**SUPPORTING STATEMENT**
**FOR**
**REPORTS OF CORRECTIONS AND REMOVALS**
**21 CFR PART 806**
**OMB Number 0910-0359**

## A. JUSTIFICATION

### 1. Circumstances Necessitating Information Collection

Reports of Corrections and Removals (21 CFR 806) (Attachment A) implements section 519(g) (21 U.S.C. 360i(g)) (Attachment B) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 301, et seq.), as amended by the Food and Drug Modernization Act of 1997 (FDAMA) (P.L. 105-115).

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(g) 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 manufacturer 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.

This information is not related to the American Recovery and Reinvestment Act of 2009.

### 2. Purpose and Use of the Information

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 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 users of the devices.

### 3. Use of Information Technology and Burden Reduction

In the Federal Register of March 20, 1997 (62 FR 13430), 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, however the agency estimates that approximately 99% of respondents will use electronic means to fulfill the information collection request.

**4. Efforts to Identify Duplication and Use of Similar Information**

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 to this regulation.

**5. Impact on Small Businesses**

The information collection will not have a significant impact on a substantial number of small entities.

FDA aids small business by providing guidance and information through the Division of Small Manufacturers, International, and Consumers Assistance (DSMICA) and the Device Registration and Listing Branch within the Center for Devices and Radiological Health. DSMICA provides workshops, on-site evaluations, and other technical and non-financial assistance to small manufacturers. The workshops make available publications and educational materials, which include medical device establishment and listing requirements. The Division also maintains a toll-free telephone number and a website, which firms may use to obtain regulatory compliance information.

FDA's small business representatives in its six regional offices and scientific and administrative staff also aid small businesses subject to medical device regulations by providing assistance upon request or through public meetings.

**6. Consequences of Collecting the Information Less Frequently**

As FDA does not require a specific frequency for this collection, respondents will submit the information occasionally. A manufacturer or importer of a device submits a written report to FDA only when it undertakes a corrective or removal action to reduce a risk to health posed by the device or to remedy a violation of the act that may pose a risk to health.

**7. Inconsistencies with 5 CFR 1320.6.**

This information collection is consistent with 5 CFR 1320.6.

**8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency**

Notice has been published in the Federal Register on November 23, 2010 (75 FR 71446) soliciting comments on this information collection prior to its submission to the Office of Management and Budget (OMB), as required by 5 CFR 1320.8(d) . No comments were received.

**9. Explanation of Any Payment or Gift to Respondents**

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

**10. Assurance of Confidentiality Provided to Respondent**

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). 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. Justification for 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. Estimates of Annualized Burden Hours and Costs**

Based on previous experience, FDA estimates a total annual cost of $272,160 to comply with this regulation; $239,760 to prepare and assemble written reports required by 21 CFR 806.10, and $32,400 to maintain records of corrections and removals required b y 21 CFR 806.20 that will not have to be reported to the agency.

Table 1. Estimated Average Annual Reporting Burden

| CFR Section | No. of Respondents | No. of Responses per Respondent | Total Annual Responses | Average Burden per Response (in hours) | Total Hours |
|---|---|---|---|---|---|
| 806.10 | 666 | 1 | 666 | 10 | 6660 |

Table 2. Estimated Average Annual Recordkeeping Burden

| CFR Section | No. of Recordkeepers | No. of Records per Recordkeeper | Total Annual Records | Average Burden per Recordkeeping (in hours) | Total Hours |
|---|---|---|---|---|---|
| 806.20 | 90 | 1 | 90 | 10 | 900 |

**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 $36 per staff-hour, the cost to prepare and assemble a report is $360 (10 staff-hours x $36 per staff-hour). For the estimated 488 reports, the final total cost would be $239,760 (666 reports x $360 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 $36 per staff hours. For the estimated 90 records, the total cost would be $32,400 (90 records x $360 per record).

**13. Estimate of the Other Total Annual Cost Burden to Respondent 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. Annualized Cost to the Federal Government**

FDA estimates that the Federal government will use 7 FTE's to ensure compliance with the Reports of Corrections and Removals regulations required by section 519(g) of the act. Based on a cost of $113,500 (the agency's average cost of an FTE, including benefits) per position at the GS-13 grade level, the estimated annual cost is $794,500.

**15. Explanation for Program Changes or Adjustments**

FDA has determined that estimates of the reporting burden for 806.10 should be revised to reflect a projected 7.3% increase (from the last PRA numbers) in reports submitted to FDA as class I and II. FDA also estimates the recordkeeping burden in 806.20 should be revised to reflect a reduction of 6.8% (from the last PRA numbers) in records filed and maintained under

this section. The estimates of time needed to collect 806 information have not changed. These totals equal a reduction by 4,124 annual responses and an increase in burden by 1,360.

**16. Plans for Tabulation and Publication and Project Time Schedule**

No tabulation of the data is planned or anticipated.

**17. Reason(s) Display of OMB Expiration Date is Inappropriate**

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

**18. Exceptions to Certification for Paperwork Reduction Act Submissions**

There are no exceptions to the certification statement identified in item 19 of OMB Form, 83-1.

**B. COLLECTION OF INFORMATION USING STATISTICAL METHODS**

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

**LIST OF ATTACHMENTS**:

Attachment A-Food and Drug Modernization Act of 1997 (FDAMA)(P.L. 105-115)
Attachment B- Electronic Signature Rule
Attachment C-Federal register 60 Day Notice