SUPPORTING STATEMENT FOR REPORTS OF CORRECTIONS AND REMOVALS

21 CFR PART 806

A. JUSTIFICATION

1. Circumstances Necessitating Information Collection

The Food and Drug Administration (FDA) is amending its regulation in 21 CFR Part 806 - Medical Devices; Reports of Corrections and Removals (Attachment A), to eliminate the requirement for distributors to submit reports to FDA. The amendments are being made to implement section 519(f) (21 U.S.C. 360i(f)) of the Federal Food, Drug, and Comestic Act (the act) (21 U.S.C. 301), as amended by the Food and Drug Administration Modernization Act of 1997 (FDAMA) (Pub. L. 105-115) (Attachment B).

The information collection requirements in part 806 prior to this direct final 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 Secs. 806.10 and 806.20 should remain the same.

The FDA is requesting approval from the Office of Management and Budget (OMB) for the collection of information required by the amendments to 21 CFR Part 806 promulgated under the statutory mandate of section 519(f) of the act as amended by FDAMA. Below is a description of the information collection requirements in 21 CFR Part 806:

21 CFR 806.10 - Reporting - Each device manufacturer or 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.

21 CFR 806.20(a) - Recordkeeping - Each device manufacturers or 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.

2. How, By Whom, and For What Purpose Information Is Used

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. This will assure that FDA has current and complete information regarding these corrections and removals and to determine 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.

3. Consideration of Information Technology

In the **Federal Register** of March 20, 1997 (62 FR 13430) (Attachment C), FDA published a final rule establishing procedures for electronic records, electronic signatures, and electronic submissions. Manufacturers or importers may use appropriate technology in accordance with this rule to comply with the reports of corrections and removals requirements.

4. Identification of Duplication and Similar Information Already Available

FDA is the only federal agency responsible for the collection of this information. No data exist from any other source that can be used to report corrections and removals subject this this direct final regulation.

5. Small Businesses

The information collection will not have a significant impact on a substantial number of small entities. FDA's Division of Small Manufacturers Assistance (DSMA) and small business representatives in its six regional offices, aid small businesses subject to medical device regulations. FDA's scientific and administrative staff also provide assistance upon request or through public meetings.

6. Consequences of Less Frequent Information Collection

FDA does not require a specific frequency for this collection. Written reports are to be submitted to FDA only if a manufacturer or importer of a device undertakes a corrective or removal action to reduce a risk to health posed by the device or to remedy a violation of the act.

7. Inconsistencies with 5 CFR 1320.6

This information collection is consistent with 5 CFR 1320.6.

8. Consultations Outside FDA

In the **Federal Register** of August 7, 1998 (63 FR 42229), FDA published a direct Final Rule. (Attachment C). There were no comments received.

9. Payments or Gifts to Respondents

No payment or gifts in any manner or from shall be provided to respondents under this final regulation.

10. Confidentiality of Information

Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), the public has broad access to government documents. Reports and other information submitted to FDA under 21 CFR Part 806 are releasable if they fall within the scope of the agency's regulation concerning "Public Information" (21 CFR Part 20) (Attachment K). However, FOIA exempts disclosures of certain government records from mandatory public disclosures (5 U.S.C. 522(b)(1-9)). One such provision exempts from public disclosure "trade secrets" and "confidential commercial or financial information" that is privileged (5 U.S.C. 522(b)(4)).

11. Sensitive Questions

This information collection does not include questions pertaining to sexual behavior, attitude, religious beliefs, or any other matters that are commonly considered private or sensitive in nature.

12. Burden and Cost to Respondents

Based on previous experience, FDA estimates a total annual cost of $396,000 to comply with this regulation; $264.000 to prepare and assemble written reports required by 21 CFR 806.10, and $132,000 to maintain records of corrections and removals required by 21 CFR 806.20 that will not have to be reported to the agency.

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	88	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	440	1	440	10	4,400

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

21 CFR 806.10 Reporting

FDA estimates that it would take 10 staff hours to prepare and assemble a written report. At an average of $30 per staff-hour, the cost to prepare and assemble a report is $300 (10 staff-hours x $30 per staff-hour). For the estimated 880 reports, the final total cost would be $264,000 (880 reports x 300 per report).

21 CFR 806.20 Recordkeeping

FDA estimates that it would take 10 staff-hours to prepare a written record at an average cost of $30 per staff hour. For the estimated 440 records, the total cost would be $132,000 (440 records x 300 per record).

13. Estimated Annual Cost to Respondents or Recordkeepers

There are no additional annual cost burdens associated with the collection of information beyond what is identified in the annualized hourly reporting and recordkeeping burden. No additional capital expenditures or related service expenses are required or associated with the reporting or recordkeeping requirements other than customary and usual business practices or required to achieve regulatory compliance with other FDA regulatory requirements.

14. Estimated Annual Cost to Government

FDA estimates that the Federal government will use 1 FTE's to implement the Reports of Corrections and Removals regulations required by section 519(f) of the act. Based on a cost of $55,969 (the agency's average cost of an FTE, including benefits) per position at the GS-13 grade level, the estimated annual cost is $6155,659.

FTE	Cost Per FTE	Total Cost
11	$52,867	$581,537

15. Changes in Burden

There are no changes in the estimated reporting and recordkeeping burdens.

16. Publication of Results

No tabulation of the data is planned or anticipated.

17. Exemption for Display of Effective Date

FDA is not seeking approval to prevent the display of expiration date or OMB approval of this request.

18. Exception to Certification Statement

There are no exceptions to the certification statement identified in item 19 of OMB Form, 83 - I.

B. Collection of Information Using Statistical Methods

The use of statistical methods is not applicable because all removals and corrections of medical devices are subject to the reporting or recordkeeping requirements.