

(Catalog of Federal Domestic Assistance Program No. 93.733, Medicare—Hospital Insurance Program; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: December 16, 2005.

**Mark B. McClellan,**

*Administrator, Centers for Medicare & Medicaid Services.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2005N-0484]

#### Agency Information Collection Activities; Proposed Collection; Comment Request; Medical Device Reporting; Manufacturer Reporting, Importer Reporting, User Facility Reporting, and Distributor Reporting

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on Medical Device Reporting; Manufacturer Reporting, Importer Reporting, User Facility Reporting, and Distributor Reporting.

**DATES:** Submit written or electronic comments on the collection of information by February 21, 2006.

**ADDRESSES:** Submit electronic comments on the collection of information to: <http://www.fda.gov/dockets/ecomments>. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Denver Presley, Office of Management Programs (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1472.

**SUPPLEMENTARY INFORMATION:** Under the PRA (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (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.

#### Medical Device Reporting; Manufacturer Reporting, Importer Reporting, User Facility Reporting, and Distributor Reporting—21 CFR Part 803 (OMB Control Number 0910-0437)

Section 519(a), (b), and (c) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360i(a), (b), and (c)) requires user facilities, manufacturers, and importers of medical devices to report adverse events involving medical devices to FDA. On December 11, 1995 (60 FR 63578 at 63597), FDA issued part 803 (21 CFR part 803) that implemented section 519 of the act. The regulation was amended to conform to the changes reflected in the FDA Modernization Act of 1997.

Information from these reports will be used to evaluate risks associated with medical devices and to enable FDA to take appropriate regulatory measures to protect the public health.

Respondents to this collection of information are businesses or other for profit and nonprofit organizations including user facilities, manufacturers, and importers of medical devices.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

| 21 CFR Section        | No. of Respondents | Annual Frequency per Response | Total Annual Responses | Hours per Response | Total Hours |
|-----------------------|--------------------|-------------------------------|------------------------|--------------------|-------------|
| 803.19                | 55                 | 4                             | 220                    | 3                  | 660         |
| 803.30                | 700                | 5                             | 3,500                  | 1                  | 3,500       |
| 803.33, FDA Form 3419 | 700                | 1                             | 700                    | 1                  | 700         |
| 803.40                | 40                 | 17                            | 680                    | 1                  | 680         |
| 803.50                | 1,465              | 57                            | 83,505                 | 1                  | 83,505      |
| 803.55, FDA Form 3417 | 700                | 5                             | 3,500                  | 1                  | 3,500       |
| Total                 |                    |                               |                        |                    | 92,545      |

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN <sup>1</sup>

| 21 CFR Section    | No. of Recordkeepers | Annual Frequency per Recordkeeping | Total Annual Records | Hours per Record | Total Hours |
|-------------------|----------------------|------------------------------------|----------------------|------------------|-------------|
| 803.17            | 220                  | 1                                  | 220                  | 3.3              | 726         |
| 803.18(c) and (d) | 30,000               | 1                                  | 30,000               | 1.5              | 45,000      |
| Total             |                      |                                    |                      |                  | 45,726      |

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

Part 803 requires user facilities to report to the device manufacturer, and to FDA in the case of a death, incidents where a medical device caused or contributed to a death or serious injury. Manufacturers of medical devices are required to report to FDA when they become aware of information indicating that one of their devices may have caused or contributed to death or serious injury or has malfunctioned in such a way that should the malfunction recur it would be likely to cause or contribute to a death or serious injury. Device importers report deaths and serious injuries to the manufacturers and FDA. Importers report malfunctions only to the manufacturers, unless they are unknown, then the reports are sent to FDA.

The number of respondents for each CFR section in table 1 of this document is based upon the number of respondents entered into FDA's internal databases. FDA estimates, based on its experience and interaction with the medical device community, that all reporting CFR sections are expected to take 1 hour to complete, with the exception of § 803.19. Section 803.19 is expected to take approximately 3 hours to complete, but is only required for reporting the summarized data quarterly to FDA. By summarizing events, the total time used to report for this section is reduced because the respondents do not submit a full report for each event they report in a quarterly summary report.

The agency believes that the majority of manufacturers, user facilities, and importers have already established written procedures to document complaints and information to meet the medical device reporting (MDR) requirements as part of their internal quality control system. There are an estimated 30,000 medical device distributors. Although they do not submit MDR reports, they must maintain records of complaints, under § 803.18(d).

The agency has estimated that on average, 220 user facilities, importers, and manufacturers would annually be required to establish new procedures, or

revise existing procedures, in order to comply with this provision.

Therefore, FDA estimates the one-time burden to respondents for establishing or revising procedures to be 2,200 hours (220 respondents x 10 hours). For those entities, a one-time burden of 10 hours is estimated for establishing written MDR procedures. The remaining manufacturers, user facilities, and importers, not required to revise their written procedures to comply with this provision, are excluded from the burden because the recordkeeping activities needed to comply with this provision are considered "usual and customary" under 5 CFR 1320.3(b)(2).

The annual burden for recordkeeping to respondents follows. Under § 803.17, FDA estimates 220 respondents will spend approximately 3.3 hours to complete the requirements for this section. The number of respondents was estimated by consolidating the total of all new reporting entities together. The 3.3 hours was estimated by FDA, as this section deals with a respondent creating new MDR procedures and is a one-time function. The "total hours" for this section equals approximately 726 hours.

Under § 803.18, 30,000 respondents represent distributors, importers, and other respondents to this information collection. FDA estimates that it should take them approximately 1½ hours to complete the recordkeeping requirement for this section. Total hours for this section equal 45,000 hours.

Dated: December 8, 2005.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

[USCG-2005-23285]

### Collection of Information Under Review by Office of Management and Budget: OMB Control Number 1625-0048

**AGENCY:** Coast Guard, DHS.

**ACTION:** Request for comments.

**SUMMARY:** In compliance with the Paperwork Reduction Act of 1995, the U.S. Coast Guard intends to seek the approval of OMB for the renewal of an Information Collection Request (ICR). The ICR is 1625-0048, Vessel Reporting Requirements. Before submitting the ICRs to OMB, the Coast Guard is inviting comments on them as described below.

**DATES:** Comments must reach the Coast Guard on or before February 21, 2006.

**ADDRESSES:** To make sure that your comments and related material do not enter the docket [USCG-2005-23285] more than once, please submit them by only one of the following means:

(1) By mail to the Docket Management Facility, U.S. Department of Transportation (DOT), room PL-401, 400 Seventh Street SW., Washington, DC 20590-0001.

(2) By delivery to room PL-401 on the Plaza level of the Nassif Building, 400 Seventh Street SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is 202-366-9329.

(3) By fax to the Docket Management Facility at 202-493-2251.

(4) Electronically through the Web Site for the Docket Management System at <http://dms.dot.gov>.

The Docket Management Facility maintains the public docket for this notice. Comments and material received from the public, as well as documents mentioned in this notice as being available in the docket, will become part of this docket and will be available for inspection or copying at room PL-401