

under § 831.110 rather than an opportunity to request reconsideration under paragraph (c) of this section. Such a decision must be in writing and state the right to appeal under § 831.110.

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COMMODITY FUTURES TRADING COMMISSION

17 CFR Parts 145 and 147

Commission Records and Information; Open Commission Meetings

AGENCY: Commodity Futures Trading Commission.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Commodity Futures Trading Commission ("Commission" or "CFTC") seeks comments on its proposal to amend rules relating to Commission records and information last revised October 5, 1989. The proposed modifications update and streamline procedures in light of the Commission's experience in the past several years and amend rules regarding open Commission meetings to conform to these modifications.

DATES: Comments are due no later than February 18, 1997.

ADDRESSES: Comments should be sent to Jean A. Webb, Secretary of the Commission, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street, NW, Washington, DC 20581; or by electronic mail to secretary@cftc.gov.

FOR FURTHER INFORMATION CONTACT: Merry Lynn, Assistant General Counsel, Office of the General Counsel, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street, NW, Washington, DC 20581. Telephone: (202) 418-5120.

SUPPLEMENTARY INFORMATION:

I. Background—Need for Revisions

Based on its experience in the nearly seven years since the rules implementing the Freedom of Information Act ("FOIA") (5 U.S.C. 552 (1994)) were last revised, the Commission has identified several rules which it believes should be modified. The Commission invites comments regarding the proposed revisions.

A. Disclosure of Nonpublic Records

1. Exemption 7

The Freedom of Information Reform Act of 1986 (§§ 1801-1804 of Public Law 99-570) ("Reform Act") amended the

FOIA by modifying the terms of Exemption 7 (5 U.S.C. 552(b)(7)) relating to requests for records compiled for law enforcement purposes, and by supplying new provisions relating to the charging and waiving of fees. On May 22, 1987, the Commission published a final rule at 52 FR 19306 implementing a Uniform Freedom of Information Act Fee Schedule and Guidelines, published by the Office of Management and Budget, 52 FR 10011 (March 27, 1987) ("OMB Guidelines"). At that time, the Commission did not modify its rule regarding Exemption 7 set forth in 17 CFR 145.5(g). Nevertheless, since early 1988, the Commission has been implementing Exemption 7 by following the guidance set forth in the "Attorney General's Memorandum on the 1986 Amendments to the Freedom of Information Act" (December 1987). The Commission proposes to revise Rule 145.5(g) to conform to its practice and the Reform Act.

Prior to the Reform Act, FOIA permitted the withholding of investigatory records, only to the extent that production "would" interfere with enforcement proceedings; "would" constitute an unwarranted invasion of personal privacy; "would" disclose the identity of a confidential source; or "would" endanger the life or safety of law enforcement personnel. 5 U.S.C. 552(b)(7) (A), (C), and (D) (1982). The Commission's current rule reflects this statutory language.

The Reform Act relaxed the test relating to the withholding of investigatory records by substituting "would" with the phrase "could reasonably be expected to" in 5 U.S.C. 552(b)(7)(A) (interfere with enforcement proceedings), (b)(7)(C) (constitute an unwarranted invasion of personal privacy), and (b)(7)(D) (disclose identity of a confidential source). The Reform Act also modified subsection (b)(7)(F) to provide for the withholding of records to protect the life or physical safety of any person, not just law enforcement personnel. The Commission proposes to amend Rule 145.5(g) to conform to its practice and the Reform Act.

Additionally, the Reform Act amended the confidential source provision of FOIA to extend it to include "a State, local or foreign agency or authority or any private institution which furnished information on a confidential basis." The Reform Act also amended FOIA to provide for expanded protection of the information itself when provided by a confidential source in a criminal or national security investigation. Both of these changes are reflected in the proposed revision of Rule 145.5(g).

Originally, FOIA had provided for the withholding of "investigative techniques and procedures." 5 U.S.C. 552(b)(7)(E) (1982). The Reform Act added an exemption for disclosure of "techniques and procedures for law enforcement investigations or prosecutions, or * * * [disclosure of] guidelines for law enforcement investigations or prosecutions if such disclosure could reasonably be expected to risk circumvention of the law." 5 U.S.C. 552(b)(7)(E), *as amended*. This statutory change is also reflected in the proposed revision of Rule 145.5(g).

Further, the Commission proposes to expand the description of enforcement proceedings. Whereas the current rule describes "enforcement proceedings" and "investigatory records" primarily as activities of the Commission, the proposed rule expressly includes the law enforcement activities of the Department of Justice, or any United States Attorney, or any Federal, State, local, foreign governmental authority or foreign futures or securities authority, or any futures or securities industry self-regulatory organization. Similarly, the proposed rule also expressly describes "investigatory record" to include material involving the possible violation of any statutory or regulatory provision administered by these same authorities.

Finally, the current rule appears to limit the exemption for investigatory sources to persons who communicated with the Commission "confidentially." As currently phrased, this suggests that a person must express a desire for "confidentiality." Because FOIA does not require a request for confidentiality, the Commission proposes to delete this phraseology. Thus, the proposal covers written communications from, or to, any person complaining or otherwise furnishing information respecting possible violations, as well as all correspondence or memoranda in connection with such complaints or information.

2. Other Changes

The introductory paragraph of Rule 145.5(d)(1), which describes certain business information which the Commission would ordinarily treat as exempt from disclosure, has led to some confusion. Some submitters have read the phrase in (d)(1) concerning "information * * * of a kind not normally disclosed by the person from whom it was obtained" as meaning that if a submitter would not normally disclose the information to the public, the submitter can choose to have the Commission withhold it. Such an interpretation is not consistent with FOIA. The balance of the language of

the introductory section concerning Commission undertakings to receive certain material "for its use or the use of specified persons only" creates additional ambiguity. The Commission believes neither phrase adds to the understanding of the rest of the rule. Accordingly, the Commission proposes to delete the entire introductory paragraph. The Commission also proposes to delete the same language found in Rule 147.3(b)(4)(i).

B. Detailed Written Justification of Request for Confidential Treatment

Under the current scheme, when there is a FOIA request for materials for which confidential treatment has been sought under Rule 145.9 by the submitter of the materials, the Assistant Secretary of the Commission for Freedom of Information, Privacy and Sunshine Acts Compliance ("Assistant Secretary") seemingly *must* require the submitter to file a detailed written justification of the confidential treatment request within ten days. However, it has been the experience of the Commission that, in some cases, the submitter's initial petition for confidential treatment of the information or its response to a prior FOIA request is so complete that the Assistant Secretary does not need it to be supplemented in order to determine that confidential treatment is justified. Consequently, the Commission is proposing that under Rule 145.9(e)(1) the Assistant Secretary request submission of a detailed justification unless (i) pursuant to an earlier FOIA request, a prior determination to release or withhold the material has been made; (ii) the submitter has already provided sufficient information to grant the request for confidential treatment; or (iii) the material is otherwise in the public domain.

Additionally, the Commission proposes to modify Commission Rules 145.9(d)(7) and 145.9(e)(1). When the Assistant Secretary determines that there has been a request for information for which confidential treatment has been requested and that it is necessary to provide the justification, it is proposed that the Assistant Secretary notify the submitter of the material that the requested information will be released after ten business days unless the submitter objects by providing a detailed written justification. In the proposal, should a submitter fail to file a detailed written justification, the submitter will not be given an opportunity to appeal an adverse determination. It is expected that the volume of correspondence will be reduced by giving the Assistant

Secretary this authority. The mandatory language is unchanged regarding what must be supplied once a request for confidential treatment is made.

In some cases, submitters of material have requested confidential treatment of the public portions of financial reports of futures commission merchants and introducing brokers filed on Form 1-FR pursuant to 17 CFR 1.10. In the past seven years, no submitter of material has been able to convince the Commission to make confidential the public portions of these reports. However, submitters continue to file such requests, requiring unnecessary consumption of time and preparation of paperwork by submitters, requesters, and Commission staff. Consequently, the Commission is proposing to modify Commission Rules 145.5 and 145.9(d)(8) by indicating that requests for confidential treatment of the public portions of the financial reports will not be processed.¹ Conforming modifications are proposed for Commission Rule 147.3(b)(4)(i). The Commission is not proposing any change regarding which portions of the Form 1-FR are treated as public and which portions are treated as nonpublic.

Similarly, submitters have requested confidential treatment of materials which have not yet been submitted to the Commission. In practice, it is often difficult to identify what subsequent material is covered, adding greatly to processing time and expense. Accordingly, the Commission proposes to amend Rule 145.9(d)(4) to indicate that requests for confidential treatment of a future submission will not be processed. In some cases, however, submitters submit materials in installments in response to Commission requests for information, e.g., pursuant to investigations or in regard to contract market designations. The proposal sets forth a labelling procedure to address this situation.

Commission Rule 145.9(d)(6) currently states that requests for confidential treatment are considered public documents. However, Commission staff routinely declines to treat requests for confidential treatment as public where disclosure of even the existence of a request would reveal nonpublic information, e.g., in the case of a request for confidential treatment made with respect to a submission in a pending investigation. Accordingly, the Commission proposes to modify

Commission Rule 145.9(d)(6) to permit withholding information about a request where disclosure of the request itself would reveal other information exempt from disclosure.

In all other cases, the request for confidential treatment will be public. Nonetheless, some requesters include confidential information in their requests for confidential treatment and seek confidential treatment of the request. Thus, the Commission proposes to amend Commission Rule 145.9(d)(6) to advise submitters of information to place information for which they want confidential treatment in an appendix to the request.

C. Appendix A—Compilation of Commission Records Available to the Public

Appendix A to 17 CFR Part 145 contains a list of publicly available Commission records and the offices which are responsible for them. Requesters are advised to contact those offices directly for access to such records.

The appendix indicates that the Office of the Secretariat maintains a binder of FOIA requests and responses. However, since 1985, on the advice of the United States Department of Justice, it has not been Commission practice to release the addresses or other personal information about requesters. See U. S. Department of Justice, Office of Information and Privacy, *Freedom of Information Act Guide & Privacy Act Overview*, September 1995 ed. at 209 (while release of the names of requesters is not an invasion of privacy, personal information about FOIA requesters such as home addresses and telephone numbers should not be disclosed), *citing FOIA Update*, Winter 1985 at 6 (personal information about an individual FOIA requester is protected under Exemption 6 absent a particularly compelling public interest in its disclosure; however, names of Privacy Act requesters should not be disclosed). Rather than redacting all correspondence, the Office of the Secretariat has been redacting personal information from the requests and responses only when an FOIA request is made as to those documents. Consequently, the Commission proposes to amend Appendix A to conform to its current practice by deleting reference to the binder from Appendix A(b)(1) and renumbering the paragraphs accordingly.

Appendix A also indicates that requesters may obtain access to public portions of registration documents at the Commission's regional office in Chicago. Since 1983 the Commission

¹ To the extent that 17 CFR 1.10 and 31.13 require separate binding procedures so that certain portions of financial reports can be accorded nonpublic treatment, the Commission has proposed to eliminate these procedures in a separate release. 61 FR 55235 (Oct. 25, 1996).

has authorized the National Futures Association ("NFA") to perform various portions of the Commission's registration functions and responsibilities under the Commodity Exchange Act, 7 U.S.C. 1 *et seq.* (1994). By notice published at 49 FR 39518, 39523 (Oct. 9, 1984), the Commission authorized NFA to make available to the public for inspection and copying the publicly available portions of all registration forms compiled or maintained in connection with its performance of registration functions under the Commodity Exchange Act. At that time, the Commission notified the public that any person seeking to inspect or copy the publicly available portions of such registration forms should contact NFA directly and that a formal request pursuant to FOIA is not necessary to obtain such information. The Commission proposes to amend Appendix A accordingly.

D. Appendix B—Schedule of Fees

The Commission last set FOIA fees on May 22, 1987 when it published a final rule at 52 FR 19306 (May 22, 1987). The OMB Guidelines require that each agency's fees for searches involving records stored in computer formats be based upon its direct reasonable operating costs of providing FOIA services. To this end, the Commission has reviewed its fees and proposes a new fee schedule to be set forth in Appendix B. The fees set forth in the proposal reflect the data the Commission currently reports to OMB. Fees are based upon the actual computer time used. The proposed fee for programming and performing searches is \$32.00 per hour. This fee represents the average of the pay scale for staff who actually perform the service—GS-13, Step 4. The Commission has calculated its direct costs, defined by OMB for the purpose of FOIA fees, as salary of \$27.86 per hour, plus 16 percent. 52 FR 10018 (Mar. 27, 1987). The Commission rounded the \$32.32 total to \$32.00.

Finally, in Appendix B(a)(3) the phrase "operation of the central processing unit" has caused some confusion. Rather than substituting a new phrase, the Commission proposes to explain the new way in which its records are stored in its computer systems and how searches are performed. This should clarify the process.

E. The Commission's Address

The Commission proposes to update the addresses and telephone numbers which appear in Part 145, which have not been updated previously.

II. Related Matter

Regulatory Flexibility Act

The Regulatory Flexibility Act ("RFA"), 5 U.S.C. 601 *et seq.* (1988), requires that agencies, in proposing rules, consider the impact of those rules on small businesses. The Commission has previously determined, pursuant to 5 U.S.C. 605(b) that Part 145 rules relating to Commission records and information do not have a significant economic impact on a substantial number of small entities. Because they do not impose regulatory obligations on commodity professionals and small commodity firms, and because, if instituted, the proposed corrections and amendments will expedite and improve the FOIA process, the Commission does not expect the proposed rule to have a significant economic impact on a substantial number of small business entities.

Accordingly, pursuant to Rule 3(a) of the RFA (5 U.S.C. 605(b)), the Chairperson, on behalf of the Commission, certifies that this proposed rule will not have a significant economic impact on a substantial number of small entities. The Commission nonetheless invites comment from any member of the public who believes that these revisions and corrections would have a significant impact on small businesses.

List of Subjects

17 CFR Part 145

Confidential business information, Freedom of information.

17 CFR Part 147

Sunshine Act.

For the reasons set forth in the preamble, title 17, parts 145 and 147 are proposed to be amended as follows:

PART 145—COMMISSION RECORDS AND INFORMATION

1. The authority for Part 145 is revised to read:

Authority: Pub. L. 99-570, 100 Stat. 3207, Pub. L. 89-554, 80 Stat. 383, Pub. L. 90-23, 81 Stat. 54, Pub. L. 93-502, 88 Stat. 1561-1564 (5 U.S.C. 552); Sec. 101(a), Pub. L. 93-463, 88 Stat. 1389 (5 U.S.C. 4a(j)); unless otherwise noted.

2. Section 145.5 is amended as set forth below:

§ 145.5 [Amended]

a. In the introductory paragraph add a sentence to the end as set forth below.

b. Remove the introductory text of paragraph (d)(1).

c. In (d)(1)(i) (B) and (E) remove the following phrase: "Provided, The

procedure set forth in 17 CFR 1.10(g) is followed".

d. In (d)(1)(i) (C) and (D) remove the following phrase: " , provided the procedure set forth in § 1.10(g) of this chapter is followed".

e. In (d)(1)(i) (F) and (G) remove the following phrase: " , if the procedure set forth in § 1.10(g) of this chapter is followed".

f. In (d)(1)(i)(H) remove the following phrase: " , provided the procedure set forth in § 31.13(m) of this chapter is followed".

g. Paragraph (g) is revised to read as set forth below.

§ 145.5 Disclosure of nonpublic records.

* * * Requests for confidential treatment of segregable public information will not be processed.

* * * * *

(g)(1) Records or information compiled for law enforcement purposes to the extent that the production of such records or information:

(i) Could reasonably be expected to interfere with enforcement activities undertaken or likely to be undertaken by the Commission or any other authority including, but not limited to, the Department of Justice, or any United States Attorney, or any Federal, State, local, foreign governmental authority or foreign futures or securities authority, or any futures or securities industry self-regulatory organization;

(ii) Would deprive a person of a right to a fair trial or an impartial adjudication;

(iii) Could reasonably be expected to constitute an unwarranted invasion of personal privacy;

(iv) Could reasonably be expected to disclose the identity of a confidential source including a State, local or foreign agency or authority or any private institution which furnished information on a confidential basis, and, in the case of a record or information compiled by a criminal law enforcement authority in the course of a criminal investigation, or by an agency conducting a lawful national security intelligence investigation, information furnished by a confidential source;

(v) Would disclose techniques or procedures or would disclose guidelines for law enforcement investigations or prosecutions if such disclosure could reasonably be expected to risk circumvention of the law; or

(vi) Could reasonably be expected to endanger the life or physical safety of any individual.

(2) The term "investigatory records" includes, but is not limited to, all documents, records, transcripts, evidentiary materials of any nature,

correspondence, related memoranda, or work product concerning any examination, any investigation (whether formal or informal), or any related litigation, which pertains to, or may disclose, the possible violation by any person of any provision of any statute, rule, or regulation administered by the Commission, by any other Federal, State, local, or foreign governmental authority or foreign futures or securities authority, or by any futures or securities industry self-regulatory organization. The term "investigatory records" also includes all written communications from, or to, any person complaining or otherwise furnishing information respecting such possible violations, as well as all correspondence or memoranda in connection with such complaints or information.

* * * * *

§ 145.6 Commission offices to contact for assistance; registration records available.

3. In § 145.6(a), remove the phrase "(816) 374-6602" and add in its place "(816) 931-7600"; remove the phrase "10880 Wilshire Blvd., suite 1005 Los Angeles, California 90024, Telephone: (310) 575-6783" and add in its place "10900 Wilshire Boulevard, Suite 400, Los Angeles, California 90024, Telephone: (310) 325-6783".

4. Section 145.9 is amended by revising paragraphs (d) (4), (6), (7), and (8) and the first sentence of (e)(1) to read as follows:

§ 145.9 Petition for confidential treatment of information submitted to the Commission.

* * * * *

(d) * * *

(4) A request for confidential treatment should accompany the material for which confidential treatment is being sought. If a request for confidential treatment is filed after the filing of such material, the submitter shall have the burden of showing that it was not possible to request confidential treatment for that material at the time the material was filed. A request for confidential treatment of a future submission will not be processed. All records which contain information for which a request for confidential treatment is made or the appropriate segregable portions thereof should be marked by the person submitting the records with a prominent stamp, typed legend, or other suitable form of notice on each page or segregable portion of each page stating "Confidential Treatment Requested by [name]." If such marking is impractical under the circumstances, a cover sheet prominently marked "Confidential

Treatment Requested by [name]" should be securely attached to each group of records submitted for which confidential treatment is requested. Each of the records transmitted in this matter should be individually marked with an identifying number and code so that they are separately identifiable. In some circumstances, such as when a person is testifying in the course of a Commission investigation or providing documents requested in the course of a Commission inspection, it may be impractical to submit a written request for confidential treatment at the time the information is first provided to the Commission. In no circumstances can the need to comply with the requirements of this section justify or excuse any delay in submitting information to the Commission. Rather, in such circumstances, the person testifying or otherwise submitting information should inform the Commission employee receiving the information, at the time the information is submitted or as soon thereafter as possible, that the person is requesting confidential treatment for the information. The person shall then submit a written request for confidential treatment within 30 days of the submission of the information. If access is requested under the Freedom of Information Act with respect to material for which no timely request for confidential treatment has been made, it may be presumed that the submitter of the information has waived any interest in asserting that the material is confidential.

* * * * *

(6) A request for confidential treatment (as distinguished from the material that is the subject of the request) shall be considered a public document unless disclosure of the request itself would reveal information exempt from disclosure. In cases in which disclosure of the request itself would reveal information exempt from disclosure, the request will not be disclosed. In all other cases, the request for confidential treatment will be disclosed. When a requester of confidential treatment deems it necessary to include, in its request for confidential treatment, information for which it seeks confidential treatment, the requester shall place that information in an appendix to the request. Information not segregated into such an appendix will be released to the public under the same considerations that the request itself will be released.

(7) On ten business days notice, a submitter shall submit a detailed written justification of a request for

confidential treatment, as specified in paragraph (e) of this section. The Assistant Secretary will notify the submitter that failure to provide timely a detailed written justification will be deemed a waiver of the submitter's opportunity to appeal an adverse determination.

(8)(i) Requests for confidential treatment for any reasonably segregable material that is not exempt from public disclosure under the Freedom of Information Act as implemented in § 145.5(d) or for confidential treatment of segregable public information contained in financial reports as specified in § 1.10 shall not be processed. Except for those materials which have been designated as nonpublic in § 145.5(d), a submitter has the burden of clearly and precisely specifying the material that is the subject of his or her confidential treatment request. A submitter may be able to meet this burden in various ways, including:

(A) Segregating material for which confidential treatment is being sought;

(B) Submitting two copies of the submission: a copy from which material for which confidential treatment is being sought has been obliterated, deleted, or clearly marked; and an unmarked copy; and

(C) Clearly describing the material within a submission for which confidential treatment is being sought.

(ii) A submitter shall not employ a method of specifying the material for which confidential treatment is being sought if that method makes it unduly difficult for the Commission to read the full submission, including all portions claimed to be confidential, in its entirety.

* * * * *

(e) * * * (1) If the Assistant Secretary or his or her designee determines that a FOIA request seeks material for which confidential treatment has been requested pursuant to § 145.9, the Assistant Secretary or his or her designee shall require the submitter to file a detailed written justification of the confidential request within ten business days of that determination unless:

(i) Pursuant to an earlier FOIA request, a prior determination to release or withhold the material has been made;

(ii) The submitter has already provided sufficient information to grant the request for confidential treatment; or

(iii) The material is otherwise in the public domain.

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Appendix A to Part 145—Compilation of Commission Records Available to the Public.

6. In Appendix A remove paragraph (b)(1) and redesignate paragraphs (b)(2) through (b)(13) as (b)(1) through (b)(12), respectively; and in paragraph (g) of Appendix A remove the phrase "from the Division of Trading and Markets, Commodity Futures Trading Commission, 300 South Riverside Plaza, suite 1600 North, Chicago, Illinois 60606 or".

7. Amend Appendix B to Part 145 by revising paragraph (a)(3) to read as follows:

Appendix B to Part 145—Schedule of Fees.

(a) * * *

(3) The Commission uses a variety of computer systems to support its operations and store records. Older systems of records, particularly systems involving large numbers of records, are maintained on a mainframe computer. More recently, systems have been developed using small, inexpensive, shared computer systems to store records. Systems of use in particular programmatic and administrative operations may also store records on the workstation computers assigned to particular staff members. For searches of records stored on the Commission's mainframe computer, the use of computer processing time will be charged at \$456.47 for each hour, \$7.61 for each minute, and \$0.1268 for each second of computer processing time indicated by the job accounting log printed with each search. When searches require the expertise of a computer specialist, staff time for programming and performing searches will be charged at \$32.00 per hour. For searches of records stored on personal computers used as workstations by Commission staff and shared access network servers, the computer processing time is included in the search time for the staff member using that workstation as set forth in the other subsections of Appendix B, section (a).

* * * * *

PART 147—OPEN COMMISSION MEETINGS

8. The authority for part 147 continues to read:

Authority: Sec. 3(a), Pub. L. 94-409, 90 Stat. 1241 (5 U.S.C. 552b); sec. 101(a)(11), Pub. L. 93-463, 88 Stat. 1391 (7 U.S.C. 4a(j)(Supp. V, 1975)), unless otherwise noted.

§ 147.3 [Amended]

9. In § 147.3 make the following changes:

a. Remove the introductory text of paragraph (b)(4)(i).

b. In paragraphs (b)(4)(i)(A) (2) and (5) remove the following phrase: "Provided, The procedure set forth in 17 CFR 1.10(g) is followed:".

c. In paragraphs (b)(4)(i)(A) (3) and (4) remove the following phrase: " , provided, the procedure set forth in § 1.10(g) of this chapter is followed" .

d. In paragraphs (b)(4)(i)(A) (6) and (7) remove the following phrase: " , if the procedure set forth in § 1.10(g) of this chapter is followed" .

e. In paragraph (b)(4)(i)(A)(8) remove the following phrase: "provided the procedure set forth in § 31.13(m) of this chapter is followed" .

Issued by the Commission.

Dated: December 11, 1996.

Jean A. Webb,

Secretary of the Commission, Commodity Futures Trading Commission.

[FR Doc. 96-31930 Filed 12-18-96; 8:45 am]

BILLING CODE 6351-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 351

[Docket No. 80N-0280]

RIN 0910-AA01

Vaginal Contraceptive Drug Products for Over-the-Counter Human Use; Reopening of the Administrative Record

AGENCY: Food and Drug Administration, HHS.

ACTION: Reopening of the administrative record.

SUMMARY: The Food and Drug Administration (FDA) is announcing the reopening of the administrative record for the proposed rulemaking for over-the-counter (OTC) vaginal contraceptive drug products to allow for comment on matters considered at the November 22, 1996, joint meeting of the Nonprescription Drugs, Reproductive Health Drugs, Anti-Infective Drugs, and Antiviral Drugs Advisory Committees. That meeting is part of the ongoing review of OTC drug products conducted by FDA.

DATES: Submit comments regarding matters discussed at the November 22, 1996, advisory committee by March 3, 1997. The administrative record will remain open until March 3, 1997.

ADDRESSES: Submit written comments to the Dockets Management Branch

(HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gloria Chang, Center for Drug Evaluation and Research (HFD-560), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-2245.

SUPPLEMENTARY INFORMATION: In the Federal Register of December 12, 1980 (45 FR 82014), FDA published an advance notice of proposed rulemaking to establish a monograph for OTC vaginal contraceptive drug products, together with the recommendations of the Advisory Review Panel on OTC Contraceptives and Other Vaginal Drug Products (the Panel). The Panel recommended that the spermicidal ingredients nonoxynol 9 and octoxynol 9 be considered generally recognized as safe and effective (45 FR 82014 at 82028 to 82030 and 82047). The Panel also recommended final formulation in vitro testing as an adequate method to determine effectiveness (45 FR 82014 at 82047).

In the Federal Register of February 3, 1995 (60 FR 6892), the agency published a proposed rule for OTC vaginal contraceptive drug products. This proposal would require manufacturers to obtain approved applications for marketing of OTC vaginal contraceptive drug products. The agency stated that although nonoxynol 9 and octoxynol 9 kill sperm in vitro and in vivo, the spermicidal activity and resulting effectiveness of these contraceptive ingredients cannot be considered separately from a product's vehicle. Thus, clinical studies are necessary to establish the effectiveness of the spermicide's final formulation when used in humans. The agency also announced the availability of a guidance document that is intended to help manufacturers of vaginal contraceptive drug products develop data in support of applications (60 FR 6892 at 6893). The administrative record for this proposed rule closed on April 3, 1996.

In response to the proposed rule, 13 professional associations, 1 health professional, 1 trade association, 10 public health groups, 4 manufacturers, 1 consumer, and 1 research laboratory submitted comments. The majority of the comments objected to the agency's proposal to require approved applications for marketing of OTC vaginal contraceptive drug products. Copies of the comments received are on public display in the Dockets Management Branch (address above).

On September 24, 1996, FDA met with the Nonprescription Drug