

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01N-0277]

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Certifier	Romoni Oliver

**Agency Information Collection Activities; Proposed Collection; Comment Request; Reports of Corrections and Removals**

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

**ACTION:** Notice.

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**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 information collection requirements for reports of corrections and removals.

**DATES:** Submit written or electronic comments on the collection of information by [*insert date 60 days after date of publication in the Federal Register*].

**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 Dockets Management Branch (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:** Peggy Schlosburg, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1223.

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**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: (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.

**Reports of Corrections and Removals—21 CFR Part 806 (OMB Control No. 0910–0359)—  
Extension**

Section 519(f) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360i(f)) directs FDA to issue regulations to require device manufacturers and importers to report promptly to FDA, any correction or removal of a device undertaken by such manufacturers and importers, if the correction or removal was 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. Under 21 CFR 806.10 and 806.20(a), FDA requires that each device manufacturer and importer shall

submit a written report to FDA of any action initiated to correct or remove a device 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 within 10-working days of initiating such correction or removal. In addition, each manufacturer and importer of a device who initiates a correction or removal of a device that is not required to be reported to FDA, shall keep a record of such correction or removal.

The information collected in the reports of corrections and removals will be used by FDA to identify marketed devices that have serious problems and to ensure that dangerous and defective devices are removed from the market, assuring that FDA has current and complete information regarding these corrections and removals and whether recall action is adequate. Failure to collect this information prevents FDA from receiving timely information about devices that may have a serious effect on the health of the users of the devices.

Respondents to this information collection are businesses or other for-profit manufacturers or importers of medical devices who must remove or correct medical devices that cause public health risk to the general public.

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
806.10	880	1	880	10	8,800

<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 Recordkeeper	Total Hours
806.20(a)	440	1	440	10	4,400

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

The following is an explanation of the burden estimate:

*Reporting Burden*

FDA estimates that it would take 10 staff hours to prepare and assemble a written report. For the estimated 880 reports, FDA estimates that respondents will spend 8,800 hours to prepare, assemble, and send the reports.

*Recordkeeping Burden*

FDA estimates that it would take 10 staff hours to prepare a written record. For the estimated 440 records, the total recordkeeping burden is estimated at 4,400 hours per recordkeeper.

Dated: 6/29/01  
June 29, 2001.

Margaret M. Dotzel

Margaret M. Dotzel,  
Associate Commissioner for Policy.

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Monica Oliver

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