)(3) and (e) or 21 CFR 514.8 (d)(3) and (e)) as appropriate. The applicant shall submit data providing the new composition and showing that the change in composition does not interfere with any assay or other control procedures used in manufacturing the drug, or that the assay and control procedures used in manufacturing the drug have been revised to make them adequate. The applicant shall also submit data available to establish the stability of the revised formulation or, if the data are too limited to support a conclusion that the drug will retain its declared potency for a reasonable marketing period, a commitment to test the stability of marketed batches at reasonable intervals, to submit the data as they become available, and to recall from the market any batch found to fall outside the approved specifications for the drug.

Each sponsor of a notice of claimed investigational exemption for a new drug (IND) or a notice of claimed investigational exemption for a new animal drug (INAD) containing the subject color should promptly amend the IND or INAD to indicate that the color additive has been deleted or a different color additive substituted.

The Commissioner is aware that supplies of alternative color additives may be difficult to obtain immediately. Consequently, drug and cosmetic labeling that states that the product contains "artificial color," or that specifically identifies Ext. D&C Green No. 1, may continue to be used with the uncolored product or products containing alternative colors during the time necessary to obtain supplies of revised labeling or until November 29, 1978, whichever occurs first.

The Commissioner has carefully considered the environmental effects of this action, and because the action will not significantly affect the quality of the human environment, has concluded that an environmental impact statement is not required. A copy of the FDA environmental assessment, together with copies of the other documents mentioned above, are on file with the Hearing Clerk (HFC-20), Food and Drug Administration, room 4-65, 5600 Fishers Lane, Rockville, Md. 20857.

Therefore, 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), Parts 81 and 82 are amended as follows:

1. Part 81 is amended:

§ 81.1 [Amended]

a. In § 81.1 *Provisional lists of color additives*, in paragraph (c), by deleting the table entry for Ext. D&C Green No. 1.

b. In § 81.10 by adding new paragraph (k), to read as follows:

§ 81.10 Termination of provisional listing of color additives.

* * * * *

(k) *Ext. D&C Green No. 1.* The Commissioner concludes that there are inadequate analytical methods to permit certification of the color additive Ext. D&C Green No. 1. In addition, the Commissioner has found that there was a failure to comply with the conditions attached to the postponement of the closing date in accordance with section 203(a)(2) of the transitional provisions of the Color Additive Amendments of 1960. The Commissioner of Food and Drugs hereby terminates the provisional listing of Ext. D&C Green No. 1 for use in externally applied drugs and cosmetics, effective November 29, 1977.

c. In § 81.30 paragraphs (k) and (l) are reserved and new paragraph (m) is added to read as follows:

§ 81.30 Cancellation of certificates.

* * * * *

(k)-(l) [Reserved]

(m) (1) Certificates issued for Ext. D&C Green No. 1 and all mixtures containing this color additive are cancelled and have no effect after November 29, 1977, and use of the color additive in the manufacture of drugs or cosmetics after this date will result in adulteration.

(2) The Commissioner finds, on the basis of the scientific evidence before him, that no action has to be taken to remove from the market drugs and cosmetics containing the color additive.

§ 82.2201 [Revoked]

2. Part 82 is amended by revoking § 82.2201 *Ext. D&C Green No. 1.*

Notice and public procedure are not necessary prerequisites to the promulgation of this order because section 203 (d)(2) of Pub. L. 86-618 so provides.

Effective date: November 29, 1977.

(Sec. 203, 74 Stat. 404-407 (21 U.S.C. 376 note).)

Dated: November 21, 1977.

JOSEPH P. HILE,
Associate Commissioner for Compliance.

[FR Doc.77-34038 Filed 11-28-77;8:45 am]

[4110-03]

SUBCHAPTER D—DRUGS FOR HUMAN USE

[Docket No. 75N-0249]

PART 314—NEW DRUG APPLICATIONS

Procedures for Filing Over Protest

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: This amendment revises the agency's regulation governing the procedure for filing a new drug application (NDA) over protest. It extends from 60 to 90 days the time within which FDA must respond to a request to file over protest, and it specifies that such requests should be submitted to the Assistant Director for Regulatory Affairs, Bureau of Drugs.

EFFECTIVE DATE: December 29, 1977.

ADDRESS: Requests for a new drug application (NDA) or abbreviated new drug application (ANDA) to be filed over protest should be sent to the Assistant Director for Regulatory Affairs (HFD-30), Bureau of Drugs, Food and Drug Administration, 5600 Fishers Lane, Rockville, Md. 20857.

FOR FURTHER INFORMATION CONTACT:

Jean Mansur, Bureau of Drugs (HFD-30), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, Md. 20857, 301-443-3640.