

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01N-0277]

DMB

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Certifier	<i>[Signature]</i>

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Reports of Corrections and Removals

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments on the collection of information by *[insert date 30 days after date of publication in the Federal Register]*.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Wendy Taylor, Desk Officer for FDA.

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.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

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

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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.

In the **Federal Register** of July 6, 2001 (66 FR 35644), the agency requested comments on the proposed collection of information. No comments were received.

FDA estimates the burden of 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 Recordkeepers	Annual Frequency of Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
806.20(a)	440	1	440	10	4,400

¹ 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:

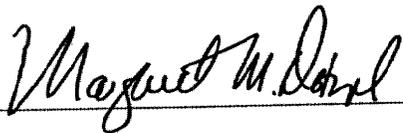
Reporting Burden

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: 10/5/01
October 5, 2001.



Margaret M. Dotzel,
Associate Commissioner for Policy.

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