requirements and associated burden estimates by contacting the Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, D.C. 20426 [Attention: Michael Miller, Office of the Chief Information Officer, (202) 208–1415], and the Office of Management and Budget [Attention: Desk Officer for the Federal Energy Regulatory Commission (202) 395–3087 (telephone), 202–395–7285 (facsimile)]. In addition, interested persons may file written comments on the collections of information required by this NOPR and associated burden estimates by sending written comments to the Desk Officer for FERC at: Office of Management and Budget, Room 10202 NEOB, Washington, D.C. 20503, within 30 days of publication of this document in the **Federal Register**. Three copies of any comments filed with the Office of Management and Budget also should be sent to the following address: Secretary, Federal Energy Regulatory Commission, Room 1A, 888 First Street, N.E., Washington, D.C. 20426.

VII. Public Comment Procedure

Prior to taking final action on this proposed rulemaking, we are inviting written comments from interested persons. All comments in response to this notice should be submitted to the Office of Secretary, Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, D.C. 20426, and should refer to Docket No. RM98–3–000. An original and fourteen (14) copies of such comments should be filed with the Commission on or before September 21, 1998. Additionally, a copy of the comments also should be submitted to the Commission on computer diskette in WordPerfect 6.1 or ASCII format.

All written submissions to this NOPR will be placed in the public file and will be available for public inspection in the Commission's Public Reference Room, 888 First Street, N.E., Washington, D.C. 20426, during regular business hours.

List of Subjects in 18 CFR Part 37

Electric utilities.

By direction of the Commission.

David P. Boergers,

Acting Secretary.

In consideration of the foregoing, the Commission proposes to amend Part 37 in Chapter I, Title 18, *Code of Federal Regulations,* as set forth below.

PART 37—OPEN ACCESS SAME-TIME INFORMATION SYSTEMS AND STANDARDS OF CONDUCT FOR PUBLIC UTILITIES

1. The authority citation for Part 37 continues to read as follows:

Authority: 16 U.S.C. 791–825r, 2601–2645; 31 U.S.C. 9701; 42 U.S.C. 7101–7352.

2. Section 37.5 is amended by redesignating paragraph (c) as paragraph (e), and by adding paragraphs (c) and (d), to read as follows:

§ 37.5 Obligations of Transmission Providers and Responsible Parties.

* * * * *

(c) A Responsible Party may not deny or restrict access to an OASIS user merely because that user makes automated computer-to-computer file transfers or queries, or extensive requests for data.

(d) In the event that an OASIS user's grossly inefficient method of accessing an OASIS node or obtaining information from the node degrades the performance of the node, the Responsible Party should instruct the user on how to obtain the information in a less resource-intensive manner, and may seek Commission approval to limit that user's OASIS access if the matter cannot be resolved informally.

* * * * *

3. Section 37.6 is amended by revising paragraphs (a) intoductory text, (a)(4), (a)(5), and (e)(3)(ii), and by adding paragraph (a)(6) to read as follows:

§ 37.6 Information to be posted on an OASIS.

(a) The information posted on the OASIS must be in such detail and the OASIS must have such capabilities as to allow Transmission Customers to:

* * * * *

(4) Clearly identify the degree to which their transmission service requests or schedules were denied or interrupted;

(5) Obtain access, in electronic format, to information to support available transmission capability calculations and historical transmission service requests and schedules for various audit purposes; and

(6) Make file transfers and automated computer-to-computer file transfers and queries.

* * * * *

(e) * * *

(3) * * *

(ii) Information to support any such curtailment or interruption, including the operating status of the facilities involved in the constraint or interruption and any other uses of the congested path at the time of the curtailment or interruption, must be maintained for three years and provided, upon request, to the curtailed or interrupted customer, the Commission's Staff, and any other person who requests it.

* * * * *

[FR Doc. 98–21016 Filed 8–6–98; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 806

[Docket No. 98N–0439]

Medical Devices; Reports of Corrections and Removals; Companion to Direct Final Rule

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend its regulations governing reports of corrections and removals of medical devices to eliminate the requirement for distributors to make such reports. This proposed rule is a companion document to the direct final rule published elsewhere in this issue of the **Federal Register**. The amendments are being made to implement provisions of the Federal Food, Drug, and Cosmetic Act (the act), as amended by the Food and Drug Administration Modernization Act of 1997 (FDAMA). This companion proposed rule is issued under FDAMA and the act as amended.

DATES: Comments must be received on or before October 21, 1998. Comments on the information collection requirements must be received on or before October 6, 1998.

ADDRESSES: Submit written comments on the companion proposed rule to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Rosa M. Gilmore, Center for Devices and Radiological Health (HFZ–215), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20857, 301–827–2970.

SUPPLEMENTARY INFORMATION:

I. Background

A. Rulemaking Action

This proposed rule is a companion to the direct final rule published in the

final rules section of this issue of the **Federal Register**. The direct final rule and this companion proposed rule are substantively identical. FDA is publishing the direct final rule because the rule contains noncontroversial changes, and FDA anticipates that it will receive no significant adverse comment. A detailed discussion of this rule is set forth in the preamble of the direct final rule. If no significant comment is received in response to the direct final rule, no further action will be taken related to this proposed rule. Instead, FDA will publish a confirmation document within 30 days after the comment period ends confirming that the direct final rule will go into effect on December 21, 1998. Additional information about FDA's direct final rulemaking procedures is set forth in a guidance published in the **Federal Register** of November 21, 1997 (62 FR 62466).

If FDA receives any significant adverse comment regarding this proposed rule, FDA will publish a document withdrawing the direct final rule within 30 days after the comment period ends and will proceed to respond to all of the comments under this companion proposed rule using usual notice-and-comment procedures. The comment period for this companion proposed rule runs concurrently with the direct final rule's comment period. Any comments received under this companion proposed rule will also be considered comments regarding the direct final rule.

A significant adverse comment is defined as a comment that explains why the rule would be inappropriate, including challenges to the rule's underlying premise or approach, or would be ineffective or unacceptable without change. In determining whether a significant adverse comment is sufficient to terminate a direct final rulemaking, FDA will consider whether the comment raises an issue serious enough to warrant a substantive response in a notice-and-comment process. Comments that are frivolous, insubstantial, or outside the scope of the rule will not be considered adverse under this procedure. For example, a comment requesting that device manufacturers report corrections and removals under part 806 (21 CFR part 806) when a report is required and has already been submitted under 21 CFR part 803 will not be considered a significant adverse comment because it is outside the scope of the rule. In addition, if a significant adverse comment applies to part of a rule and that part can be severed from the remainder of the rule, FDA may adopt as final those parts of the rule that are not the subject of a significant adverse comment.

This action is part of FDA's continuing effort to achieve the objectives of the President's ''Reinventing Government'' initiative, and it is intended to reduce the burden of unnecessary regulations on medical devices without diminishing the protection of public health.

B. Changes Required by FDAMA

FDAMA amended section 519(f) of the act (21 U.S.C. 360i(f)) to eliminate the requirement that distributors report corrections and removals. Section 519(f)(1) of the act previously required FDA to require device manufacturers, distributors, and importers to report promptly to FDA any correction or removal of a device undertaken : (1) To reduce a risk to health posed by the device; or (2) to remedy a violation of the act caused by a device which may present a risk to health. Section 519(f)(1) of the act also had required that manufacturers, distributors, and importers keep records of those corrections and removals that are not required to be reported to FDA. In accordance with the changes required by FDAMA, the reporting and recordkeeping requirements relating to corrections and removals have been eliminated for distributors. The requirements of the statute and FDA's implementing regulations remain unchanged for manufacturers and importers. In addition, FDAMA did not change the remaining provisions of 519(f) of the act. Section 519(f)(2) of the act provides that no report of a correction or removal action under section 519(f)(1) may be required if a report of the correction or removal is required and has been submitted to FDA under section 519(a), which prescribes rules for reporting and keeping records of certain significant device-related events. Section 519(f)(3) of the act states that the terms ''correction'' and ''removal'' do not include routine servicing.

C. History of 21 CFR Part 806

In the **Federal Register** of May 17, 1997 (62 FR 27183), FDA issued a final rule implementing the reports of corrections and removals provisions of the Safe Medical Devices Act of 1990, which required device manufacturers, distributors, and importers to report promptly to FDA any corrections or removals of a device undertaken to reduce a risk to health posed by the device or to remedy a violation of the act caused by the device which may present a risk to health. These regulations were codified in part 806.

In the **Federal Register** of December 24, 1997 (63 FR 67274), FDA announced that it was staying the effective date of the information collection requirements of part 806 because the information collection requirements in the final rule had not yet received approval from the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA). Following OMB's approval of the collection of information provisions for reports of corrections and removals (see the **Federal Register** of February 17, 1998 (63 FR 7811)), FDA published in the **Federal Register** of April 16, 1998 (63 FR 18836) a final rule lifting the stay of effective date and the information collection requirements became effective May 18, 1998.

On November 21, 1997, the President signed FDAMA into law (Pub. L. 101–115). Section 213 of FDAMA amended section 519(f) of the act by eliminating ''distributors'' from the reporting requirements of the reports of corrections and removals provisions of the act. FDAMA did not change the obligations of device manufacturers and importers, who continue to be required to comply with the existing reporting and recordkeeping provisions of the act for corrections and removals.

II. Changes to Part 806—Medical Device; Reports of Corrections and Removals

Section 519(f)(1) of the act, as amended by section 213 of FDAMA, no longer requires ''distributors'' to report corrections and removals of medical devices. Accordingly, the following changes are being proposed to part 806 to implement the FDAMA provision:

1. Section 806.1 would be amended in paragraphs (a) and (b)(1) by changing the words ''manufacturers and distributors, including importers,'' to ''manufacturers and importers.''

2. Section 806.2(f) would be amended by eliminating the definition of ''distributor'' that included a person who imports devices into the United States, and replacing that definition of distributor with a separate definition of ''importer.'' For the purposes of this part, ''importer'' would mean any person who imports a device into the United States.

3. Section 806.10 would be revised in paragraphs (a), (b), (c), (c)(2), (c)(4), (d), and (e) to remove the word ''distributor'' each time it appears.

4. Section 806.20 would be amended in paragraphs (a) and (c) to remove the words ''importer, or distributor'' each time they appear and replace them with ''or importer.''

5. Section 806.30 would be amended to remove the words ''importer, or distributor'' each time they appear and replace them with ''or importer.''

III. Environmental Impact

The agency has determined under 21 CFR 25.30(h) that this proposed action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IV. Analysis of Impact

FDA has examined the impact of this companion proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612) (as amended by subtitle D of the Small Business Regulatory Fairness Act of 1996 (Pub. L. 104–121)), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Order 12866 directs agencies to assess all costs of available regulatory alternatives and, when regulatory action is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this proposed rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the proposed rule is not a significant regulatory action as defined by the Executive Order and therefore not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. The proposed rule eliminates the reporting requirements for ''distributors,'' as mandated by FDAMA, thereby reducing regulatory burdens. The agency, therefore, certifies that this proposed rule, if issued, will not have a significant economic impact on a substantial number of small entities. In addition, this proposed rule will not impose costs of $100 million or more in either the private sector or State, local, and tribal governments in the aggregate, and therefore a summary statement of analysis under section 202(a) of the Unfunded Mandates Reform Act is not required.

V. Paperwork Reduction Act of 1995

This proposed rule contains information collection provisions that are subject to review by OMB under the PRA (44 U.S.C. 3501–3520). The title, description, and respondent description of the information collection provisions are shown below with an estimate of the annual reporting and recordkeeping burden. Included in the estimate is the time for reviewing the instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Medical Devices; Reports of Corrections and Removals.

Description: FDA is issuing this proposed rule to amend the reporting and recordkeeping requirements for corrections and removals under part 806 to eliminate those requirements for distributors of medical devices. This amendment implements changes made by FDAMA to section 519(f) of the act. FDAMA did not amend section 519(f) of the act with respect to manufacturers and importers. Manufacturers and importers continue to be subject to the requirements of part 806.

Description of Respondents: Business or other for profit organizations.

FDA estimates the burden for this collection of information as follows:

TABLE 1.—Estimated Annual Reporting Burden[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
806.10	880	1	880	10	8,800

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2.—Estimated Annual Recordkeeping Burden[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
806.20	440	1	440	10	4,400

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

The information collection requirements in part 806 prior to this proposed rule have been approved by OMB and assigned control number 0910–0359. When preparing the earlier package for approval of the information collection requirements in part 806, FDA reviewed the reports of corrections and removals submitted in the previous 3 years under 21 CFR part 7 (the agency's recall provisions). During that period of time, no reports of corrections or removals were submitted by distributors. For that reason, FDA did not include distributors among the respondents estimated in the collection burden for the requirements previously approved by OMB. Because distributors were not included in that earlier estimate and because FDAMA now has eliminated requirements for distributor reporting, FDA has determined that estimates of the reporting burden for §§ 806.10 and 806.20 should remain the same.

For consistency with the direct final rule to which this proposed rule is a companion, FDA is following the PRA comment procedures for direct final rules in this proposed rule. As provided

in 5 CFR 1320.5(c)(1), collections of information in a direct final rule are subject to the procedures set forth in 5 CFR 1320.10. Interested persons and organizations may, by October 6, 1998, submit to the Dockets Management Branch (address above) comments on the information collection provisions of this proposed rule.

At the close of the 60-day comment period, FDA will review the comments received, revise the information collection provisions as necessary, and submit these provisions to OMB for review. FDA will publish a document in the **Federal Register** when the information collection provisions are submitted to OMB, and an opportunity for public comment to OMB will be provided at that time. Prior to the effective date of the final rule, FDA will publish a document in the **Federal Register** of OMB's decision to approve, modify, or disapprove the information collection provisions. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

VI. Comments

Interested persons may, on or before October 21, 1998, submit to the Dockets Management Branch (address above) written comments regarding this proposal. This comment period runs concurrently with the comment period for the direct final rule. 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 the 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. All comments received will be considered comments regarding the direct final rule and this proposed rule. In the event the direct final rule is withdrawn, all comments received will be considered comments on this proposed rule.

List of Subjects in 21 CFR Part 806

Corrections and removals, Medical devices, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act, and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 806 be amended as follows:

1. The part heading for part 806 is revised to read as follows:

PART 806—MEDICAL DEVICES; REPORTS OF CORRECTIONS AND REMOVALS

2. The authority citation for 21 CFR part 806 continues to read as follows:

Authority: 21 U.S.C. 352, 360, 360i, 360j, 371, 374.

3. Section 806.1 is amended by revising paragraphs (a) and (b)(1) to read as follows:

§ 806.1 Scope.

(a) This part implements the provisions of section 519(f) of the Federal Food, Drug, and Cosmetic Act (the act) requiring device manufacturers and importers to report promptly to the Food and Drug Administration (FDA) certain actions concerning device corrections and removals, and to maintain records of all corrections and removals regardless of whether such corrections and removals are required to be reported to FDA.

(b) * * *

(1) Actions taken by device manufacturers or importers to improve the performance or quality of a device but that do not reduce a risk to health posed by the device or remedy a violation of the act caused by the device.

* * * * *

4. Section 806.2 is amended by revising paragraph (f) to read as follows:

§ 806.2 Definitions.

* * * * *

(f) ''Importer'' means, for the purposes of this part, any person who imports a device into the United States.

* * * * *

5. Section 806.10 is amended by revising paragraphs (a) and (b), the introductory text of paragraph (c), paragraph (c)(2), and the last sentence of paragraph (c)(4); and in paragraphs (d) and (e) by removing the word '', distributor,'' each time it appears to read as follows:

§ 806.10 Reports of corrections and removals.

(a) Each device manufacturer or importer shall submit a written report to FDA of any correction or removal of a device initiated by such manufacturer or importer if the correction or removal was initiated:

(1) To reduce a risk to health posed by the device; or

(2) To remedy a violation of the act caused by the device which may present a risk to health unless the information has already been provided as set forth in paragraph (f) of this section or the corrective or removal action is exempt from the reporting requirements under § 806.1(b).

(b) The manufacturer or importer shall submit any report required by paragraph (a) of this section within 10-working days of initiating such correction or removal.

(c) The manufacturer or importer shall include the following information in the report:

* * * * *

(2) The name, address, and telephone number of the manufacturer or importer, and the name, title, address, and telephone number of the manufacturer or importer representative responsible for conducting the device correction or removal.

* * * * *

(4) * * * A manufacturer or importer that does not have an FDA establishment registration number shall indicate in the report whether it has ever registered with FDA.

* * * * *

6. Section 806.20 is amended by revising paragraphs (a) and (c) to read as follows:

§ 806.20 Records of corrections and removals not required to be reported.

(a) Each device manufacturer or importer who initiates a correction or removal of a device that is not required to be reported to FDA under § 806.10 shall keep a record of such correction or removal.

* * * * *

(c) The manufacturer or importer shall retain records required under this section for a period of 2 years beyond the expected life of the device, even if the manufacturer or importer has ceased to manufacture or import the device. Records required to be maintained under paragraph (b) of this section must be transferred to the new manufacturer or importer of the device and maintained for the required period of time.

7. Section 806.30 is revised to read as follows:

§ 806.30 FDA access to records.

Each device manufacturer or importer required under this part to maintain records and every person who is in charge or custody of such records shall, upon request of an officer or employee designated by FDA and under section 704(e) of the act, permit such officer or employee at all reasonable times to have access to, and to copy and verify, such records and reports.

Dated: July 9, 1998.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 98–21092 Filed 8–6–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR PART 165

[CGD09–97–002]

RIN 2115–AE84

Regulated Navigation Area—Air Clearance Restrictions at the Entrance to Lakeside Yacht Club and the Northeast Approach to Burke Lakefront Airport in Cleveland Harbor, OH

AGENCY: Coast Guard, DOT.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to establish a regulated navigation area at the entrance to the Lakeside Yacht Club in Cleveland Harbor, Ohio, underneath the northeast approach to the Burke Lakefront Airport, in order to avoid conflict with the safety parameters for an instrument-guided aircraft approach slope. The regulation would create a set of restricted areas, some of which would prohibit docking of vessels of certain heights, others which would require vessels of certain heights to obtain clearance from the Airport before entering or leaving the entrance to the yacht club during times when the instrument system is in use. Vessels with masts less than 41 feet above the waterline would not be affected at all, and vessels less than 45 feet in height would not be required to make any change in their normal areas of navigation or docking. Vessels with masts between 45 and 95 feet would be subject to a requirement to obtain a routine clearance by radio or telephone before navigating through the area, and vessels between 53 and 95 feet would be limited to certain specified areas for docking. Vessels 95 feet and above, none of which are currently using the area, would be prohibited from any entry into the area.

DATES: Comments must be received on or before November 5, 1998.

ADDRESSES: Comments and supporting materials may be mailed or delivered to Lieutenant Lynn Goldhammer, Assistant Chief, Marine Safety Analysis and Policy Branch, Ninth Coast Guard District, Room 2069, 1240 E. Ninth Street, Cleveland, Ohio, 44199–2060. Comments may also be telefaxed to (216) 902–6059. Please reference the name of the proposal and the docket number [CGD09–97–002] in any communication. If you wish receipt of your mailed comment to be acknowledged, please include a stamped self-addressed envelope or postcard for that purpose. Comments and materials received will be available for public inspection at the above location from 9 a.m. to 3 p.m. Monday through Friday except federal holidays.

FOR FURTHER INFORMATION CONTACT: Lieutenant Lynn Goldhammer, Assistant Chief, Marine Safety Analysis and Policy Branch, Ninth Coast Guard District, Room 2069, 1240 E. Ninth Street, Cleveland, Ohio, 44199–2060, (216) 902–6050.

Request for Comments: The Coast Guard encourages interested persons to participate in this rulemaking by submitting comments which may consist of data, views, arguments, or proposals for amendments to the proposed regulations. The Coast Guard does not currently plan to have a public hearing. However, consideration will be given to holding a public hearing if it is requested. Such a request should indicate how a public hearing would contribute substantial information or views which cannot be received in written form. If it appears that a public hearing would substantially contribute to this rulemaking and there is sufficient time to publish a notice, the Coast Guard will announce such a hearing by a later notice in the **Federal Register.** The Coast Guard will consider all comments received before the closing date indicated above, and may amend or revoke this proposal in response to such comments.

Background and Purpose

Burke Lakefront Airport, located next to Cleveland Harbor in Cleveland, Ohio, proposes to install an instrument-guided approach system for the northeast approach to the Airport which is important to maintaining safe and commercially viable airport operations. Under Federal Aviation Administration flight standards, this instrument-guided approach, during times when available for use, will require a more extensive zone of air clearance than the existing visual approach. The Lakeside Yacht Club is located in Cleveland Outer harbor near the northeast end of the runway, and the entrance channel leading into the yacht club docks is immediately adjacent to the end of the runway (Runway 24R). The configuration of the area between the airport and the yacht club is depicted in Figure 1.

BILLING CODE 4910–15–M