developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. Communications should identify the airspace docket number and be submitted in triplicate to the address listed above. Commenters wishing the FAA to acknowledge receipt of their comments on this notice must submit with the comments a self-addressed, stamped postcard on which the following statement is made: ''Comments to Airspace Docket No. 96–AWP–19.'' The postcard will be date/time stamped and returned to the commenter. All communications received on or before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this notice may be changed in light of comments received. All comments submitted will be available for examination in the Operations Branch, Air Traffic Division, at 15000 Aviation Boulevard, Lawndale, California 90261, both before and after the closing date for comments. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRM

Any person may obtain a copy of this Notice of Proposed Rulemaking (NPRM) by submitting a request to the Federal Aviation Administration, Operations Branch, P.O. Box 92007, Worldway Postal Center, Los Angeles, California 90009. Communications must identify the notice number of this NPRM. Persons interested in being placed on a mailing list for future NPRM's should also request a copy of Advisory Circular No. 11–2A, which describes the application procedures.

The Proposal

The FAA is considering an amendment to part 71 of the Federal Aviation Regulations (14 CFR part 71) revoking the Class D airspace area at Alameda, CA. The base closure of Alameda Naval Air Station (NAS) has made this action necessary. The intended effect of this action is to revoke controlled airspace since the purpose and requirements for the surface area no longer exist at Alameda NAS (Nimitz Field), CA. Class D airspace designations are published in paragraph 5000 of FAA Order 7400.9C dated August 17, 1995, and effective September 16, 1995, which is incorporated by reference in 14 CFR 71.1. The Class D airspace designations listed in this document would be removed subsequently in this Order.

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. Therefore, this proposed regulation—(1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 10034; February 26, 1979); and (3) does not warrant preparation of a Regulatory Evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this proposed rule would not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—[AMENDED]

1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389; 14 CFR 11.69.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of the Federal Aviation Administration Order 7400.9C, Airspace Designations and Reporting Points, dated August 17, 1995, and effective September 16, 1995, is amended as follows:

Paragraph 5000 Class D airspace.

* * * * *

AWP CA D Alameda NAS, CA [Removed]

* * * * *

Issued in Los Angeles, California, on August 12, 1996.

James H. Snow,

Acting Manager, Air Traffic Division, Western-Pacific Region.

[FR Doc. 96–21855 Filed 8–26–96; 8:45 am]

BILLING CODE 4910–13–M

COMMODITY FUTURES TRADING COMMISSION

17 CFR Part 4

Use of Electronic Media by Commodity Pool Operators and Commodity Trading Advisors

AGENCY: Commodity Futures Trading Commission.

ACTION: Proposed rule.

SUMMARY: The Commodity Futures Trading Commission (the ''Commission'') today is proposing technical changes to its rules requiring filing and distribution of Disclosure Documents by commodity pool operators (''CPOs'') and commodity trading advisors (''CTAs''). These proposals are intended to clarify certain rule provisions that are premised upon the filing and distribution of paper documents, in light of the interpretations set forth in a recent interpretative release ''Interpretation Regarding Use of Electronic Media by Commodity Pool Operators and Commodity Trading Advisors'' (61 FR 42146 (August 14, 1996)) outlining the Commission's views concerning the use of electronic media by CPOs and CTAs.

DATES: Comments must be received on or before October 28, 1996.

ADDRESSES: Comments should be submitted to Jean A. Webb, Secretary of the Commission, Commodity Futures Trading Commission, 1155 21st Street, N.W., Washington, D.C. 20581. In addition, comments may be sent by facsimile transmission to FAX number (202) 418–5521, or by electronic mail to secretary@cftc.gov.

FOR FURTHER INFORMATION CONTACT: Susan C. Ervin, Deputy Director/Chief Counsel, or Christopher W. Cummings, Attorney/Advisor, or Gary L. Goldsholle, Attorney/Advisor, or Tina Paraskevas Shea, Attorney/Advisor, Division of Trading and Markets, Commodity Futures Trading Commission, 1155 21st Street, N.W., Washington, D.C. 20581. Telephone number: (202) 418–5450. FAX number: (202) 418–5536.

SUPPLEMENTARY INFORMATION: In order to clarify certain rules in light of the interpretations relating to electronic distribution of information under the Commodity Exchange Act (the ''Act'')[1] and the Commission's regulations promulgated under the Act,[2] published

[1] 7 U.S.C. 1 *et seq.* (1994).

[2] Commission rules are found at 17 CFR Ch. I (1996). The rules governing CPO and CTA disclosure, reporting and recordkeeping requirements are found at 17 CFR part 4 (1996).

in a recent interpretative release (61 FR 42146 (August 14, 1996)) (the ''Interpretative Release''), the Commission is proposing minor technical amendments to the following rules: 4.1; 4.2; 4.21; 4.26; 4.31; and 4.36. The proposed rule changes are intended to facilitate, among other things, a pilot program for electronic filing of Disclosure Documents with the Commission by CPOs and CTAs.

I. Proposed Amendments

In the Interpretative Release, the Commission states its views with respect to the use of electronic media by CPOs and CTAs to disseminate certain information in compliance with the Act and the Commission's rules. Part 4 of the Commission's rules sets forth the disclosure and filing requirements for CPOs and CTAs. The rules that are the subject of the proposals set forth herein relate to the required filing with the Commission and distribution to current and prospective pool participants and managed account clients of Disclosure Documents by CPOs and CTAs. These rules were adopted on the assumption that Disclosure Documents would be filed and distributed in paper ''hard copy'' form. The Commission believes that it is appropriate to modify these rules in light of the views set forth in the Interpretative Release, in order to clarify that the Commission's rules do not limit a CPO's or a CTA's means of document delivery and filing to paper documents, to the exclusion of electronic media, and to facilitate the implementation of a pilot program for electronic filing of Disclosure Documents, as more fully described in the Interpretative Release.

A. General formatting

Commission Rule 4.1(a) requires that each document distributed pursuant to Part 4 must be clear and legible, paginated and fastened in a secure manner. These requirements presume that the document is composed of one or more sheets of paper. Their application to a document that is transmitted electronically, and that exists only as data stored on electronic media, may be subject to question. Similarly, Rule 4.1(b) states that information required to be ''prominently'' disclosed, as provided in various Part 4 rules, must be displayed in boldface capital letters. The increased emphasis attained by boldface capital letters in a paper format may be lost on a computer screen, where the only difference may be an insignificant color change. Further, paper and electronic versions of a particular document may differ because graphic, pictorial or audio material in one version of the document may not be readily included in the other version.

The Commission believes that the same critical information can be presented in electronic communication as in paper form. However, presentation adjustments may be required in the context of electronic media to assure that all versions of a CPO or CTA Disclosure Document convey the same information with equivalent emphasis, whether or not identical presentation of the information is possible. Proposed new paragraph (c) to Rule 4.1 states that in lieu of the paper-based formatting requirements of Rule 4.1(a), electronically distributed documents must present all required information in a format ''readily communicated'' to the recipient. Electronically delivered information is readily communicated for purposes of Part 4 if it is accessible in a single ''package'' or by a single data retrieval process, without the need to download and assemble multiple files, and preferably without the need to use special ''viewer'' software. Moreover, an electronically transmitted document must be organized in substantially the same manner as a paper document with respect to the order of presentation and relative prominence of information. Where a table of contents is required, the electronic document should retain page numbers or employ an equivalently user-friendly cross reference or indexing tool. The Commission requests comment as to whether greater specificity should be provided in the rule as to the meaning of ''readily communicated'' or whether this type of simple performance standard is preferable.

Where information is required to be ''prominently'' disclosed, electronically distributed documents must present such information in a manner reasonably calculated to draw the recipient's attention to it and must accord it greater emphasis than other portions of the text. For example, underlining that appears as such onscreen, color changes that contrast with the surrounding text without decreasing legibility, and pictorial characters designed to call attention (*e.g.*, an arrow or a pointing hand), may serve to highlight portions of text sufficiently to give the desired level of prominence. Finally, if graphic, image or audio material is included in one version of a document but not in the version filed with the Commission, whether for technological reasons or otherwise, the filed version of the document must contain a fair and accurate description or transcript of the omitted material. As noted in the Interpretative Release, audio, video, graphic or other enhancements must be used in a manner that is consistent with Commission requirements as to the order of presentation of information and the relative prominence of various types of information. Thus, if video or audio material, for example, is used to convey content that would constitute supplemental information under Rule 4.24(v) or 4.34(n) (*e.g.*, a video comparison of trading program rates of return to the movement of the Standard & Poor's 500 Index over time, or an audio discussion of modern portfolio theory), such material must be presented after all required information, and it must not overwhelm or obscure required information.

Comment is solicited as to whether more specific requirements as to formatting of electronically distributed documents are appropriate and, if so, as to what specific standards should be established. For example, should electronically-transmitted documents be required to retain page breaks and page numbers corresponding to paper-based documents?

B. Filing

Rule 4.2 states that material required to be filed with the Commission is considered filed when received at the Commission's postal address specified in Rule 4.2(a). In order to facilitate electronic filing of Disclosure Documents, the proposed amendment to Rule 4.2(a) states that such documents may be filed at the Commission's electronic mail address designated for that purpose.[3] Rule 4.2 is otherwise unchanged.

Currently, Rules 4.26(d) and 4.36(d) require CPOs and CTAs to file two copies of each Disclosure Document and each amendment to a Disclosure Document with the Commission. Where a document is filed electronically, this requirement for two copies is unnecessary and potentially confusing. Proposed amendments to Rules 4.26(d) and 4.36(d) would clarify that only one copy of the Disclosure Document and of each amendment is required to be filed if the registrant elects to file electronically with the Commission.

C. Acknowledgments

Rule 4.21(b) for CPOs and Rule 4.31(b) for CTAs currently provide that a CPO may not accept or receive funds, securities or other property from a prospective pool participant, and a CTA may not enter into an agreement to guide or direct a prospective client's

[3] Currently, this address is tm-pilot-program@cftc.gov.

account, unless the CPO or CTA first obtains a signed and dated acknowledgement stating that a Disclosure Document has been received by the prospective participant or client. As discussed in the Interpretative Release, the Commission believes that adequate evidence of receipt of a Disclosure Document may be obtained in ways other than a manually signed paper receipt. Accordingly, the proposed amendments to Rules 4.21(b) and 4.31(b) will permit registrants to obtain acknowledgments by such electronic means as the Commission may approve, in each case subject to the requirement that an acknowledgment be received before a CPO accepts property from a prospective pool participant or a CTA contracts to direct or guide a prospective client's account. At the present time, the only approved alternative to a signed paper receipt is the use of a personal identification or ''PIN'' number in lieu of the manual signature, as described in the Interpretative Release. CPOs and CTAs remain obligated under Rules 4.23(a)(3) and 4.33(a)(2), respectively, to retain all acknowledgments, and the proposed amendments permit retention in hard copy form or by other Commission-approved means.

Comment is sought as to whether the Commission should specify in the rules the acceptable means by which registrants can establish receipt of Disclosure Documents, or whether a more flexible approach is advisable.

II. Solicitation of Comments

Any interested persons wishing to submit written comments relating to the rule proposals, as explained above, are invited to do so by submitting them by postal mail to Jean A. Webb, Secretary of the Commission, Commodity Futures Trading Commission, 1155 21st Street, N.W., Washington, D.C. 20581. Comments may be sent by facsimile transmission to FAX number (202) 418–5521, or by electronic mail to secretary@cftc.gov.

III. Cost-Benefit Analysis

Although the Commission anticipates that increased use of electronic media by registrants will benefit market participants by making disclosure more efficient and expeditious, it does not expect the rule amendments proposed herein, in and of themselves, to result in substantial economic costs or benefits. The proposed amendments are intended to clarify the application of existing requirements under the Act and Commission rules in the context of newly developed information technology. Use of electronic media by CPOs and CTAs for document filing or delivery of information is optional, and registrants can weigh for themselves the relative costs and benefits of using electronic media in specific circumstances. Nevertheless, commenters are invited to identify any costs or benefits associated with the proposed amendments that the Commission may have overlooked. Commenters are also invited to describe any additional actions that they believe that the Commission should take in connection with the proposed amendments to reduce compliance burdens and to maximize the benefits of Disclosure Document delivery while minimizing unnecessary costs.

IV. Related Matters

A. Regulatory Flexibility Act

The Regulatory Flexibility Act (''RFA''), 5 U.S.C. 601–611 (1988), requires that agencies, in proposing rules, consider the impact of those rules on small businesses. The rule amendments discussed herein would affect registered CPOs and CTAs. 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.[4] The Commission previously determined that registered CPOs are not small entities for the purpose of the RFA.[5] With respect to CTAs, the Commission has stated that it would evaluate within the context of a particular rule proposal whether all or some affected CTAs would be considered to be small entities and, if so, the economic impact on them of any rule.[6]

The amendments proposed herein do not impose any new burdens upon CPOs or CTAs. The proposed amendments facilitate the use of alternative media to meet existing requirements, and they clarify the application of existing regulations to the use of such media. As a result, the Commission anticipates that adoption of the proposed amendments will in many cases reduce the burden of compliance by CPOs and CTAs. Accordingly, pursuant to Rule 3(a) of the RFA (5 U.S.C. 605(b)), the Acting Chairman, on behalf of the Commission, certifies that these proposed amendments would not have a significant economic impact on a substantial number of small entities. The Commission nonetheless invites comment from any registered CPO or CTA who believes that these rules would have a significant impact on its operations.

B. Paperwork Reduction Act

The Paperwork Reduction Act of 1980 (Act), 44 U.S.C. 3501 *et. seq.*, imposes certain requirements on federal agencies (including the Commission) in connection with their conducting or sponsoring any collection of information as defined by the Paperwork Reduction Act. While these proposed amendments have no burden, the group of rules (3038–0005) of which this is a part has the following burden:

Average Burden Hours per Response: 124.75.

Number of Respondents: 4,654.

Frequency of Response: on occasion.

Persons wishing to comment on the information which would be required by this proposed/amended rule should contact Jeff Hill, Office of Management and Budget, Room 3228, NEOB, Washington, DC 20503, (202) 395–7340. Copies of the information collection submission to OMB are available from Joe F. Mink, CFTC Clearance Officer, 1155 21st Street NW, Washington, DC 20581, (202) 418–5170.

List of Subjects in 17 CFR Part 4

Advertising, Commodity futures, Consumer protection, Reporting and recordkeeping requirements.

In consideration of the foregoing, and pursuant to the authority contained in the Commodity Exchange Act, and in particular, sections 2(a)(1), 4b, 4c, 4*l*, 4m, 4n, 4*o*, and 8a, 7 U.S.C. 2, 6b, 6c, 6*l*, 6m, 6n, 6*o*, and 12a, 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

Subpart A—General Provisions, Definitions and Exemptions

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

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

2. Section 4.1 is proposed to be amended by adding new paragraphs (c) and (d) to read as follows:

§ 4.1 Requirements as to form.

(a) * * *

(b) * * *

(c) Where a document is distributed through an electronic medium:

(1) The requirements of paragraph (a) of this section shall mean that all required information must be presented

[4] 47 FR 18618–18621 (April 30, 1982).

[5] 47 FR 18619–18620.

[6] 47 FR 18618, 18620.

in a format readily communicated to the recipient. For purposes of this paragraph (c), information is readily communicated to the recipient if it is accessible as a single file by means of commonly available hardware and software, and if the electronically delivered document is organized in substantially the same manner as would be required for a paper document with respect to the order of presentation and the relative prominence of information. Where a table of contents is required, the electronic document must either include page numbers in the text or employ a substantially equivalent cross-reference or indexing method or tool;

(2) The requirements of paragraph (b) of this section shall mean that such information must be presented in a manner reasonably calculated to draw the recipient's attention to the information and accord it greater prominence than the surrounding text; and

(3) A complete paper version of the document must be provided to the recipient upon request.

(d) If graphic, image or audio material is included in a document delivered to a prospective or existing client or pool participant, and such material cannot be reproduced in an electronic filing, a fair and accurate narrative description, tabular representation or transcript of the omitted material must be included in the filed version of the document. Inclusion of such material in a Disclosure Document shall be subject to the requirements of § 4.24(v) in the case of pool Disclosure Documents, and § 4.34(n) in the case of commodity trading advisor Disclosure Documents.

3. Section 4.2 paragraph (a) is proposed to be revised to read as follows:

§ 4.2 Requirements as to filing.

(a) All material filed with the Commission under this part 4 must be filed with the Commission at its Washington, D.C. office (Att: Special Counsel, Front Office Audit Unit, Division of Trading and Markets, C.F.T.C., 1155 21st Street N.W., Washington, D.C. 20581). Disclosure Documents may be filed at an electronic mail address for the Commission, as designated by the Commission.

* * * * *

Subpart B—Commodity Pool Operators

4. Section 4.21, paragraph (b) is proposed to be revised to read as follows:

§ 4.21 Required delivery of pool Disclosure Document.

(a) * * *

(b) The commodity pool operator may not accept or receive funds, securities or other property from a prospective participant unless the pool operator first receives from the prospective participant an acknowledgment signed and dated by the prospective participant stating that the prospective participant received a Disclosure Document for the pool. Where a Disclosure Document is delivered to a prospective pool participant by electronic means, in lieu of a manually signed and dated acknowledgment the pool operator may establish receipt by electronic means approved by the Commission, *Provided, however,* That the requirement of § 4.23(a)(3) to retain the acknowledgment specified in this paragraph (b) applies equally to such substitute evidence of receipt, which must be retained either in hard copy form or in another form approved by the Commission.

5. Section 4.26, paragraph (d) is proposed to be revised to read as follows:

§ 4.26 Use, amendment and filing of Disclosure Document.

(a) * * *

(b) * * *

(c) * * *

(d) Except as provided by § 4.8:

(1) The commodity pool operator must file with the Commission two copies of the Disclosure Document for each pool that it operates or that it intends to operate not less than 21 calendar days prior to the date the pool operator first intends to deliver the Document to a prospective participant in the pool; *Provided, however,* that a pool operator electing to file electronically pursuant to § 4.2(a) must file a single copy of the Disclosure Document; and

(2) The commodity pool operator must file with the Commission two copies of all subsequent amendments to the Disclosure Document for each pool that it operates or that it intends to operate within 21 calendar days of the date upon which the pool operator first knows or has reason to know of the defect requiring the amendment; *Provided, however,* that a pool operator electing to file electronically pursuant to § 4.2(a) must file a single copy of each such amendment.

Subpart C—Commodity Trading Advisors

6. Section 4.31, paragraph (b) is proposed to be revised to read as follows:

§ 4.31 Required delivery of Disclosure Document to prospective clients.

(a) * * *

(b) The commodity trading advisor may not enter into an agreement with a prospective client to direct the client's commodity interest account or to guide the client's commodity interest trading unless the trading advisor first receives from the prospective client an acknowledgment signed and dated by the prospective client stating that the client received a Disclosure Document for the trading program pursuant to which the trading advisor will direct his account or will guide his trading. Where a Disclosure Document is delivered to a prospective client by electronic means, in lieu of a manually signed and dated acknowledgment the trading advisor may establish receipt by electronic means approved by the Commission, *Provided, however,* That the requirement of § 4.33(a)(2) to retain the acknowledgment specified in this paragraph (b) applies equally to such substitute evidence of receipt, which must be retained either in hard copy form or in another form approved by the Commission.

7. Section 4.36, paragraph (d) is proposed to be revised to read as follows:

§ 4.36 Use, amendment and filing of Disclosure Document.

(a) * * *

(b) * * *

(c) * * *

(d)(1) The trading advisor must file with the Commission two copies of the Disclosure Document for each trading program that it offers or that it intends to offer not less than 21 calendar days prior to the date the trading advisor first intends to deliver the Document to a prospective client in the trading program; *Provided, however,* that a trading advisor electing to file electronically pursuant to § 4.2(a) must file a single copy of the Disclosure Document.

(2) The commodity trading advisor must file with the Commission two copies of all subsequent amendments to the Disclosure Document for each trading program that it offers or that it intends to offer within 21 calendar days of the date upon which the trading advisor first knows or has reason to know of the defect requiring the amendment; *Provided, however,* that a trading advisor electing to file electronically pursuant to § 4.2(a) must file a single copy of each such amendment.

Issued in Washington, D.C. on August 19, 1996, by the Commission.

Jean A. Webb,

Secretary of the Commission.

[FR Doc. 96–21674 Filed 8–26–96; 8:45 am]

BILLING CODE 6351–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 730

[Docket No. 96N–0174]

RIN 0910–AA69

Food and Cosmetic Labeling; Revocation of Certain Regulations; Opportunity for Public Comment; Extension of the Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA) is extending to October 10, 1996, the comment period on the proposal to revoke certain cosmetic regulations that appear to be obsolete. The proposed rule was published in the Federal Register of June 12, 1996 (61 FR 29708). The agency is taking this action in response to a request from a trade association. This extension of the comment period is intended to allow interested persons additional time to submit comments to FDA on the proposed revocation of certain cosmetic regulations.

DATES: Written comments by October 10, 1996.

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: Corinne L. Howley, Center for Food Safety and Applied Nutrition (HFS–24), 200 C St. SW., Washington, DC 20204, 202–205–4272.

SUPPLEMENTARY INFORMATION: In the Federal Register of June 12, 1996 (61 FR 29708), FDA issued a proposed rule to revoke certain regulations that appear to be obsolete. These regulations were identified by FDA as candidates for revocation following a page-by-page review of its regulations that the agency conducted in response to the Administration's ''Reinventing Government'' initiative. Interested person were given until August 26, 1996, to comment on the proposed rule.

FDA received a request from a trade association for an extension of the comment period on the agency's June 12, 1996, proposed revocation of part 730 of FDA's regulations (21 CFR part 730), on voluntary reporting of cosmetic product experiences. The trade association requested more time so that the proposed action could be considered by the association's board of directors. After careful consideration, FDA has decided to extend the comment period to October 10, 1996, to allow additional time for the submission of comments on whether it should revoke part 730. The extension is only for comments on this aspect of the proposed rulemaking.

Interested persons may, on or before October 10, 1996, submit to Dockets Management Branch (address above) written comments regarding whether part 730 should be revoked. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 21, 1996.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 96–21818 Filed 8–26–96; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Part 880

[Docket No. 85N–0285]

Medical Devices; Reclassification of the Infant Radiant Warmer

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to reclassify the infant radiant warmer from class III (premarket approval) into class II (special controls) based on new information regarding the device. The infant radiant warmer is a device consisting of an infrared heating element intended to maintain the infant's body temperature by means of radiant heat. This document summarizes the basis for the agency's findings that sufficient valid scientific evidence is available to support reclassification of the infant radiant warmer and to establish special controls to provide reasonable assurance of the safety and effectiveness of the device. This action implements the Medical Device Amendments of 1976 (the amendments) as amended by the Safe Medical Devices Act of 1990 (the SMDA).

DATES: Written comments by November 25, 1996. FDA proposes that any final rule based on this proposal become final 30 days after publication in the Federal Register.

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: Janet L. Scudiero, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1287.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Classification and Reclassification of Devices Under the Medical Device Amendments of 1976
II. Reclassification Under the Safe Medical Devices Act of 1990
III. History of the Proceedings
IV. Device Description
V. Recommendation of the Panel
VI. Summary of the Reasons for the Recommendation
VII. Risks to Health
VIII. Summary of Data Upon Which the Recommendation is Based
IX. FDA's Tentative Findings
X. Environmental Impact
XI. Analysis of Impacts
XII. Paperwork Reduction Act of 1995
XIII. Request for Comments
XIV. References

I. Classification and Reclassification of Devices Under the Medical Device Amendments of 1976

Under section 513 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c), as established by the amendments (Pub. L. 94–295) and amended by the SMDA (Pub. L. 101–629), FDA must classify devices into one of three regulatory classes: Class I, class II, or class III. FDA's classification of a device is determined by the amount of regulation necessary to provide reasonable assurance of safety and effectiveness of a device. Except as provided in section 520(c) of the act (21 U.S.C. 360j(c)), FDA may not use confidential information concerning a device's safety and effectiveness as a basis for reclassification of the device from class III into class II or class I.

Under the original 1976 act, devices were to be classified into class I (general controls) if there was information showing that the general controls of the act were sufficient to assure safety and effectiveness; into class II (performance