

(2) Stay the effectiveness of such orders for up to 30 days if the review is unsatisfactory.

By the Civil Aeronautics Board:

Phyllis T. Kaylor,

Secretary.

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SECURITIES AND EXCHANGE COMMISSION

17 CFR Parts 275 and 279

[Release No. IA-805]

Amendments To Investment Adviser Requirements Concerning Disclosure, Application for Registration and Annual Report

AGENCY: Securities and Exchange Commission.

ACTION: Adoption of amendments to rules and forms; request for comment.

SUMMARY: The Commission is amending certain disclosure and reporting requirements applicable to investment advisers under the Investment Advisers Act of 1940. The amendments adopted on a final basis make certain changes, both substantive and technical, in the investment adviser registration, disclosure, and reporting requirements. The effect of the amendments will be to clarify and simplify the investment adviser registration and disclosure requirements. In addition, the Commission is adopting temporary amendments to other reporting requirements which will further simplify such requirements and is inviting public comments on these amendments.

DATES: Effective May 25, 1982. Comments on the temporary amendments must be received on or before July 16, 1982.

ADDRESSES: Comments should be submitted in triplicate to: George A. Fitzsimmons, Secretary, Securities and Exchange Commission, 500 North Capitol Street, NW., Washington, D.C. 20549. Comment letters should refer to File No. S7-932. All comments received will be available for public inspection and copying in the Commission's public reference room, 1100 L Street, NW., Washington, D.C.

FOR FURTHER INFORMATION CONTACT: Arthur E. Dinerman, Esq., Investment Advisers Study Group, Division of Investment Management, Securities and Exchange Commission, Washington, D.C. 20549; (202) 272-2079.

SUPPLEMENTARY INFORMATION:

I. Background and Summary

On July 21, 1981, the Commission issued a release soliciting public comments on proposed amendments to certain disclosure and reporting requirements applicable to investment advisers under the Investment Advisers Act of 1940 (15 U.S.C. 80b-1 et seq.) ("Advisers Act").¹ The proposed amendments involved a number of technical and clarifying changes in the investment adviser disclosure, registration and reporting requirements. In addition, the Commission proposed to delete Item 17 of Part I of Form ADV (17 CFR 279.1), the investment adviser registration form, and related requirements which obliged certain investment advisers to file an unaudited balance sheet with the Commission and to update it annually. The release also proposed a new Item 17 for Part I pertaining to newsletter publishers.

Having considered the comments submitted, the Commission has decided to adopt the proposed amendments in all but three respects. The Commission is also adopting certain conforming amendments to reflect the deletion of Item 17 from Part I of Form ADV. In addition, the Commission is adopting certain temporary amendments relating to Part I of Form ADV and is soliciting public comments on the temporary amendments.

II. Amendments

The Commission received eleven comment letters in response to its notice of proposed rulemaking. Although several commentators expressed general support for the proposed amendments, the majority criticized some aspect of the proposal.

Seven commentators objected to the proposal to adopt new Item 17 of Part I of Form ADV requiring publishers of periodical publications to disclose annually the number of their subscribers as of the end of their last fiscal year. The principal criticisms of proposed new Item 17 were that such disclosure was unnecessary or would be burdensome, that disclosure would place smaller publishers at a competitive disadvantage, and that the information disclosed could be used by a publisher's competitors to gauge the success of the marketing techniques used by the publisher. Although the Commission questions the extent to which these results would occur, the Commission has reconsidered its need for the information that would be obtained by proposed new Item 17. As discussed in greater detail in Advisers Act Release

¹ Investment Advisers Act Release No. 766 (46 FR 38529, July 28, 1981).

No. 766, the Commission proposed new Item 17 in order to obtain information which would assist the Commission's staff in deciding which advisers to inspect at a particular time as well as to provide useful additional data about the advisory industry. However, the information is not essential to the inspection program. Therefore, the Commission has determined not to adopt the proposed new item.

There were two comments pertaining to the proposed change in Rule 204-3(d) (17 CFR 275.204-3(d)) which would permit an investment adviser who renders different types of advisory services to omit from its disclosure statement any information (as opposed to only certain specified information as is now the case) required by Part II of Form ADV which is not applicable to the particular client receiving the statement. Two commentators criticized the proposal for failing to set forth standards as to the meaning of the phrase "different types of investment advisory services to different advisory clients" and offered clarifying language.² The Commission agrees that the standards set forth in the commentators' suggestion describe circumstances in which use of a tailored disclosure statement generally would be appropriate. The Commission is concerned, however, that the specific standards suggested by the commentators might be read to limit unnecessarily the circumstances under which use of a tailored brochure would be permitted and that it is not feasible to set forth standards which would encompass all circumstances in which use of a tailored brochure would be appropriate. The Commission believes that use of the general phrase contained in the proposal is preferable to the suggested alternative in that it provides registrants maximum flexibility in determining for themselves when they can use a tailored disclosure statement. Therefore, the Commission is adopting

² The Commission proposed to amend rule 204-3(d) to read: Omission of inapplicable information. If an investment adviser renders substantially different types of investment advisory services to different advisory clients, any information required by Part II of Form ADV may be omitted from the statement furnished to an advisory client or prospective advisory client if such information is applicable to a type of advisory service or fee which is not rendered or charged, or proposed to be rendered or charged, to that client or prospective client.

The commentators suggested substituting for the underlined language the following: " * * * services that differ as among investment advisory clients classified in terms of account size, investment objective, types of permissible investments or nature of accounts involved (e.g., ERISA vs. non-ERISA), * * * "

the revision to Rule 204-3(d) as proposed.

The Commission is also not adopting the proposed amendments to Items 15(iii) and 16(iii) of Part I of Form ADV which would have added an additional size category to these questions. As discussed below, the Commission has determined to delete Items 15(iii) and 16(iii) of Part I of Form ADV in their entirety.

In addition, the Commission is adopting conforming amendments to reflect the deletion of old Item 17 from Part I of Form ADV. Specifically, the Commission is amending Instructions 12 and 24 and Schedule G of Form ADV, Instruction 6 and Item 4 of Form ADV-S, and rule 204-1(b)(2) (17 CFR 275.204-1(b)(2)), by deleting reference to Item 17.

III. Temporary Amendments

The Commission, as part of a comprehensive re-evaluation of the regulatory system applicable to investment advisers,³ has reviewed the reporting and disclosure requirements applicable to investment advisers, including Form ADV, the investment adviser registration application form. As a result of this review, the Commission has decided to adopt certain temporary amendments to Form ADV which will delete a number of items from Part I of Form ADV. These items are Items 5(b), 7(b), 13(b), 15(i) and 15(iii), and 16(i) and 16(iii).

The Commission has determined that the information contained in the items to be deleted, although generally useful to the Commission in its understanding of the investment advisory industry, may not be sufficiently important to justify continuation of the requirements. Items 15(i) and (iii) and 16(i) and (iii) are being deleted because compliance with these items, which require certain registrants to rank by size of assets under management their ten largest categories of clients and to set forth the number of clients which fall into various size categories, appears to involve substantial effort for many registrants. Collection of this information in the past has enabled the Commission to build a data base useful for developing a profile of the investment advisory industry. However, it now appears that the benefits of continuing to collect the information are insufficient in view of the apparent cost and burden to investment advisers in supplying it.

Item 13(b), which requires the investment adviser to disclose whether

or not a substantial part of its business consists of rendering "investment supervisory services" as defined in section 202(a)(13) of the Advisers Act (15 U.S.C. 80b-2(a)(13)), is being deleted because it is somewhat duplicative of Item 1(a) of Part II of Form ADV, which requires the investment adviser to disclose whether it furnishes such services. Item 5(b), which requires disclosure of each class of equity security of the investment adviser, and Item 7(b), which requires the investment adviser to disclose and explain any merger with or acquisition of another registered investment adviser during the previous ten years, have been deleted in order to simplify further Part I of Form ADV, and the utility of this information to the Commission's regulatory program is marginal.

The Commission has determined to adopt these temporary amendments without affording prior notice and opportunity for comment because it finds that prior notice and opportunity for public comment are unnecessary under section 553(b)(B) of the Administrative Procedure Act ("APA") (5 U.S.C. 553(b)(B)). All of these amendments relate to Part I of Form ADV, the part of the form which contains information required by the Commission for its own regulatory purposes. The information which registrants are required to deliver or offer to deliver to clients and prospective clients under Rule 204-3 under the Advisers Act, the "brochure rule," is contained in Part II of Form ADV. Accordingly, none of the changes made by the temporary amendments involve information regularly disclosed by registrants to clients and prospective clients. Since the deletions relieve registrants of the obligation to file certain information with the Commission and do not diminish disclosure to clients, the Commission does not believe that any person will be adversely affected by elimination of these items from Part I of Form ADV and, accordingly, has determined that soliciting public comment prior to adopting such deletions is unnecessary.

Although, as discussed above, the Commission finds that prior notice and opportunity for comment with respect to adoption of the temporary amendments are not required under Section 553(b)(B) of the APA, the Commission nonetheless has determined to adopt the amendments on only a temporary basis and is soliciting public comment as to whether the amendments should be made permanent. The temporary amendments will be effective until March 31, 1983, and, accordingly, will be

applicable to all initial registrations and amendments filed prior to that date as well as all fiscal year 1982 Form ADV-S filings.

The Commission has also determined to make the amendments and temporary amendments effective immediately in accordance with section 553(d)(1) of the APA (5 U.S.C. 553(d)(1)). None of the amendments or temporary amendments imposes additional substantive requirements on investment advisers. The amendments and temporary amendments to the investment adviser registration application procedures and forms adopted today involve deletions of information previously required to be filed, simplification of procedures to be followed by investment advisers, or technical changes and clarifications of existing requirements. Accordingly, the Commission finds good cause for making the amendments and temporary amendments adopted today effective immediately, so that they will be applicable, as discussed above, to new registrants as well as current registrants meeting their annual filing requirements during fiscal year 1982.

Although the amendments and temporary amendments adopted herein are effective upon publication in the **Federal Register**, forms revised to reflect these amendments will not be available immediately. Until revised forms become publicly available, investment advisers filing initial registration applications with the Commission and registrants who are amending their investment adviser registration application on Form ADV or filing Form ADV-S should use old Form ADV and ADV-S respectively but need not respond to Items 5(b), 7(b), 13(b), 15(i) and (iii) and 16(i) and (iii) of Part I of Form ADV, or file unaudited balance sheets pursuant to Item 17 of Form ADV. Similarly, registrants should respond to Form ADV-S as if the modifications being made in this release were already reflected in the form.

Regulatory Flexibility Act

The Chairman of the Commission has certified that the amendments being adopted will not have a significant economic impact on a substantial number of small entities. Accordingly, no regulatory flexibility analysis is required under Section 604 of the Regulatory Flexibility Act (5 U.S.C. 601 et seq.).

List of Subjects in 17 CFR Parts 275, 279

Investment advisers, Reporting requirements, Securities.

³In Securities Act Release No. 6323 (June 24, 1981) (46 FR 33287), the Commission stated that Advisers Act Rules 204-1 and 204-3 (17 CFR 275.204-1 and 275.204-3) would be reviewed in 1981.

PART 275—RULES AND REGULATIONS, INVESTMENT ADVISERS ACT OF 1940

Commission Action

I. The Commission hereby amends Part 275 of Chapter II of Title 17 of the Code of Federal Regulations as follows:

1. By adding paragraphs (c) and (d) to § 275.203-1 to read as follows:

§ 275.203-1 Application for registration of investment adviser.

(c) A Form ADV filed by an investment adviser corporation which is not registered when such form is filed and which succeeds to and continues the business of a predecessor corporation registered as an investment adviser shall be deemed to be an application for registration even though designated as an amendment if the succession is based solely on a change in the predecessor's state of incorporation and the amendment is filed to reflect that change.

(d) A Form ADV filed by an investment adviser corporation, partnership, sole proprietorship or other entity which is not registered when such form is filed and which succeeds to and continues the business of a predecessor corporation, partnership, sole proprietorship or other entity registered as an investment adviser shall be deemed to be an application for registration even though designated as an amendment if the succession is based solely on a change in the predecessor's form of organization and the amendment is filed to reflect that change.

2. By revising paragraphs (b)(2) and (b)(3) of § 275.204-1 to read as follows:

§ 275.204-1 Amendments to application for registration.

(b) ***
(2) If the information contained in response to questions 5, 7, 8, 9 and 11 of Part I, or any question in Part II (Except question 13), or any application for registration as an investment adviser, or in any amendment thereto, becomes inaccurate but not in a material manner, or the information contained in response to questions 12(c), 13, 15 and 16 of Part I of any application for registration as an investment adviser, or in any amendment thereto, becomes inaccurate for any reason, the investment adviser shall file an amendment on Form ADV (Section 279.1 of this chapter) correcting such information within 90 days of the end of its fiscal year. In addition, a balance sheet, as required by question 13 of Part II, shall be filed within 90 days of the end of applicant's fiscal year.

(3) If the information contained in response to question 3 of Part I becomes inaccurate, the investment adviser shall file an amendment on Form ADV correcting such information within 90 days of the end of the applicant's fiscal year. However, if the investment adviser's registration or license in another jurisdiction has been restricted, suspended, terminated (either voluntarily or involuntarily) or withdrawn, the investment adviser shall promptly file an amendment.

3. By revising paragraph (d) of § 275.204-3 to read as follows:

§ 275.204-3 Written disclosure statements.

(d) *Omission of inapplicable information.* If an investment adviser renders substantially different types of investment advisory services to different advisory clients, any information required by Part II of Form ADV may be omitted from the statement furnished to an advisory client or prospective advisory client if such information is applicable only to a type of investment advisory service or fee which is not rendered or charged, or proposed to be rendered or charged, to that client or prospective client.

PART 279—FORMS PRESCRIBED UNDER THE INVESTMENT ADVISERS ACT OF 1940

II. The Commission hereby amends Part 279 of Chapter II of Title 17 of the Code of Federal Regulations as follows:

§ 279.1 [Amended]

1. By amending Form ADV as follows:

(i) Instruction 12 is amended by deleting the last sentence from the first paragraph thereof and substituting the following:

In addition, a balance sheet, as required by question 13 of Part II shall be filed no later than 90 days after the end of applicant's fiscal year.

Instruction 12 is also amended by deleting the last sentence of the second paragraph thereof and substituting therefor the following:

However, if the investment adviser's license or registration has been restricted, suspended, terminated (either voluntarily or involuntarily), or withdrawn, the investment adviser shall promptly file an amendment.

(ii) Instruction 15 is amended by deleting the word "State" in the first line thereof.

(iii) Instruction 24 is amended by deleting the phrase "Item 17 of Part I and."

(iv) Item 3(b) of Part I is amended by deleting the words "or involuntarily terminated or withdrawn or voluntarily terminated" in the second line thereof and substituting therefor the words, "terminated (either voluntarily or involuntarily), or withdrawn."

(v) Item 10(i) of Part I is amended by deleting the comma between the words "desist" and "and" in the first line thereof.

(vi) Item 17 of Part I is amended by deleting such item in its entirety.

(vii) Items 6(a) and 6(b) of Part II are amended by deleting the word "age" in the first line of Item 6(a) and in the second line of Item 6(b) and substituting therefor the words "year of birth."

(viii) The unnumbered note to item 8(b) of Part II is amended to read in its entirety as follows:

Note.—Pursuant to Section 202(a)(12) of the Act (15 U.S.C. 80b-2(a)(12)), the term "affiliated person" has the same meaning as in Section 2(a)(3) of the Investment Company Act of 1940 (15 U.S.C. 80a-2(a)(3)), which provides that an "affiliated person" of another person means:

(A) any person directly or indirectly owning, controlling, or holding with power to vote, 5 per centum or more of the outstanding voting securities of such other person; (B) any person 5 per centum or more of whose outstanding voting securities are directly or indirectly owned, controlled, or held with power to vote, by such other person; (C) any person directly or indirectly controlling, controlled by, or under common control with, such other person; (D) any officer, director, partner, co-partner, or employee of such other person; (E) if such other person is an investment company, any investment adviser thereof or any member of an advisory board thereof; and (F) if such other person is an unincorporated investment company not having a board of directors, the depositor thereof.

(ix) Item 9(c) of Part II is amended by adding the parenthetical phrase "(investment advisory)" immediately after the word "from" in the second line thereof.

(x) Item 9(d) of Part II is amended by adding the parenthetical phrase "(investment advisory)" immediately after the word "prospective" in the first line thereof.

(xi) Item 13 of Part II is amended by deleting the text of such item in its entirety and substituting therefor the following:

Balance Sheet. Every applicant who has custody or possession of clients' funds or securities, or requires prepayment of advisory fees six months or more in advance and in excess of \$500 per client, shall provide on Schedule G a balance sheet as of the end

of applicant's most recent fiscal year. The balance sheet shall be audited by an independent public accountant and shall be prepared in accordance with generally accepted accounting principles. The balance sheet shall be accompanied by a note stating the accounting principles and practices followed in its preparation, the basis at which securities are included and other notes as may be necessary for an understanding of the statement. If securities are included at cost, their market or fair value shall be shown parenthetically. The If securities are included at cost, their market or qualifications and any report of an independent accountant which accompanies a balance sheet shall conform with the requirements of Article 2 of Regulation S-X (17 CFR 210.2-01 et seq.).

A sole proprietor investment adviser must show assets and liabilities related to his advisory business separately from his other business and personal assets and liabilities. However, appropriate aggregation of the other business and personal assets and liabilities is permitted except where a deficiency of assets exists in his overall financial position, in which case full details of the other business and personal assets and liabilities shall be presented on the balance sheet or included in a note referred to on the balance sheet.

Has applicant provided a balance sheet on Schedule G pursuant to this Item? Yes No

(xii) Schedule D, page 2 is amended by adding a request for the name and social security number of the person for whom the schedule is being completed.

(xiii) Schedule G is amended by deleting the phrase "Item 17 of Part I or" from the description of the form.

(A copy of Form ADV, as amended, has been filed with the Office of the Federal Register as part of the original document.)

§ 279.3 [Amended]

2. By amending Form ADV-S as follows:

(i) Instruction 2 is amended by adding after the last sentence thereof the following:

Note.—The filing of Form ADV-S does not relieve a registrant of any requirement of Rule 204-1 under the Act to amend its Form ADV. Failure to amend Form ADV, as required by Rule 204-1, could result in enforcement action by the Commission. Any amendment to registrant's Form ADV, which is made at the time registrant's Form ADV-S is filed, may be filed with the Commission concurrently with the filing of Form ADV-S. However, any amendments to Form ADV so filed should not be attached to Form ADV-S and should include a properly completed execution page and page one of Part I of Form ADV.

(ii) Instruction 5 is amended by deleting the second and third sentences thereof and substituting therefor the following:

Any registrant which provides an affirmative answer to Item 3(a) should file the required amendment(s) with the Commission on Form ADV, pursuant to the instructions thereto, and indicate in Item 3(b) whether such amendment(s) have been filed concurrently with the filing of Form ADV-S.

Such instruction is amended further by deleting in its entirety the second note to that instruction.

(iii) Instruction 6 is amended to read as follows:

Item 4 requires a registrant to indicate whether it has filed with the Commission on Schedule G of Form ADV, as an amendment to Form ADV, a balance sheet as of the end of such registrant's most recent fiscal year, if applicable. The balance sheet must meet the requirements of Item 13 of Part II of Form ADV.

(iv) Item 4 is amended by deleting the text of such item in its entirety and substituting therefor the following:

(a) Is the registrant subject to the filing requirements of Item 13 of Part II of Form ADV? (Pursuant to Item 13 of Part II of Form ADV, every applicant who has custody or possession of clients' funds or securities or requires prepayment of advisory fees six months or more in advance and in excess of \$500 per client, shall provide on Schedule G a balance sheet as of the end of applicant's most recent fiscal year. The balance sheet shall be audited by an independent public accountant and shall be prepared in accordance with generally accepted accounting principles. The balance sheet shall be accompanied by a note stating the accounting principles and practices followed in its preparation, the basis at which securities are included and other notes as may be necessary for an understanding of the statement. If securities are included at cost, their market or fair value shall be shown parenthetically. The qualifications and any report of an independent accountant which accompanies a balance sheet shall conform with the requirements of Article 2 of Regulation S-X (17 CFR 210.2-01 et seq.)). Yes No

(b) If the answer to Item 4(a) is yes, has the registrant, pursuant to Rule 204-1(b)(2) and Item 13 of Part II of Form ADV, filed with the Commission on Schedule G of Form ADV, a balance sheet as of the end of registrant's most recent fiscal year? Yes No

(A copy of Form ADV-S, as amended, has been filed with the Office of the Federal Register as part of the original document.)

III. The Commission hereby temporarily amends, until March 31, 1983, Part 279 of Chapter II of Title 17 of the Code of Federal Regulations as follows:

§ 279.1 [Suspended in part]

1. By amending Part I of Form ADV as follows:

(i) Item 5 of Part I is amended by deleting part (b) in its entirety and by deleting the designation "(a)."

(ii) Item 7 of Part I is amended by deleting part (b) in its entirety and by deleting the designation "(a)."

(iii) Item 13 of Part I is amended by deleting part (b) in its entirety and by deleting the designation "(a)."

(iv) Item 15 of Part I is amended by deleting parts (i) and (iii) in their entirety and by deleting the designation "(ii)."

(v) Item 16 of Part I is amended by deleting parts (i) and (iii) in their entirety and by deleting the designation "(ii)."

Statutory Authority

The Commission (i) amends Rules 204-1 and 204-3 and Form ADV-S pursuant to the authority contained in sections 204, 206(4) and 211(a) of the Advisers Act (15 U.S.C. 80b-4, 80b-6(4) and 80b-11(a)) and (ii) amends Rule 203-1 Form ADV pursuant to the authority contained in Sections 203 (15 U.S.C. 80b-3), 204, 206(4) and 211(a) of the Act.

George A. Fitzsimmons

Secretary.

May 14, 1982.

Regulatory Flexibility Act Certification

I, John S. R. Shad, Chairman of the Securities and Exchange Commission, hereby certify, pursuant to 5 U.S.C. 605(b), that the amendments and temporary amendments adopted herein to Rules 203-1, 204-1 and 204-3 and Forms ADV and ADV-S under the Investment Advisers Act of 1940 ("Advisers Act") will not have a significant economic impact on a substantial number of small entities. The reasons for this certification are that the amendments will impose no additional burdens on investment advisers subject to registration under the Advisers Act; some of the amendments and temporary amendments adopted herein clarify existing requirements while others eliminate previously existing requirements for certain registrants; and these amendments and temporary amendments will reduce the burden on investment advisers subject to registration in complying with Rules 203-1, 204-1 and 204-3 and Forms ADV and ADV-S under the Advisers Act.

Dated: May 14, 1982.

John S. R. Shad,
Chairman.

[FR Doc. 82-14183 Filed 5-24-82; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 74, 81, and 82

[Docket No. 82N-0127]

D&C Red No. 30

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is permanently listing D&C Red No. 30 for general use in drugs and cosmetics excluding use in the area of the eye. This rule will remove D&C Red No. 30 from the provisional list of color additives for general use in drugs and cosmetics.

DATES: Effective June 25, 1982; objections by June 24, 1982.

ADDRESS: Written objections may be sent to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-82, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Andrew D. Laumbach, Bureau of Foods (HFF-334), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-472-5690.

SUPPLEMENTARY INFORMATION: In the Federal Register of November 20, 1968 (33 FR 17205), FDA announced that a petition (CAP 7C0058) for the permanent listing of D&C Red No. 30 as a color additive for use in ingested drugs, lipsticks, and externally applied drugs and cosmetics had been filed by the Toilet Goods Association, Inc. (now the Cosmetic, Toiletry and Fragrance Association (CTFA)), the Pharmaceutical Manufacturers Association (PMA), and the Certified Color Industry Committee (now the Certified Color Manufacturers Association, Inc. (CCMA)), c/o Hazelton Laboratories, Inc., Post Office Box 30, Falls Church, VA 22046 (now 9200 Leesburg Turnpike, Vienna, VA 22180).

The petition was filed under section 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 376). A later notice (41 FR 9584; March 5, 1976) amended the notice of filing of the petition to include the use of D&C Red No. 30 in all types of cosmetics subject to ingestion and the additional use of D&C Red No. 30 in cosmetics intended for use in the area of the eye.

Toxicological Concerns

The provisional regulations published in the Federal Register of February 4, 1977 (42 FR 6992) required new chronic toxicity studies for D&C Red No. 30 as a

condition of its continued provisional listing for ingested uses. FDA placed these requirements on 31 color additives, including D&C Red No. 30, because the toxicity studies the petitioners had submitted to support the safe use of these color additives were deficient in several respects. FDA described these deficiencies in the Federal Register of September 23, 1976 (41 FR 41863):

1. Many of the studies were conducted using groups of animals, i.e., control and those fed the color additive, that are too small to permit conclusions to be drawn today on the chronic toxicity or carcinogenic potential of the color. The small number of animals used does not, in and of itself, cause this result, but when considered together with the other deficiencies in this listing, does do so. By and large, the studies used 25 animals in each group; today FDA recommends using at least 50 animals per group.

2. In a number of the studies, the number of animals surviving to a meaningful age was inadequate to permit conclusions to be drawn today on the chronic toxicity or carcinogenic potential of the color additives tested.

3. In a number of the studies, an insufficient number of animals was reviewed histologically.

4. In a number of the studies, an insufficient number of tissues was examined in those animals selected for pathology.

5. In a number of the studies, lesions or tumors detected under gross examination were not examined microscopically.

The closing date for the provisional listing of the color additive was postponed until January 31, 1981, for the completion of required chronic toxicity studies.

Chemistry Concerns

The provisional regulations of February 4, 1977, also established a closing date of October 31, 1977, for developing chemistry data and analytical methods necessary for defining chemical specifications for certifying batches of D&C Red No. 30. FDA requires chemical specifications based on sufficiently precise analytical methods, so that the agency can certify that batches of each color additive are equivalent to the batches of the color additive used in conducting animal studies to establish the safety of the color additive.

The petitioners had been actively engaged in efforts to provide the chemistry information needed to establish specifications for the color additive since the petition was

submitted to the agency. By 1977 it was evident from experimental data that D&C Red No. 30 contained unidentified components for which specifications would have to be considered by the agency. FDA expected that the chemical nature and amount of these unidentified components, which are soluble in acetone, would be resolved during the postponement of the closing date until October 31, 1977. The petitioner notified the agency that work was underway to provide the necessary information in response to the new closing date. FDA expected that the use of new analytical techniques, such as high-pressure liquid chromatography (HPLC), would lead to rapid resolution of the chemistry issues. However, this task proved to be more difficult to complete during the short postponement period than the agency expected. As a result, the petitioners, in a letter dated October 6, 1977, requested a further extension of time to complete the chemistry analysis of D&C Red No. 30. On the basis of chemistry reports showing satisfactory progress in developing the analytical methods necessary to define specifications for D&C Red No. 30, FDA allowed the continued provisional listing for the color additive until January 31, 1981, the same closing date the agency established for completion of the toxicity studies discussed above.

FDA later again extended the closing date for completing the chronic toxicity studies and submitting data. In a proposal in the Federal Register of November 14, 1980 (45 FR 75226), the agency outlined the reasons for the need to postpone the closing dates for 23 provisionally listed color additives under test, including D&C Red No. 30, beyond January 31, 1981.

Although the agency had decided to postpone the closing date for D&C Red No. 30 and the other color additives before expiration of the January 31, 1981 closing date, the order did not publish before President Reagan signed his Executive Memorandum of January 29, 1981, which directed Federal agencies to postpone for 60 days all pending regulations, with certain exemptions inapplicable to postponements of closing dates for provisionally listed color additives. As soon as possible after the end of the regulatory postponement, FDA issued, in the Federal Register of March 27, 1981 (46 FR 18958), the rule establishing new closing dates for D&C Red No. 30 and the other color additives. Therefore, the current closing date for the provisional listing of the color additive is May 30, 1982.

Resolution of Toxicological and Chemical Concerns

The agency has completed its evaluation of the color additive petition for D&C Red No. 30, including two new chronic toxicity studies in rats and mice. These new long-term chronic studies represent current state-of-the-art toxicological testing. The protocols for these studies have benefited from knowledge or deficiencies in previously conducted carcinogenesis bioassays and other chronic toxicity protocols. The use of large numbers of animals of both sexes, pilot studies to determine maximum tolerated dosages, two control groups (thereby effectively doubling the number of controls), and in utero exposure in one of the two species tested significantly increase the power of these tests to detect dose-related effects. The studies were designed and conducted in full compliance with the good laboratory practices regulations and were subject to inspections by FDA officials during their course.

Based on the evaluation of the results of the two new chronic toxicity studies, the agency has determined that D&C Red No. 30 is not carcinogenic to Charles River Sprague-Dawley rats or CD-1 mice after lifetime dietary exposure of 2.0 percent and 5.0 percent, respectively. Using appropriate safety factors (see 21 CFR 70.40), the agency has also estimated a maximum acceptable daily intake for humans—1.25 milligrams per kilogram of body weight per day.

FDA has also evaluated the scientific data regarding the chemical characterization of D&C Red No. 30 and its acetone-soluble components. Modern HPLC analytical methods establish that the acetone-soluble portion of the color additive is a complex mixture consisting of several compounds, each being present in very small amounts. The batch of D&C Red No. 30 fed in the test diets of the animals in the chronic toxicity studies contained approximately 2.8 percent acetone-soluble material. Therefore, the feeding tests also served to test the toxicity of the impurities. These tests provided no evidence that the acetone-soluble material is toxic.

To ensure the safety of future batches of this color additive, however, FDA is establishing a specification limit on the amount of acetone-soluble material that it will permit in D&C Red No. 30. Analysis of batches of this color additive that have been produced in recent years reveals that the acetone-soluble material is typically present in the finished color additive at a level of 2 to 5 percent. The exaggerated doses

used in the feeding studies establish the safety of the color additive when the acetone-soluble matter is present at these typical levels. Therefore, FDA is setting the specification at 5 percent for this matter.

To ensure further the safety of the color additive, the agency has determined that it is necessary to control the qualitative and quantitative character of the acetone-soluble fraction. To ensure that the quantity and quality of the acetone-soluble components in individual batches conform to current good manufacturing practice, FDA will analyze by the HPLC method samples of the color additive submitted for certification, and FDA will compare the results of that analysis to those obtained with the sample tested toxicologically. Details of the HPLC method will be provided upon request from the contract person listed above.

Conclusion on Safety

The agency concludes that D&C Red No. 30 is safe under conditions of use set forth below for general use in drugs and cosmetics, and that certification is necessary for the protection of the public health. The final toxicity study reports, interim reports, and the agency's toxicology evaluations of these studies are on file at the Dockets Management Branch (address above). They may be reviewed there during working hours, between 9:30 a.m. and 4 p.m.

FDA notified the petitioners by letters, dated May 14, 1976, August 15, 1977, and August 4, 1978, of the need for data to support the use of D&C Red No. 30 in cosmetics intended for use in the area of the eye. In the latest letter, dated October 24, 1978, FDA advised the petitioners to consider withdrawing their petition that sought approval of use of D&C Red No. 30 in cosmetics intended for use in the area of the eye because it appeared that the required data from eye-area studies would not be readily available.

The required data for eye-area use have not been submitted to the agency. Therefore, that portion of the petition that was amended by the filing on March 5, 1976 (Docket No. 76C-0044) to include the permanent listing of D&C Red No. 30 for eye-area use is now considered by the agency to be withdrawn without prejudice in accordance with the provisions of § 71.4 (21 CFR 71.4). Section 71.4 requires that such requested information be submitted within 180 days after filing of the petition, or the petition will be considered withdrawn without prejudice. Use of D&C Red No. 30 in the area of the eye has never been covered

by provisional listing. Future consideration by FDA of the permanent listing of D&C Red No. 30 for eye-area use will require the submission of a new color additive petition for that use. The agency's listing of a color additive for general use in drugs and cosmetics does not encompass eye-area use.

The agency has determined under 21 CFR 25.24 (b)(12) and (d)(5) (proposed December 11, 1979; 44 FR 71742) that this action is of a type that does not individually or cumulatively have a significant effect on the environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

List of Subjects in 21 CFR Parts 74, 81, 82

Color additives, Cosmetics, Drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 706 (b), (c), and (d), 74 Stat. 399-403 (21 U.S.C. 376 (b), (c), and (d))) and the Transitional Provisions of 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 of Food and Drugs (21 CFR 5.10 (formerly 5.1); see 46 FR 26052; May 11, 1981), Parts 74, 81, and 82 are amended as follows:

PARTS 74—LISTING OF COLOR ADDITIVES SUBJECT TO CERTIFICATION

1. Part 74 is amended:

a. By adding new § 74.1330 to Subpart B, to read as follows:

§ 74.1330 D&C Red No. 30.

(a) *Identity.* (1) The color additive D&C Red No. 30 is principally 6-chloro-2-(6-chloro-4-methyl-3-oxobenzothien-2(3H)-ylidene)-4-methyl-benzothiofen-3(2H)-one (CAS Reg. No. 2379-74-0).

(2) Color additive mixtures for drug use made with D&C Red No. 30 may contain only those diluents that are suitable and that are listed in Part 73 of this chapter as safe for use in color additive mixtures for coloring drugs.

(b) *Specifications.* D&C Red No. 30 shall conform to the following specifications and shall be free from impurities other than those named to the extent that such impurities may be avoided by current good manufacturing practice:

Volatile matter (at 135° C), not more than 5 percent.
Chlorides and sulfates (calculated as sodium salts), not more than 3 percent.
Matter soluble in acetone, not more than 5 percent.
Total color, not less than 90 percent.

Lead (as Pb), not more than 20 parts per million.
 Arsenic (as As), not more than 3 parts per million.
 Mercury (as Hg), not more than 1 part per million.

(c) *Uses and restrictions.* D&C Red No. 30 may be safely used for coloring drugs generally in amounts consistent with current good manufacturing practice.

(d) *Labeling.* The label of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification.* All batches of D&C Red No. 30 shall be certified in accordance with regulations in Part 80 of this chapter.

b. By adding new § 74.2330 to Subpart C, to read as follows:

§ 74.2330 D&C Red No. 30.

(a) *Identity and specifications.* The color additive D&C Red No. 30 shall conform in identity and specifications to the requirements of § 74.1330 (a)(1) and (b).

(b) *Uses and restrictions.* D&C Red No. 30 may be safely used for coloring cosmetics generally in amounts consistent with current good manufacturing practice.

(c) *Labeling requirements.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Certification.* All batches of D&C Red No. 30 shall be certified in accordance with regulations in Part 80 of this chapter.

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

2. Part 81 is amended:

§ 81.1 [Amended]

a. In paragraph (b) of § 81.1 *Provisional lists of color additives* by removing the entry for "D&C Red No. 30."

§ 81.27 [Amended]

b. In § 81.27 *Conditions of provisional listing*, by removing the entry for D&C Red No. 30 in the introductory text of paragraph (c) and in paragraphs (c)(1) and (d).

PART 82—LISTING OF CERTIFIED PROVISIONALLY LISTED COLORS AND SPECIFICATIONS

3. Part 82 is amended by revising § 82.1330, to read as follows:

§ 82.1330 D&C Red No. 30.

The color additive D&C Red No. 30 shall conform in identity and specifications to the requirements of § 74.1330 (a)(1) and (b) of this chapter.

Any person who will be adversely affected by the foregoing regulation may at any time on or before June 24, 1982, file with the Dockets Management Branch (address above) written objections thereto. Objections shall show wherein the person filing will be adversely affected by the regulation, specify with particularity the provisions of the regulation deemed objectionable, and state the grounds for the objections. Objections shall be filed in accordance with the requirements of 21 CFR 71.30. If a hearing is requested, the objections shall state the issues for the hearing and shall be supported by grounds factually and legally sufficient to justify the relief sought, and shall include a detailed description and analysis of the factual information intended to be presented in support of the objections in the event that a hearing is held. Three copies of all documents shall be filed and shall be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Effective date. This regulation shall become effective June 25, 1982, except as to any provisions that may be stayed by the filing of proper objections. Notice of the filing of objections or lack thereof will be announced by publication in the Federal Register.

(Sec. 706 (b), (c), and (d), 74 Stat. 399-403 (21 U.S.C. 376 (b), (c), and (d)); sec. 203, Pub. L. 86-618, 74 Stat. 404-407 (21 U.S.C. 376, note))

Dated: May 18, 1982.

William F. Randolph,
 Acting Associate Commissioner for
 Regulatory Affairs.

[FR Doc. 82-14084 Filed 5-24-82; 8:45 am]

BILLING CODE 4160-01-M

21 CFR Part 81

[Docket No. 76N-0366]

Provisional Listing of D&C Red No. 30; Postponement of Closing Date

AGENCY: Food and Drug Administration.
ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is postponing the closing date for the provisional listing of D&C Red No. 30 for general use in drugs and cosmetics excluding use in the area of the eye. A new closing date for D&C

Red No. 30 is being established to provide for receipt and evaluation of any objections submitted in response to the final regulation approving the petition for the listing of D&C Red No. 30 for this use. The regulation that lists D&C Red No. 30 is published elsewhere in this issue of the Federal Register. The new closing date will be July 29, 1982.

EFFECTIVE DATE: May 28, 1982.

FOR FURTHER INFORMATION CONTACT: Andrew D. Laumbach, Bureau of Foods (HFF-334), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-472-5690.

SUPPLEMENTARY INFORMATION: The current closing date of May 30, 1982, for the provisional listing of D&C Red No. 30 was established by a rule published in the Federal Register of March 27, 1981 (46 FR 18958). The May 30, 1982 closing date for D&C Red No. 30 was established to provide time for determining the applicability of the statutory standard for the listing of color additives to the results of scientific investigations of D&C Red No. 30.

After reviewing and evaluating the data, the agency has concluded that D&C Red No. 30 is safe for that use. Therefore, elsewhere in this issue of the Federal Register, FDA is publishing a regulation that lists D&C Red No. 30.

The regulation set forth below will postpone the May 30, 1982 closing date for the provisional listing of that color additive until July 29, 1982. This postponement will provide sufficient time for receipt and evaluation of comments or objections submitted in response to the regulation that lists D&C Red No. 30 for general use in drugs and cosmetics, excluding use in the area of the eye.

Because of the shortness of time until the May 30, 1982 closing date, FDA concludes that notice and public procedure on this regulation are impracticable. Moreover, good cause exists for issuing this postponement as a final rule, because the agency has concluded that D&C Red No. 30 is safe for its intended use under the Color Additive Amendments of 1960. This regulation will permit the uninterrupted use of this color additive until July 29, 1982. To prevent any interruption in the provisional listings of D&C Red No. 30, and in accordance with 5 U.S.C. 553(d) (1) and (3), this regulation is being made effective on May 30, 1982.

List of Subjects in 21 CFR Part 81

Color additives, Cosmetics, Drugs.

Therefore, under the Transitional Provisions of the Color Amendments of 1960 to the Federal Food, Drug, and