is issued, and notice to the Board is not required in that event.

(Sec. 204, 416, Federal Aviation Act of 1958, as amended, 72 Stat. 743, 771, 49 U.S.C. 1324, 1386.)

By the Civil Aeronautics Board: [2]

PHYLLIS T. KAYLOR,
Secretary.

[FR Doc.77-34211 Filed 11-28-77;8:45 am]

[6320-01]

SUBCHAPTER E—ORGANIZATION REGULATIONS

[Reg. OR-123, Amdt. 65]

PART 385—DELEGATIONS AND REVIEW OF ACTION UNDER DELEGATION: NONHEARING MATTERS

Expansion of Delegated Authority to the Director, Bureau of Operating Rights, the Chief, Passenger and Cargo Rates Division, of the Bureau of Fares and Rates, and the Chief, Legal Division, of the Bureau of Fares and Rates

AGENCY: Civil Aeronautics Board.

ACTION: Final rule.

SUMMARY: These rules expand the authority delegated by the Board to the Director. Bureau of Operating Rights (BOR), to the Chief, Passenger and Cargo Rates Division, Bureau of Fares and Rates (BFR), and to the Chief, Legal Division, BFR. The Director of BOR is granted authority to act, when no person disclosing a substantial interest objects, on applications for exemptions by direct air carriers from the requirement that they obtain a certificate of public convenience and necessity, and from applicable parts of Board regulations. Authority is also given the Director of BOR to act on applications by foreign air carriers for on-route charter authority, and requests by foreign air carriers for waivers of conditions placed in their permits. The Chief of the Passenger and Cargo Rates Division is delegated authority to act on applications from carriers for exemptions from the requirement that they file tariffs and from applicable Board regulations, when those applications are consistent with Board policy. The Chief of the Legal Division of BFR is given authority to approve variations of the texts of overbooking disclosure notices, which are displayed at airline ticket counters and distributed with tickets. The delegations are at the initiative of the Board, and will expedite decision on these matters and relieve unnecessary administrative burdens. The Board is also correcting the designation of two paragraphs recently added to the delegated authority of the Director, BOR.

DATES: Effective: November 22, 1977. Adopted: November 22, 1977.

FOR FURTHER INFORMATION CONTACT:

Stephen L. Babcock, Office of the General Counsel, Civil Aeronautics Board, 1825 Connecticut Avenue NW., Wash-

[2] CAB Forms 257 and 262 were filed as a part of the original document.

SUPPLEMENTARY INFORMATION:

DELEGATION TO DIRECTOR, BUREAU OF OPERATING RIGHTS

The Board has, at present, delegated to the Director, Bureau of Operating Rights, under section 385.13 of the Organization Regulations (14 CFR § 385.13), authority to approve or deny certain applications for exemptions from provisions of the Act and the Board's regulations. Many uncontested exemption applications, filed pursuant to section 416 (b) of the Act, involve no controversial issues, and could similarly be handled by the staff. For example, air carriers may apply for renewal of exemptions previously ganted, in situations in which circumstances have not materially changed. Also, commuter air carriers may apply for authority to use aircraft which do not meet the size or capacity limitations specified in Part 298 of the Economic Regulations (14 CFR Part 298), at points, or in markets, where no competitive certificated service is provided. As another example, route carriers may apply to temporarily use, as a substitute, airports at or near certificated points, due to airport construction or other circumstances beyond their control.

In instances in which the course of action is clear under current Board policies, we have decided to expand the delegated authority of the Director of BOR by adding a new paragraph (b) to section 385.13 of the Organization Regulations (14 CFR § 385.13). The new paragraph will allow the Director to act, when no person disclosing a substantial interest objects, on applications by direct air carriers for exemptions from section 401 of the Act and the applicable sections of the Board's regulations.

Under section 212.4(b) of the Economic Regulations (14 CFR § 212.4(b)), the Board may require prior approval of the on-route charters of foreign air carriers if it finds that action is necessary in the public interest. As a general rule, the Board order placing the foreign air carrier's charter operations under prior approval sets forth the conditions which will govern disposition of any application filed under the order. Action on such an application is usually not controversial, therefore, and can be taken by the Board staff without our direct consideration. In addition, while requests for on-route charter authority are required to be filed at least 30 days in advance of the flight, the carriers frequently do not, or cannot, comply with this requirement, causing considerable last-minute difficulties in preparing the matter for Board action. We are therefore amending section 385.13(i) of our regulations (14 CFR § 385.13(i)) to authorize staff action on these requests, and on waivers of the time limit for the filing of these requests. In a case where the staff recommends denial of the request (which must be submitted to the President), or where Board consideration is necessary, the request will continue to be forwarded to us for action.

On occasion, the Board also receives from foreign air carriers requests for ad hoc waivers of restrictions imposed by their foreign air carrier permits. As with requests for on-route charter authority, the applications are generally filed on short notice, and are noncontroversial. The Board's rationale in imposing the permit restriction is clearly set forth at the time the permit is issued, and is sufficient for the staff to determine what action should be taken. For this reason, we are adding a new section to the delegation of authority given the Director, Bureau of Operating Rights, to allow staff action on these waiver requests when no person with a substantial interest objects, and where there is a provision in the foreign air carrier's permit which authorizes them.[1]

The Board is also taking this opportunity to make a technical change in section 385.13(jj) of the Organization Regulations (14 CFR § 385.13(jj)). By OR-115, adopted April 12, 1977 (42 FR 20120), the Board delegated authority to the Director, Bureau of Operating Rights, in coordination with the Chief, Tariffs Section, to grant or deny applications for exemption from section 403 of the Act to the extent necessary to allow performance of operations authorized by exemption under § 385.13(a)(2) of the regulations. Since a similar exemption of section 403 of the Act is needed for operations conducted under subparagraph (a)(1) and new paragraph (b) of § 385.13, we are revising paragraph (jj) to reflect this fact.

DELEGATION TO THE CHIEF, PASSENGER AND CARGO RATES DIVISION, BUREAU OF FARES AND RATES

With limited exceptions,[2] the Board's regulations now contain no specific delegation of authority for the approval of exemption applications filed by air carriers seeking permission to deviate from section 403 of the Act, the carrier's tariff, or applicable Board regulations. Examples of such exemptions recently granted by the Board include authorizations of reduced-rate transportation to transport stranded charter passengers on scheduled service at charter rates, free transportation of persons other than travel agents to travel agent training

[1] The Board is taking this opportunity to correct a clerical error in two previous amendments. In Regulation OR-121, Amendment No. 63 to Part 385, 42 FR 53599, October 3, 1977, the new paragraph added to section 385.13 should have been designated (kk) instead of (jj). In Regulation OR-122, Amendment No. 64 to Part 385, 42 FR 54798, October 11, 1977, the new paragraph added to section 385.13 should have been designated (ll) instead of (kk).

[2] The exceptions are contained in § 385.13 (jj), discussed earlier in this preamble, and in sections 385.14(e), 385.14(h) and 385.15 (j). Section 385.15(h) also delegates authority to the Chief, Tariffs Section. Passenger and Cargo Rates Division, Bureau of Fares and Rates, to act upon applications filed under § 223.8 of the regulations and section 403(b) of the Act for permission to furnish free or reduced-rate overseas or foreign air transportation; however, no comparable delegated authority exists for interstate air transportation.

programs, free transportation for Congressional Medal of Honor Society members to their convention, and an exemption from tariffs to permit more than one dog in a plane cabin for transportation to a Bermuda dog show. The processing of applications such as these, which raise no significant policy questions, nevertheless requires a substantial amount of time on the part of the Board and the staff under present procedures. We believe that, in cases where the requested exemptions fall within past Board policy and precedent, more efficient use of our limited resources will be made if authority to act upon the applications is delegated to the Chief, Passenger and Cargo Rates Division of the Bureau of Fares and Rates. Furthermore, in order to facilitate action by the staff on such applications we are providing that the grant or denial of the application may be made in a variety of forms, including a stamp or notation on the application, by letter or by order.

DELEGATION TO CHIEF, LEGAL DIVISION, BUREAU OF FARES AND RATES

Earlier this year the Board adopted a rule which requires carriers to display at their ticket counters, and distribute with tickets, a notice describing the industry practice of deliberately overbooking airline flights.[3] The text of the notice was prescribed in the rule but a provision was made for allowing a carrier to substitute, after Board approval, a notice in its own wording. One carrier has since requested, and the Board has granted, permission to substitute its own notice of overbooking. Action by Board members on such requests, which do not raise significant policy considerations, increases the time required for disposition of these matters, since the staff must prepare memoranda for the Board dealing with each request. The Board is therefore delegating authority to the Chief, Legal Division, Bureau of Fares and Rates, to act upon such applications. This delegation is parallel to an existing delegation of authority [4] to the same staff element to pass upon variations in the text of Warsaw Convention liability notices, upon which the rule for overbooking notices was largely modeled.

Since these amendments are of an administrative nature, affecting rules of agency organization and procedure, the Board finds that notice and public procedure are unnecessary, and that the rules may become effective immediately.

Accordingly, the Board amends Part 385 of its Organization Regulations (14 CFR Part 385) as follows:

1. Section 385.13 is amended by adding a new paragraph (b), presently reserved, revising paragraph (i), correcting the designation of the second paragraph (jj) to (kk) and paragraph (kk) to (ll), revising paragraph (jj), and by adding a new paragraph (mm), to read as follows:

§ 385.13 Delegation to the Director, Bureau of Operating Rights.

* * * * *

(b) Approve, when no person disclosing a substantial interest objects, or deny applications of direct air carriers for exemptions from section 401 of the Act, and from applicable regulations under this chapter. This authority may not be redelegated.

* * * * *

(i) When filed in accordance with Part 212 of this chapter, approve or deny applications for authorization to conduct off-route charter trips, and approve requests for on-route charter flights for which prior approval is required under an order of the Board, including waivers of the time limitation for advance filing of such requests prescribed in the order.

* * * * *

(jj) Approve or deny, with the concurrence of the Chief, Tariffs Section, applications for exemption from section 403 of the Act to the extent necessary to permit performance of air carrier operations otherwise authorized by exemption granted under subparagraphs (a)(1) and (a)(2), and paragraph (b) of this section. This authority may not be redelegated.

(kk) Dismiss applications filed * * *

(ll) With respect to interaffiliate * * *

(mm) Approve or deny applications of foreign air carriers or waivers of permit limitations or restrictions, in accordance with permit provisions authorizing such waivers, when no person disclosing a substantial interest objects. This authority may not be redelegated.

2. Section 385.14 is amended by adding a new paragraph (b), presently reserved, to read as follows:

§ 385.14 Delegation to the Chief, Passenger and Cargo Rates Division, Bureau of Fares and Rates.

* * * * *

(b) Approve or disapprove air carrier applications filed under section 416(b) of the Act for exemption from section 403 of the Act, air carrier tariffs, and applicable Board regulations, in cases where the disposition of the application is governed by established Board policy and precedent. Such approval or disapproval may be taken by order, by letter, or by stamp or notation on a copy of the application.

* * * * *

3. Section 385.16a is revised to read as follows:

§ 385.16a Delegation to the Chief, Legal Division, Bureau of Fares and Rates.

The Board hereby delegates to the Chief, Legal Division, Bureau of Fares and Rates, the authority to:

(a) grant or deny applications for relief under paragraphs (e) and (f) of § 221.176 of this chapter.

(b) grant or deny applications for relief under paragraph (d) of § 221.177 of this chapter.

(Section 204 (a) of the Federal Aviation Act of 1958, as amended, 72 Stat. 743, 49 U.S.C. 1324; Reorganization Plan No. 3 of 1961, 75 Stat. 837, 26 FR 5989, 49 U.S.C. 1324 (note).)

By the Civil Aeronautics Board.

PHYLLIS T. KAYLOR,
Secretary.

[FR Doc.77-34210 Filed 11-28-77;8:45 am]

[3] See 14 (CFR § 221.177, adopted by Regulation ER-987, February 28, 1977, 42 FR (12420) March 4, 1977.

[4] 14 CFR § 385.16a.

[6750-01]

Title 16—Commercial Practices

CHAPTER I—FEDERAL TRADE COMMISSION

[Docket No. 8910]

PART 13—PROHIBITED TRADE PRACTICES, AND AFFIRMATIVE CORRECTIVE ACTIONS

Standard Oil Co. (Ohio)

AGENCY: Federal Trade Commission.

ACTION: Order to cease and desist.

SUMMARY: In settlement of alleged violations of federal law prohibiting unfair acts and practices and unfair methods of competition, this consent order, among other things, requires a Cleveland, Ohio manufacturer of petroleum and automotive products, to cease prohibiting its dealers from obtaining nongasoline products from independent sources or requiring them to deal exclusively with Sohio for automotive accessories. The order requires the firm to offer its lessee dealers new agreements which comply with the terms of the order, or to give notice that agreements will not be offered. Additionally, the order provides that where Sohio seeks to cancel an agreement prior to its expiration for "good cause", dealer may request that determination of good cause be submitted to arbitration.

DATES: Complaint issued Jan. 18, 1973; Decision and Order issued Nov. 2, 1977.[1]

FOR FURTHER INFORMATION CONTACT:

Alan K. Palmer, Asst. Director, Bureau of Competition, Federal Trade Commission, 6th & Pennsylvania Avenue NW., Washington, D.C. 20580, 202-724-1341.

SUPPLEMENTARY INFORMATION: On Friday, July 15, 1977, there was published in the FEDERAL REGISTER [42 FR 36480] a proposed consent agreement with analysis In the Matter of Standard Oil Co. (Ohio), a corporation, for the purpose of soliciting public comment. Interested parties were given sixty (60) days in which to submit comments, suggestions, or objections regarding the proposed form of order.

Comments were filed and considered by the Commission.

[1] Copies of the Complaint, and the Decision and Order filed with the original document.

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]

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[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."