

revocation will become final through the issuance of a written decision to the laboratory in the event that the laboratory does not appeal the proposed denial or revocation within the thirty-day period.

(2) If accreditation is revoked, the laboratory may be given the option of voluntarily terminating the accreditation.

(3) A laboratory whose accreditation has been revoked must cease use of the NVLAP logo on any of its reports, correspondence, or advertising related to the area(s) affected by the revocation. If the revocation is total, NVLAP will instruct the laboratory to return its Certificate and Scope of Accreditation and to remove the NVLAP logo from all test or calibration reports, correspondence, or advertising. If the revocation affects only some, but not all of the items listed on a laboratory's Scope of Accreditation, NVLAP will issue a revised Scope that excludes the revoked area(s) in order that the laboratory might continue operations in accredited areas.

(d) A laboratory whose accreditation has been voluntarily terminated, denied or revoked, may reapply and be accredited if the laboratory:

(1) Completes the assessment and evaluation process; and

(2) Meets the NVLAP conditions and criteria for accreditation.

§ 285.14 Criteria for accreditation.

The requirements for laboratories to be recognized by the National Voluntary Laboratory Accreditation Program as competent to carry out tests and/or calibrations are contained in clauses 4 and 5 of ISO/IEC 17025, General requirements for the competence of testing and calibration laboratories, including revisions from time to time.

§ 285.15 Obtaining documents.

(1) Application forms, NVLAP handbooks, and other NVLAP documents and information may be obtained by contacting the NVLAP, National Institute of Standards and Technology, 100 Bureau Drive, Mail Stop 2140, Gaithersburg, Maryland 20899-2140; phone: 301-975-4016; fax: 301-926-2884; e-mail: nvlap@nist.gov.

(b) Copies of all ISO/IEC documents are available from the American National Standards Institute, 11 West 42nd Street, 13th Floor, New York, New York, 10036; phone: 212-642-4900; fax: 212-398-0023; web site:

www.ansi.org. You may inspect copies of all applicable ISO/IEC documents at the National Voluntary Laboratory Accreditation Program, National Institute of Standards and

Technology, 820 West Diamond Avenue, Room 297, Gaithersburg, MD.

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BILLING CODE 3510-13-M

COMMODITY FUTURES TRADING COMMISSION

17 CFR Part 4

Extension of Time To File Annual Reports for Commodity Pools

AGENCY: Commodity Futures Trading Commission.

ACTION: Proposed rule amendments.

SUMMARY: Commodity Futures Trading Commission ("Commission") Rules 4.22(c) and (d)¹ require that commodity pool operators ("CPOs") distribute annual reports containing specified information, certified by an independent public accountant, to each pool participant within 90 calendar days after the end of the pool's fiscal year.² The proposed revisions to Rule 4.22 would permit CPOs to file a claim for an extension of time to file the pool's annual report where the pool is invested in other collective investment vehicles, and the CPO's independent accountant cannot obtain the information necessary to comply with the rule in a timely manner.

DATES: Comments must be received by December 7, 2000.

ADDRESSES: Interested persons should submit their views and comments to Jean A. Webb, Secretary of the Commission, Commodity Futures Trading Commission, 1155 21st Street, N.W., Washington, DC 20581. In addition, comments may be sent by facsimile transmission to facsimile number (202) 418-5521, or by electronic mail to secretary@cftc.gov. Reference should be made to "Extension of Time to File Annual Reports for Commodity Pools."

FOR FURTHER INFORMATION CONTACT:

Kevin P. Walek, Assistant Director, Division of Trading and Markets, Commodity Futures Trading Commission, 1155 21st Street, NW., Washington, DC 20581. Telephone: (202) 418-5463; electronic mail: kwalek@cftc.gov.

SUPPLEMENTARY INFORMATION:

¹ Commission rules referred to herein can be found at 17 CFR Ch. I (2000).

² Rule 4.7(b)(3) provides the requirements for annual report filings for pools for which exemption from the specific requirements of Rules 4.22(c) and (d) has been claimed pursuant to Rule 4.7(b)(3)(i).

I. Background

Commission Rule 4.22(c) requires a CPO to distribute to pool participants, and file with the Commission, an Annual Report containing specified financial information for each pool that it operates. The annual report requirement is intended to ensure that the CPO is dealing fairly with its participants and to provide a mechanism to facilitate the Commission's inspection of the registrant's operations. Rule 4.22(d) requires that an independent public accountant certify the financial statements contained in the Annual Report. The CPO must file this certified Annual Report within 90 days of the close of the pool's fiscal year. Rule 4.22(f) currently allows CPOs to apply for extensions of the 90-day time requirement where the CPO cannot distribute the report in the required time period without "substantial undue hardship." The Commission has had the benefit of the assistance of National Futures Association ("NFA") in processing these requests.

In recent years, the number of extensions has risen dramatically.³ The majority of such requests are made by CPOs of commodity pools that invest in other collective investment vehicles. (These commodity pools are commonly referred to as "funds of funds.") The CPOs of these funds of funds have explained that they cannot obtain the information necessary for their independent public accountants to finish auditing the pools' financial statements by the time specified in Rule 4.22(c). In order to complete the audit of the financial statements of the pool, the independent public accountant needs information establishing the value of the pool's material investments. These investments may be in a number of collective investment vehicles, such as other commodity pools, securities funds, or hedge funds, both domestic and offshore. The information that the independent accountant requires is frequently unavailable until the collective investment vehicles complete their own certified financial statements. Thus, in many cases, the CPO cannot obtain the information its independent accountant requires about the collective investment vehicle in time for the pool's Annual Report to be prepared, audited, and distributed by the due date.

Due to the increasing number of requests for extensions of time to file annual reports for funds of funds, the Commission proposes to amend its

³ For filing year 1998 there were more than 200 such extensions and for filing year 1999 there were over 300 such extensions.

regulations to make these extensions available on a standardized basis. In order to treat similarly situated pools fairly and equitably, the Commission proposes that the rules contained herein apply whether or not a CPO was previously granted an extension of time to file the annual reports of funds of funds. As detailed in the next section, CPOs would file the initial notice, containing specified representations, in advance of the annual report's due date for the first year the extension is claimed. In subsequent years, the representations could be made in a statement filed at the same time as the pool's Annual Report.

II. Description of the Proposed Extension

The proposed extension provisions would be added to existing Rule 4.22(f), which will be reorganized and renumbered, as discussed further below. The salient features of the extension provisions are proposed to be included in Rule 4.22(f)(2) as follows.

Subparagraph (i) requires that the pool's first notice claiming the extension be filed within 90 days after the end of the pool's fiscal year (the normal deadline for filing the annual report). Subparagraph (ii) requires that the CPO identify itself and the pool for which the request is being made. Subparagraph (iii) requires that the CPO indicate the date by which it intends to file and distribute the annual report, which date must be no more than 150 calendar days after the end of the pool's fiscal year (that is, a maximum extension of 60 days). Thus, the CPO must analyze the circumstances related to the operation of its pool and specify the period for which relief is needed. Commission staff have reviewed past requests and found that, in general, the requested extension period ranged from 30 to 60 days. Thus, the Commission believes that up to a 60 day extension should be sufficient in most situations. Subparagraph (iv) requires that the CPO provide, as part of the notice, specified representations demonstrating the need for the extension. The CPO will not be required to obtain a written statement from the independent accountant selected to audit the pool confirming that information in the CPO's notice. The CPO will be required to name the independent accountant who has informed the CPO of the necessity of that information. Subparagraph (v) provides that, in subsequent years, the requisite representations may be made in a statement filed at the same time as the annual report. Finally, subparagraph (vi) requires that the CPO responsible

for the pool's operation sign the notice or statement.

III. Technical Changes to Rule 4.22(f)

The new fund of funds extension provisions are proposed to be added as Rule 4.22(f)(2). Existing Rule 4.22(f) would be retained. Current subsections 4.22(f)(1), 4.22(f)(2) and 4.22(f)(3) are proposed to be renumbered as subsections 4.22(f)(1)(i) through (iii), respectively.

IV. Additional Consideration Regarding Rule 4.7 Entities

Pursuant to Commission Rule 4.7, CPOs of pools whose participants are limited to qualified eligible persons⁴ may claim exemption from certain Part 4 requirements. Among the provisions from which the CPO may claim relief is the requirement that the exempt pool's financial statements distributed to pool participants be certified by an independent public accountant. In the experience of Commission staff, most CPOs operating pools for which relief under Rule 4.7 has been claimed nonetheless obtain certified financial statements to include in their annual report. The Commission does not wish to discourage this practice. Therefore, CPOs may claim the relief provided in proposed Rule 4.22(f)(2) without regard to whether they have claimed relief pursuant to Rule 4.7. This point is clarified in proposed Rule 4.22(f)(2).

V. Related Matters

A. Regulatory Flexibility Act

The Regulatory Flexibility Act ("RFA"), 5 U.S.C. 601-611 (1994), requires that agencies, in proposing rules, consider the impact of those rules on small businesses. The Commission has previously established certain definitions of "small entities" to be used by the Commission in evaluating the impact of its rules on such entities in accordance with the RFA.⁵ The Commission previously has determined that registered CPOs are not small entities for the purpose of the RFA.⁶ Therefore, the Chairman, on behalf of the Commission, hereby certifies, pursuant to 5 U.S.C. 605(b), that the rule amendments proposed herein, if adopted, will not have a significant economic impact on a substantial number of small entities.

⁴ The criteria for qualified eligible persons are contained in Rule 4.7(a), as amended effective August 4, 2000 (65 FR 67848 (August 4, 2000)).

⁵ 47 FR 18618-18621 (April 30, 1982).

⁶ 47 FR 18619-18620.

B. Paperwork Reduction Act

Proposed Rule 4.22(f)(2) affects information collection requirements. As required by the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)), the Commission has submitted a copy of this section to the Office of Management and Budget for its review. Collection of Information Rules Relating to the Operations and Activities of Commodity Pool Operators and Commodity Trading Advisors and to Monthly Reporting by Futures Commission Merchants, OMB Control Number 3038-0005.

The expected effect of the proposed rule will be to increase the burden previously approved by OMB for this collection of information by 175 hours. Specifically, the burden associated with proposed Rule 4.22(f)(2) is expected to be increased by 175 hours:

Estimated number of respondents (after proposed extension): 350.

Annual responses by each respondent: 1.

Estimated average hours per response: 0.5.

Annual reporting burden: 175.

Organizations and individuals desiring to submit comments on the information collection requirements should direct them to the Office of Information and Regulatory Affairs, OMB, Room 10235 New Executive Office Building, Washington, DC 20503; Attention: Desk Officer for the Commodity Futures Trading Commission. The Commission considers comments by the public on this proposed collection of information in—

- Evaluating whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information will have a practical use;

- Evaluating the accuracy of the Commission's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

- Enhancing the quality, usefulness, and clarity of the information to be collected; and

- Minimizing the burden of collection of information on those who are to respond, including through the use of appropriate automated electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

OMB is required to make a decision concerning the collection of information contained in these proposed regulations between 30 and 60 days after publication of this document in the

Federal Register. Therefore, a comment to OMB is best assured of having its full effect if OMB receives it within 30 days of publication. This does not affect the deadline for the public to comment to the Commission on the proposed regulations. Copies of the information collection submission to OMB are available from the CFTC Clearance Officer, 1155 21st Street N.W., Washington, DC 20581, (202) 418-5160.

List of Subjects in 17 CFR Part 4

Brokers, Commodity futures.

In consideration of the foregoing and pursuant to the authority contained in the Commodity Exchange Act and in particular sections 2(a)(1), 4l, 4m, 4n, 4o, and 8a, 7 U.S.C. 2, 6l, 6m, 6n, 6o, and 12(a), the Commission hereby proposes to amend Chapter I of Title 17 of the Code of Federal Regulations as follows:

PART 4—COMMODITY POOL OPERATORS AND COMMODITY TRADING ADVISORS

1. The authority citation for part 4 continues to read as follows:

Authority: 7 U.S.C. 1a, 2, 4, 6b, 6c, 6l, 6m, 6n, 6o, 12a, and 23.

2. Section 4.22 is amended by:

a. redesignating paragraphs (f)(1) introductory text, (f)(1)(i), (f)(1)(ii), (f)(1)(iii), and (f)(1)(iv) as (f)(1)(i) introductory text, (f)(1)(i)(A), (f)(1)(i)(B), (f)(1)(i)(C), and (f)(1)(i)(D);

b. redesignating paragraphs (f)(2) introductory text, (f)(2)(i), and (f)(2)(ii) as (f)(1)(ii) introductory text, (f)(1)(ii)(A), and (f)(1)(ii)(B);

c. redesignating paragraphs (f)(3) introductory text, (f)(3)(i), and (f)(3)(ii) as (f)(1)(iii) introductory text, (f)(1)(iii)(A), and (f)(1)(iii)(B); and

d. adding a new paragraph (f)(2) to read as follows:

§ 4.22 Reporting to pool participants.

* * * * *

(f) * * *

(2) In the event a commodity pool operator finds that it cannot obtain information necessary to prepare certified financial statements for a pool that it operates within the time specified in either paragraph (c) of this section or § 4.7(b)(3)(i), as a result of the pool investing in another collective investment vehicle, it may claim an extension of time under the following conditions:

(i) The commodity pool operator must, within 90 calendar days of the end of the pool's fiscal year, file a notice with National Futures Association and the Commission, except as provided in paragraph (f)(2)(v) of this section.

(ii) The notice must contain the name, main business address, main telephone number and the National Futures Association registration identification number of the commodity pool operator, and name and the identification number of the commodity pool.

(iii) The notice must state the date by which the Annual Report will be distributed and filed (the "Extended Date"), which must be no more than 150 calendar days after the end of the pool's fiscal year. The Annual Report must be distributed and filed by the Extended Date.

(iv) The notice must include representations by the commodity pool operator that:

(A) The pool for which the Annual Report is being prepared has investments in one or more collective investment vehicles (the "Investments");

(B) The commodity pool operator has been informed by the certified public accountant selected to audit the commodity pool's financial statements that specified information establishing the value of the Investments is necessary in order for the accountant to render an opinion on the commodity pool's financial statements. The notice must include the name of the accountant; and

(C) The information specified by the accountant cannot be obtained in sufficient time for the Annual Report to be prepared, audited, and distributed before the Extended Date.

(v) For each fiscal year following the filing of the notice described in paragraph (f)(2)(i) of this section, the commodity pool operator may claim the extension of time by filing a statement containing the representations specified in paragraph (f)(2)(iv) of this section, at the same time as the pool's annual report.

(vi) Any notice or statement filed pursuant to paragraph (f)(2) of this section must be signed by the commodity pool operator in accordance with paragraph (h) of this section.

* * * * *

Issued in Washington, D.C. on October 31, 2000 by the Commission.

Jean A. Webb,

Secretary of the Commission.

[FR Doc. 00-28367 Filed 11-6-00; 8:45 am]

BILLING CODE 6351-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 314

[Docket No. 00N-1545]

Applications for FDA Approval to Market a New Drug; Proposed Revision of Postmarketing Reporting Requirements

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend its regulations describing postmarketing reporting requirements to implement certain provisions of the Food and Drug Administration Modernization Act of 1997 (the Modernization Act). The proposed changes apply to drug products that are life supporting, life sustaining, or intended for use in the prevention of a serious disease or condition and that were not originally derived from human tissue and replaced by a recombinant product. The proposed rule would implement provisions of the Modernization Act by requiring an applicant who is the sole manufacturer of one of these products to notify FDA at least 6 months before discontinuing manufacture of the drug product.

DATES: Submit written comments by February 5, 2001.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should be identified with the docket number found in brackets in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance for industry referred to in this proposed rule. Submit written requests for single copies of the guidance referred to in this proposal to the Drug Information Branch (HFD-210), Center for Drug Evaluation and Research (CDER), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857; or the Office of Communication, Training, and Manufacturers Assistance (HFM-40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, FAX 1-888-CBERFAX or 301-827-3844. Send two self-addressed adhesive labels to assist the office in processing your request. Requests should be identified with the