

such other reports of efforts to divest the Assets as may be required by the Commission.

XVI

In the event RSR, as a result of the enforcement of a bona fide lien, mortgage, deed of trust or other form of security, reacquires possession of any of the divested Assets, RSR shall so notify the Commission within 30 days of such repossession, and within one year thereafter shall divest the reacquired Assets in accordance with the terms and conditions set by the Commission.

By direction of the Commission.

Issued: September 12, 1983.

Emily H. Rock,
Secretary.

[FR Doc. 83-26212 Filed 9-27-83; 8:45 am]

BILLING CODE 6750-01-M

SECURITIES AND EXCHANGE COMMISSION

17 CFR Part 210

[Release Nos. 33-6483; 34-20186; 35-23060; FR-14; S7-956]

Oil and Gas Producers; Full Cost Accounting Practices; Amendment of Rules

AGENCY: Securities and Exchange Commission.

ACTION: Final rules.

SUMMARY: The Commission is adopting amendments to its rules for application of the full cost method of accounting by oil and gas producers to permit the general exclusion of all unevaluated costs from immediate amortization. The Commission is also adopting requirements to provide for more specific disclosures of the category and age of such excluded costs. The amendments are intended to narrow the diversity of practice resulting from varying interpretations of the Commission's existing rules which permit the exclusion from amortization of "unusually significant" costs of unproved properties and major development projects.

EFFECTIVE DATE: The rules for cost exclusions are effective for costs incurred in fiscal years beginning after December 15, 1983. However, the disclosure provisions shall be effective for financial statements covering fiscal years ending after December 15, 1983.

FOR FURTHER INFORMATION CONTACT: John W. Albert or Lawrence S. Jones (202-272-2130), Office of the Chief Accountant, Securities and Exchange Commission, Washington, D.C. 20549.

SUPPLEMENTARY INFORMATION: The Securities and Exchange Commission is adopting final rules which amend its requirements for application of the full cost method of accounting by oil and gas producers to permit the general exclusion of all unevaluated costs from immediate amortization. However, the costs of exploratory dry holes are considered to be evaluated costs under the amended rules and therefore are to be immediately included in the amortization base. The amended rules also provide for (1) use of an aggregate estimate of impairment on individually insignificant properties; and (2) allocations of costs of major development projects based on ultimate expected reserves or on the projected total number of wells drilled, depending on which is more appropriate in the circumstances. Amendments are also being adopted to provide for more specific disclosures of the category and age of excluded costs.

The proposing release related to these final rules also included provisions related to income recognition on the sale or transfer of oil and gas producing properties. As discussed more fully in the proposing release (Release No. 33-6484) being issued concurrently, the Commission is reproposing rules on this issue. However, the final rules do include an amendment to the provisions for income recognition to clarify that the rules apply equally to all properties held for production, regardless of whether or not they are being amortized currently.

Background

On December 21, 1982, the Commission issued Securities Act Release No. 33-6445 (47 FR 58281) which proposed amendments to its rules on application of the full cost method of accounting by oil and gas producers. The proposed amendments were intended to clarify the criteria for determining (1) which capitalized costs may be excluded from immediate amortization and (2) when gain or loss on the sale or transfer of oil and gas producing properties may be recognized.

The Commission issued the proposed rule amendments because it was aware of a significant lack of consistency in the application of its existing rules. The Commission was concerned that the extensive diversity in current practice created serious problems of comparability among companies which are in essentially similar circumstances and ostensibly use the same method of accounting for their oil and gas producing activities.

With respect to the issue of exclusions of costs from the full-cost amortization base, the Commission identified two

alternative approaches for amended rules. The first proposed alternative was to permit exclusion of all unevaluated costs in a cost center from the amortization base, while the second alternative was based on the concept of always including a normal inventory of unevaluated costs in the amortization base. The Commission also invited commentators to suggest any other appropriate criteria for determining exclusions from current amortization.

The Commission's proposed rules relating to income recognition on sales or other conveyances of oil and gas properties retained in place the existing general rule that the proceeds received from sales of mineral properties by full cost companies should ordinarily be treated as adjustments of capitalized costs with no gain or loss recognized, except where a sale caused a significant alteration in the relationship between costs and reserves in a cost center. The proposal would have established an exception to this general prohibition against income recognition for sales or properties segregated and accounted for as a separate lease brokerage business. The proposed amendments also clarified that the general prohibition applies to all properties held for production purposes, regardless of whether or not such properties are being amortized currently.

The lease brokerage exception was based on the concept that oil and gas companies may be involved in two separate aspects of the oil and gas business—the one being oil and gas exploration and production and the other lease brokerage activities. The amendments proposed to restrict gain or loss recognition to properties segregated and accounted for as a distinct lease brokerage operation and to clarify that income recognition was not appropriate for typical "farm-out" or production arrangements, which are primarily financing or risk-sharing transactions.

Evaluation of Comments

The Commission received 47 comment letters addressing the criteria for exclusion of costs from the amortization base. Approximately two thirds of the commentators expressed support for the first proposed alternative, which would permit the exclusion of all unevaluated costs for immediate amortization.

These commentators indicated that the full exclusion method was more objective and easier to apply than other alternatives, and also asserted that this method would achieve greater consistency and comparability in financial reporting. One analyst group criticized the existing rules as too

discretionary to allow comparability and viewed the first alternative as a more precise, consistent, and cost-effective method. Supportive commentators also viewed this approach as providing for a better matching of amortization of evaluated costs with the revenues from production of the related proved reserves. Other commentators supported this method on the basis that it appropriately would allow for capitalization of interest on unevaluated costs.

At the same time, certain commentators supporting a blanket exclusion recommended that the guidance provided under this alternative be modified in three respects: (1) The commentators suggested that the proposal to require that excluded properties be assessed individually for impairment would often be impracticable in cases where there are large numbers of properties with individually insignificant costs. Instead, these commentators suggested permitting an aggregate estimation of impairment of such properties, based on historical experience or some other factors. (2) Several commentators argued that dry hole cost are nonproductive costs which constitute evidence of impairment and should thus be considered as evaluated and included in the full cost amortization base. (3) Certain commentators also suggested that the proposed guidance relating to the allocation of costs incurred or to be incurred of major development projects be broadened to permit an alternative allocation method based on total expected proved reserves.

Normal Inventory Concept

Only a few commentators expressed support for the Commission's second proposed alternative, which was to permit exclusion of unevaluated costs in excess of a normal inventory of such costs, computed based on specific percentage criteria. Supportive commentators viewed the normal inventory method as a reasonable and workable compromise between immediate amortization of all unevaluated costs and full exclusion of all unevaluated costs. These commentators rejected immediate amortization on the basis that it would misstate financial results by understating both income and asset values in early years. They also opposed full exclusion because they believe that method would front-end income by deferring normal and unavoidable nonproductive costs.

some other method also specifically opposed the normal inventory approach. The opposition was generally based on the view that the proposed percentage criteria were arbitrary and the implementation of the three-year moving average would be complex without any offsetting benefits in terms of providing data useful for analysis of financial results. These commentators also criticized the normal inventory method as being based on the invalid assumption that all companies have comparable exploration and development strategies and philosophies. The commentators thus questioned whether the computed "normal inventory" would realistically represent any individual company's situation.

Other Suggested Alternatives

Approximately one fourth of the commentators responded to the Commission's invitation to suggest alternatives other than the two specifically identified in the proposing release. Among this group, the most frequently suggested approaches were maintenance of the existing rules which permit exclusion of "unusually significant" costs and a prohibition against any exclusions.

Commentators advocating retention of the existing rules expressed differing views as to whether the rules should provide specific guidance for the determination of "unusual significance" or whether the rules should rely on management judgment. Commentators advocating no exclusion of costs from amortization based their position in consistency with the original full cost theory and on general revenue recognition concepts—that is, immediate inclusion prevents the future distortion of the asset base and amortization rate which would result from initial deferral of unproductive costs.

Discussion of Final Rules

In adopting final rules on this issue, the Commission agrees with the majority of commentators that it is appropriate to permit the exclusion of substantially all unevaluated costs from current amortization. The Commission concurs with the majority of the commentators that this approach is objective and conducive to consistent, comparable application. The Commission also believes that it properly associates evaluated costs with proved (or evaluated) reserves. Moreover, since unevaluated properties are required to be assessed periodically for impairment and to have value at

exclusion from immediate amortization should not distort future income statements by postponing the recognition of nonproductive costs.

In view of the importance of timely assessment of impairment, the Commission is modifying its original proposals in several respects suggested by the commentators. First the Commission finds convincing the arguments that drilling a dry hole on an unevaluated property provides evidence of impairment of the lease carrying costs at least to the extent of the dry hole costs. Accordingly, the final rules specify that dry hole costs should be included in the amortization base immediately upon determination that the well is dry. The Commission believes that drilling a dry hole also may be an indication that part or all of the other related leasehold carrying costs (property acquisition costs, related geological and geophysical costs, and other costs) have been impaired. Accordingly, the Commission cautions registrants to assess such leasehold costs particularly closely.

With respect to the assessment of impairment generally, the Commission also sees merit in the suggestion that an aggregate assessment of impairment be permitted on individually insignificant properties, and the final rules have been revised to permit, but not require, that approach. The rules do not include any specific guidance on the determination of "significance." However, the Commission believes that in general individual properties or projects would be expected to be individually significant if their costs exceed 10% of the net capitalized costs of the cost center. Where individual properties or projects with costs representing less than 10% of the cost center are involved, the Commission believes it is still appropriate to test impairment on an individual basis but will permit companies to aggregate such properties for purposes of this assessment.

In addition, the final rules revise the proposed guidance for allocation of costs on major development projects for purposes of transfers to the amortization base. On this issue, the Commission has concluded, as suggested by commentators, that it is appropriate to allow allocation, either on the basis of the ratio of wells to which proved reserves have been assigned to the total expected number of wells or on the basis of the ratio of proved reserves already established to total proved reserves ultimately expected, whichever

Finally, the Commission is revising its disclosure requirements to provide for more specific information as to the category and age of capitalized costs excluded from current amortization. Because the rules being adopted in this release will have a significant effect on the financial condition and operating results of full cost oil and gas producers, the Commission believes it appropriate to provide for specific information as to the nature of these costs. Consequently, the Commission's existing requirements for disclosure of the nature of costs by category and approximate date such costs were first incurred are also being expanded to require footnote disclosure in tabular form as to the age and category of costs excluded from current amortization.

The revised rules call for an aging of excluded costs as of a registrant's most recent fiscal year end both by category and by date incurred. Disclosure is required of the amounts of each category of excluded costs (1) In total as of the end of the most recent fiscal year, (2) separately by year for amounts incurred in each of the three most recent fiscal years, and (3) in the aggregate for costs incurred in any earlier fiscal years. Categories of cost are to include acquisition costs, exploration costs, development costs in the case of significant development projects, and interest capitalized.

In addition, existing requirements for balance sheet disclosure of the aggregate amount of excluded costs and footnote description of the current status of the projects or properties involved, including information as to the timing of the inclusion of the costs in the amortization computation, have been carried forward in the revised rules. However, the existing requirement to disclose the potential future impact on the amortization rate of excluded costs has been deleted based on experience which has shown that many companies are unable to calculate this information. In complying with the requirements to describe the current status of properties or projects excluded from amortization, registrants may find it appropriate to provide the information as to the age and category of excluded costs in a format which distinguishes offshore and onshore properties.

In taking final action on this issue, the Commission is rejecting the normal inventory method as a basis for final rules in this area. The Commission finds persuasive the arguments of various commentators that the normal inventory method should not be adopted because it is conceptually inferior to full exclusion and, due to its arbitrary and

complex nature, not sufficiently representative of an individual company's situation. The Commission appreciates the arguments of certain commentators that some level of nonproductive costs is unavoidable and shares the concern that unrecoverable costs should not be excluded from amortization. However, the Commission does not find that these arguments provide compelling support for the normal inventory method. Rather, the Commission believes these concerns underscore the need for the modifications to the original proposal to require the immediate inclusion of dry hole costs in the amortization base and to permit an aggregate assessment of impairment for individually insignificant properties.

While the final rules permit the general exclusion of all unevaluated costs from immediate amortization, the Commission emphasizes that as soon as it can be determined whether or not proved reserves can be assigned, the related costs should be included in the amortization base. Once these costs are included in the amortization base, they lose their identity for all future accounting purposes. Consequently, individual cost elements cannot subsequently be removed from this base.

Transition Provisions

The amended rules for cost exclusions shall be applied prospectively effective for costs incurred in fiscal years beginning after December 15, 1983. Earlier application is permitted in financial statements for fiscal years beginning prior to that date. However, annual financial statements previously filed with the Commission shall not be restated. The disclosure provisions of the amended rules shall be effective for financial statements covering fiscal years ending after December 15, 1983.

Technical Amendments

The Commission is also adopting technical amendments to its requirements for disclosure of oil and gas reserve information to specify that the maximum period for presentation of an earnings summary prepared on basis of Reserve Recognition Accounting is limited to three years. These requirements apply only for periods for which FASB Statement 69 disclosures are not provided. The Commission is also revising the authority section originally cited in Financial Reporting Release 12.

Codification Update

The "Codification of Financial Reporting Policies" announced in

Financial Reporting Release No. 1 (April 15, 1982) [47 FR 21028] is updated to:

1. Remove Section 406.01.c.i and add a new Section 406.01.c.i as follows:

406.01.c Full Cost Method

1. Exclusion of capitalized costs.
2. Include in Section 406.01.c.i the section of this release entitled "Discussion of Final Rules."

This codification is a separate publication issued by the Commission. It will not be published in the Federal Register/Code of Federal Regulations.

Regulatory Flexibility Act Analysis

Pursuant to the Regulatory Flexibility Act, 5 U.S.C. 604(a), the Commission has prepared a final regulatory flexibility analysis of the economic impact which the amendments proposed herein will have on small entities. This analysis is attached to this release.

List of Subjects in 17 CFR Part 210

Accounting, Reporting and recordkeeping requirements, Securities.

Text of Rules

Chapter II of Title 17 of the Code of Federal Regulations is amended as follows:

PART 210—FORM AND CONTENT OF AND REQUIREMENTS FOR FINANCIAL STATEMENTS, SECURITIES ACT OF 1933, SECURITIES EXCHANGE ACT OF 1934, PUBLIC UTILITY HOLDING COMPANY ACT OF 1935, INVESTMENT COMPANY ACT OF 1940, AND ENERGY POLICY AND CONSERVATION ACT OF 1975

1. By revising paragraphs (i)(3)(ii), (i)(6)(i) and (i)(7)(ii), (k)(7) first sentence of introductory text, (k)(8) first sentence of introductory text, and by adding new paragraph (i)(3)(ii)(C) of § 210.4-10 as follows:

§ 210.4-10 Financial accounting and reporting for oil and gas producing activities pursuant to the Federal securities laws and the Energy Policy and Conservation Act of 1975.

(i) Application of the full cost method of accounting.

(3) Amortization of capitalized costs.

(ii) The cost of investments in unproved properties and major development projects may be excluded from capitalized costs to be amortized, subject to the following:

(A) All costs directly associated with the acquisition and evaluation of unproved properties may be excluded from the amortization computation until

it is determined whether or not proved reserves can be assigned to the properties, subject to the following conditions: (1) Until such a determination is made, the properties shall be assessed at least annually to ascertain whether impairment has occurred. Unevaluated properties whose costs are individually significant shall be assessed individually. Where it is not practicable to individually assess the amount of impairment of properties for which costs are not individually significant, such properties may be grouped for purposes of assessing impairment. Impairment may be estimated by applying factors based on historical experience and other data such as primary lease terms of the properties, average holding periods of unproved properties, and geographic and geologic data to groupings of individually insignificant properties and projects. The amount of impairment assessed under either of these methods shall be added to the costs to be amortized. (2) The costs of drilling exploratory dry holes shall be included in the amortization base immediately upon determination that the well is dry. (3) If geological and geophysical costs cannot be directly associated with specific unevaluated properties, they shall be included in the amortization base as incurred. Upon complete evaluation of a property, the total remaining excluded cost (net of any impairment) shall be included in the full cost amortization base.

(B) Certain costs may be excluded from amortization when incurred in connection with major development projects expected to entail significant costs to ascertain the quantities of proved reserves attributable to the properties under development (e.g., the installation of an offshore drilling platform from which development wells are to be drilled, the installation of improved recovery programs, and similar major projects undertaken in the expectation of significant additions to proved reserves). The amounts which may be excluded are applicable portions of (1) the costs that relate to the major development project and have not previously been included in the amortization base, and (2) the estimated future expenditures associated with the development project. The excluded portion of any common costs associated with the development project should be based, as is most appropriate in the circumstances, on a comparison of either (i) existing proved reserves to total proved reserves expected to be established upon completion of the project, or (ii) the number of wells to

which proved reserves have been assigned and total number of wells expected to be drilled. Such costs may be excluded from costs to be amortized until the earlier determination of whether additional reserves are proved or impairment occurs.

(C) Excluded costs and the proved reserves related to such costs shall be transferred into the amortization base on an ongoing (well-by-well or property-by-property) basis as the project is evaluated and proved reserves established or impairment determined. Once proved reserves are established, there is no further justification for continued exclusion from the full cost amortization base even if other factors prevent immediate production or marketing.

(6) *Mineral property conveyances and related transactions.* * * *

(i) *Sales and abandonments of oil and gas properties.* Sales of oil and gas properties, whether or not being amortized currently, shall be accounted for as adjustments of capitalized costs, with no gain or loss recognized, unless such adjustments would significantly alter the relationship between capitalized costs and proved reserves of oil and gas attributable to a cost center. For instance, a significant alteration would not ordinarily be expected to occur for sales involving less than 25 percent of the reserve quantities of a given cost center. If gain or loss is recognized on such a sale, total capitalization costs within the cost center shall be allocated between the reserves sold and reserves retained on the same basis used to compute amortization, unless there are substantial economic differences between the properties sold and those retained, in which case capitalized costs shall be allocated on the basis of the relative fair values of the properties. Abandonments of oil and gas properties shall be accounted for as adjustments of capitalized costs; that is, the cost of abandoned properties shall be charged to the full cost center and amortized (subject to the limitation on capitalized costs in paragraph (b) of this section).

(7) *Disclosures.* * * *

(ii) State separately on the face of the balance sheet the aggregate of the capitalized costs of unproved properties and major development projects that are excluded, in accordance with paragraph (i)(3) of this section, from the capitalized costs being amortized. Provide a description in the notes to the financial statements of the current status of the significant properties or projects

involved, including the anticipated timing of the inclusion of the costs in the amortization computation. Present a table that shows, by category of cost, (A) the total costs excluded as of the most recent fiscal year; and (B) the amounts of such excluded costs, incurred (1) in each of the three most recent fiscal years and (2) in the aggregate for any earlier fiscal years in which the costs were incurred. Categories of cost to be disclosed include acquisition costs, exploration costs, development costs in the case of significant development projects and capitalized interest.

(k) *Disclosure of oil and gas reserve information and historical financial data.* * * *

(7) *Summary of oil and gas producing activities.* For each fiscal year for which an income statement is required a summary shall be presented that sets forth the current year's additions and revisions to the Present Value of Estimated Future Net Revenues, and the costs associated with the additions and revisions to proved oil and gas reserves, together with all costs determined to be nonproductive during the period. * * *

(8) *Summary of changes in Present Value of Estimated Future Net Revenues.* For each fiscal year for which an income statement is presented, provide a reconciliation between the total Present Value of Estimated Future Net Revenues of an entity's proved oil and gas reserves at the beginning and end of the year. * * *

2. Correction of Financial Reporting Release 12.

The authority section included in Financial Reporting Release 12, 48 FR 36566 on page 36569, third column, first 5 lines was incorrect. The authority section should have read as follows:

"These amendments are adopted pursuant to the authority in Sections 5, 6, 7, 10, 19(a) and Schedule A[25] and [26] of the Securities Act of 1933, 15 U.S.C. 77e, 77f, 77g, 77j, 77s[a] and 77aa[25] and [26]; and Sections 12, 13, 14, 15(d), and 23(a) of the Securities Exchange Act of 1934, 15 U.S.C. 78l, 78m, 78n, 78o(d), and 78w(a)."

Authority: These amendments are adopted pursuant to the authority in Sections 5, 6, 7, 8, 10, 19(a) and Schedule A[25] and [26] [15 U.S.C. 77e, 77f, 77g, 77h, 77j, 77s(a) and 77aa[25] and [26]] of the Securities Act of 1933; Sections 12, 13, 14, 15(d) and 23(a) [15 U.S.C. 78l, 78m, 78n, 78o(d), 78w(a)] of the Securities Exchange Act of 1934; Sections 5(b), 14 and 20(a) [15 U.S.C. 79e(b), 79n, 79f(a)] of the Public Utility Holding Company

Act of 1935 and Section 503 [42 U.S.C. 6383] of the Energy Policy and Conservation Act of 1975.

By the Commission.

George A. Fitzsimmons,

Secretary.

September 16, 1983.

Final Regulatory Flexibility Analysis

This final regulatory flexibility analysis, which relates to amendments of the Regulation S-X rules for application of the full cost method of accounting by oil and gas producers, has been prepared in accordance with 5 U.S.C. 604(a). The corresponding initial regulatory flexibility analysis appears at 47 FR 58286 (Release No. 33-6445).

1. *Need for and Objectives of Rule*—As discussed in the section of the release entitled, "Background," the Commission became aware of widely varying interpretations of the existing provisions of Regulation S-X which allow oil and gas producing companies using the full cost method to exclude certain capitalized costs from immediate amortization. The Commission is concerned that the resulting diversity in practice creates a serious lack of comparability between financial statements of companies which are essentially in similar circumstances and are using the same basic method of accounting. The financial statement impact of the reduced current amortization expense resulting from the exclusions is intensified because under generally accepted accounting principles (GAAP) excluded properties are usually eligible for interest capitalization.

The objective of the rule amendments is to narrow the diversity of current practice resulting from varying interpretations of the previously existing rules. To that end, the amendments clarify the criteria for exclusion of capitalized costs from immediate amortization.

2. *Issues Raised by Public Comments*—The only commentator to specifically address the Initial Regulatory Flexibility Analysis published with the proposed rules discussed the proposed gain recognition rules. This comment is addressed in the Initial Regulatory Flexibility Analysis of the revised rules related to gain recognition being proposed in a release issued concurrently.

3. *Significant Alternatives*—With respect to the criteria for exclusions from current amortization, the proposing release was specifically drafted to encourage consideration of alternative approaches which would achieve the stated objective of reducing the current diversity in practice. The release therefore proposed two separate sets of

rule amendments which embodied considerably different approaches to the issue. The release also explicitly encouraged commentators to discuss other possible criteria.

Consideration of differing reporting or compliance requirements or reporting timetables that take into account different resources of small entities is not necessary since the amendments do not change the recordkeeping requirements or other compliance burdens. Furthermore, since the amendments involve fundamental accounting issues for full cost oil and gas producing companies, and since comparability of financial statements is an essential aspect of accounting and financial reporting, an exemption or an alternative approach designed particularly for small entities would not be appropriate. Moreover, the large majority of registrant commentators supported the alternative which was adopted in the final rules on exclusions. They cited objectivity and ease of application as factors in favor of this approach.

In the Commission's view, the fundamental performance standard for financial reporting is the presentation of all information material for rational investment decisions. The existence of many alternative approaches to disclosure may result in reduced comparability in the data reported and the form of presentation, thereby adversely affecting the ability to analyze the financial statements. Because comparability in financial reporting is important in evaluating issuers' operational and managerial performance, the Commission has historically acted to minimize excessive diversity in reporting of material information when it occurs among companies in essentially the same circumstances. This is generally accomplished by establishing design standards for reporting as the Commission seeks to do in the present case with full cost accounting by oil and gas producers.

[FR Doc. 83-26439 Filed 9-27-83; 8:45 am]

BILLING CODE 8010-01-M

17 CFR Parts 239 and 274

[Release Nos. 33-6454, IC-13049; File No. S7-963]

Advertising by Investment Companies

Correction

In FR Doc. 83-6342 beginning on page 10297 in the issue of Friday, March 11, 1983, make the following corrections:

1. In §§ 239.15 and 274.11, item 17, on page 10300, third column, twelve lines from the bottom, insert a parenthesis between the equal sign and the word "base".

2. On page 10301, in the appendix, in the line for "Net change in account value", there should be a dollar sign in front of the figure.

3. After the lines for "Seven days proportional charge . . ." and "Adjusted change in account value", there should have been equal signs.

4. In the line for "Base period return . . .", the figure in the right-hand column now reading "0.01804320" should have read "0.001804320".

BILLING CODE 1505-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 73

[Docket No. 83C-0051]

Listing of Color Additives for Coloring Contact Lenses; Correction

AGENCY: Food and Drug Administration.

ACTION: Final rule; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting the document that amended the color additive regulations to provide for the safe use of four color additives for coloring contact lenses. This document corrects an erroneous statement.

EFFECTIVE DATE: August 8, 1983.

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

SUPPLEMENTARY INFORMATION: In FR Doc. 83-18370 appearing at page 31374 in the issue for Friday, July 8, 1983, the following correction is made on page 31375: In the second column, the first sentence of the second full paragraph is revised to read "FDA will issue shortly a separate order for dibromodibenzo[b, def]chrysene-7,14-dione and is deferring final action on the color additive 6,6'-diethoxy-2,2'-(3H,3'H)bibenzo[b] thiophene-3,3'dione pending receipt and evaluation of additional studies."

Dated: September 22, 1983.

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

[FR Doc. 83-26347 Filed 9-27-83; 8:45 am]

BILLING CODE 4160-01-M

21 CFR Part 175

[Docket No. 82F-0046]

Indirect Food Additives: Adhesive Coatings and Components

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

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of ethylene oxide adduct of 2,4,7,9-tetramethyl-5-decyn-4,7-diol as an adjuvant in can coating formulations. This action is in response to a petition filed by Air Products & Chemicals, Inc.

DATES: Effective September 28, 1983, objections by October 28, 1983.

ADDRESS: Written objections to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Julius Smith, Bureau of Foods (HFF-334), Food and Drug Administration, 200 C ST. SW., Washington, DC 20204, 020-472-5690.

SUPPLEMENTARY INFORMATION: In a notice published in the Federal Register of March 19, 1982 (47 FR 11970), FDA announced that a petition (FAP OB3515) had been filed by Air Products & Chemicals, Inc., Box 538, Allentown, PA 18105, proposing that § 175.300 (b)(3)(xxix) (21 CFR 175.300(b)(3)(xxix)) of the food additive regulations be amended to provide for the safe use of ethylene oxide adduct of 2,4,7,9-tetramethyl-5-decyn-4, 7-diol as an adjuvant in can coating formulations. FDA has evaluated data in the petition and other relevant material and concludes that the proposed food additive use is safe and that § 175.300 should be amended as set forth below.

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Bureau of Foods (address above) by appointment with the information contact person listed above. As provided in § 171.1 (h)(2), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

The agency has carefully considered the potential environmental effects of this action and has concluded that the action will not have a significant impact on the human environment and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence

supporting that finding may be seen in the Dockets Management Branch (address above), between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 175

Adhesives, Food additives, Food packaging.

PART 175—INDIRECT FOOD ADDITIVES: ADHESIVE COATINGS AND COMPONENTS

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 201(s), 409, 72 Stat. 1784-1788 as amended (21 U.S.C 321(s), 348)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10), Part 175 is amended in § 175 is amended in § 175.300(b)(3)(xxix) by alphabetically inserting a new item in the list of substances to read as follows:

§ 175.300 Resinous and polymeric coatings.

- • • • •
- (b) • • •
- (3) • • •
- (xxix) • • •

Ethylene oxide adduct of 2,4,7,9-tetramethyl-5-decyn-4,7-diol (CAS Reg. No. 9014-85-1).

Any person who will be adversely affected by the foregoing regulation may at any time on or before October 28, 1983 submit to the Dockets Management Branch (address above) written objections thereto and may make a written request for a public hearing on the stated objections. Each objection shall be separately numbered and each numbered objection shall specify with particularity the provision of the regulation to which objection is made. Each numbered objection on which a hearing is requested shall specifically so state; failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held; failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this regulation. Received objections may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Effective date. This regulation shall become effective September 28, 1983.

(Secs. 201(s), 409, 72 Stat. 1784-1788 as amended (21 U.S.C. 321(s), 348))

Dated: September 23, 1983.

Joseph P. Hile,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 83-26337 Filed 9-27-83; 8:45 am]

BILLING CODE 4160-01-M

21 CFR Part 520

Oral Dosage Form New Animal Drugs Not Subject To Certification; Febantel-Trichlorfon Paste

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

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a new animal drug application (NADA) filed by Bayvet Division of Miles Laboratories, Inc., providing for safe and effective use of febantel-trichlorfon oral paste as an anthelmintic and boticide for horses.

EFFECTIVE DATE: September 28, 1983.

FOR FURTHER INFORMATION CONTACT: Sandra K. Woods, Bureau of Veterinary Medicine (HFV-114), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3240.

SUPPLEMENTARY INFORMATION: Bayvet Division of Miles Laboratories, Inc., P.O. Box 390, Shawnee Mission, KS 66201, filed NADA 131-412, which provides for use of a febantel-trichlorfon oral paste (Combotel Paste and Negabot® Plus Paste) to treat horses for infections of large and small strongyles, adult and immature ascarids, adult and 4th stage larval pinworms, and mouth and stomach stages of bots. Febantel is approved for use in horses in 21 CFR 520.903a. Trichlorfon is approved in horses in 21 CFR 520.2520d. Febantel suspension and trichlorfon oral liquid in combination are approved for use in horses in 21 CFR 520.903b. The NADA is approved and the regulations are amended to reflect the approval. The basis for approval of this NADA is discussed in the freedom of information summary.

In accordance with the Freedom of information provisions of Part 20 (21 CFR Part 20) and § 514.11(e)(2)(ii) (21 CFR 514.11(e)(2)(ii)), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers