Medical Device Reporting: Manufacturer Reporting, Importer Reporting, User Facility Reporting, Distributor Reporting
0910-0437
SUPPORTING STATEMENT

Terms of Clearance: None.

A. JUSTIFICATION

1. Circumstances Making the Collection of Information Necessary

Section 519(a), (b), and (c) of the Federal Food Drug and Cosmetic Act (the FD&C 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 the Food and Drug Administration (FDA). On December 11, 1995, FDA published a notice of rulemaking amending 21 CFR part 803 implementing section 519 of the FD&C Act (60 FR 63578). The regulation was amended to conform with the changes reflected in the 1997 FDA Modernization Act (FDAMA) and the Medical Device User Fee and Modernization Act of 2002. On February 28, 2005 (70 FR 9516), FDA rewrote the regulation into plain language. On June 13, 2008, FDA published a Notice of Proposed Rulemaking (73 FR 33749) and a Direct Final Rule (73 FR 33692) eliminating 21 CFR 803.55. The rule became effective October 27, 2008. In the Federal Register of August 21, 2009 (74 FR 42203), FDA proposed to amend the regulation to require electronic submission of all reports. As of the date of this submission, FDA has not published a final rule based on the proposal.

21 CFR 803.17 – MDR Procedures – Recordkeeping
Manufacturers, user facilities, and importers must develop, implement, and maintain written MDR procedures for internal systems that provide for timely and effective identification of events.

21 CFR 803.18 – MDR Files – Recordkeeping
Manufacturers, user facilities, and importers must establish and maintain MDR event files (§ 803.18(a)). MDR event files must contain information related to the adverse event, including documentation of the respondent's deliberations and decisionmaking processes used to determine if a device-related death, serious injury, or malfunction was or was not reportable under the regulations and copies of all MDR forms and other information related to the event that the respondent submitted to FDA and other entities (§ 803.18(b)). Under § 803.18(c), User facilities must retain an MDR event file relating to an adverse event for a period of 2 years from the date of the event. Manufacturers and importers of medical devices must retain an MDR event file relating to an adverse event for a period of 2 years from the date of the event or a period of time equivalent to the expected life of the device, whichever is greater. Under § 803.18(d), Distributors of medical devices are required to establish complaint records and to retain them for 2 years after the date of event, or the expected life of the device which ever is greater. FDAMA removed the requirement that medical device distributors submit MDR reports to FDA.

21 CFR 803.19 – Exemptions – Reporting
Allows manufacturers, importers, or user facilities of medical devices to request an exemption or variance from the Medical Device Reporting requirements (MDR).

21 CFR 803.20 – General Reporting Requirements
Medical device user facilities, importers, and manufacturers are required to submit individual medical device adverse event reports on the FDA MedWatch 3500A, approved under OMB control number 0910-0291.

21 CFR 803.30 and 803.32 – User Facility Reporting – Reporting
User facilities are required to submit MDR reports when a device causes or contributes to a death or serious injury.

21 CFR 803.33 – User Facility Annual Reporting – Reporting
User facilities are required to annually submit the number and summary of events reported during the previous calendar year (Form FDA 3419). (See attachment A.)

21 CFR 803.40 and 803.42 – Importer Reporting – Reporting and Third-Party Disclosure
Importers of medical devices are required to submit MDR death and serious injury reports to the manufacturer and the FDA. Importers send malfunction reports to the manufacturers of the problem devices, unless the manufacturers are unknown, then the reports are submitted to FDA.

21 CFR 803.50, 803.52 and 803.53 – Manufacturer Reporting – Reporting
Manufacturers of medical devices are required to submit MDR death, serious injury, and malfunction reports.
21 CFR 803.56 – Supplemental Reports – Reporting
Within 1 month of receiving the information, manufacturers must submit to FDA supplemental information that they did not previously provide because it was not known or available when they submitted the initial report.

2. Purpose and Use of the Information Collection

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.

3. Use of Improved Information Technology and Burden Reduction

FDA developed a voluntary program supporting electronic submission of Medical Device Reports in lieu of mailing paper reports. FDA provides software for low volume reporters to enter their reports and transmit the reports electronically. High volume reporters develop custom programs to extract information from their internal databases and submit the reports electronically to FDA. On May 8, 2008, FDA identified Medical Device Reports as records that could be submitted electronically instead of paper. In the Federal Register of August 21, 2009 (74 FR 42203), FDA proposed to amend the regulation to

require electronic submission of all reports. As of the date of this submission, FDA has not published a final rule based on the proposal.

4. Efforts to Identify Duplication and Use of Similar Information

The FDA is the only Federal agency responsible for the collection of such information, and charged with the responsibility of regulating medical devices and establishments. Therefore, duplication with other data sources is nonexistent.

5. Impact on Small Businesses or Other Small Entities

The requirements set forth in the MDR regulation do not fall disproportionately upon small businesses. The threshold assessment conducted for this regulation shows that no more than 22 percent of the anticipated annual impact of the regulation should be attributed to small business establishments. The FDA continues to pursue ways and means of reducing the reporting burden for both small and large medical device manufacturers and will continue to assess the latest technology for receipt of reports, consistent with the intent of the MDR regulation and protection of the public health.

FDA aids small business by providing guidance and information through the Center for Devices and Radiological Health's Division of Small Manufacturers International and Consumer Assistance (DSMICA). The Division produces workshops, onsite evaluations and other technical and nonfinancial assistance to small manufacturers. In the workshops, publications and educational materials, which include medical device reporting requirements, are generously distributed. DSMICA also maintains a toll-free "800" telephone number which firms may use to obtain regulatory compliance information. CDRH also has a postmarket and MDR reporting information site with detailed guidance and instructions on the Internet. Small businesses can download FDA's free electronic submission software and use it to enter and submit reports electronically saving mailing costs.

6. Consequences of Collecting the Information Less Frequently

FDA allows manufacturers to report less frequently for certain well documented and well known products and events.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

This regulation is consistent with principles in 5 CFR 1320.5. There are no special circumstances.

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

The Medical Device Reporting (MDR) regulation, promulgated pursuant to the Safe Medical Devices Act of 1990 and the Medical Device Amendment of 1992, was finalized

on December 11, 1995. Since that time, the Agency has been in constant consultation with regulated industry regarding the MDR requirements. The amendments to the MDR requirements, required by FDAMA, reflect and respond to the concerns of industry.

In accordance with 5 CFR 1320.8(d), on February 14, 2012, a 60-day notice for public comment on this collection was published in the Federal Register (77 FR 8260). FDA received no comments.

9. Explanation of Any Payment or Gift to Respondents

No payment or gifts will be provided to respondents to this information collection.

10. Assurance of Confidentiality Provided to Respondents

Information contained in the information collections is available as described by 21 CFR 803.9, as amended. FDA may disclose the identity of a device user facility only in connection with an action concerning a failure to report or false or fraudulent reporting, in a communication to the manufacturer of the device, or to the employees of the Department of Health and Human Services, the Department of Justice, and duly authorized committees and subcommittees of Congress.

11. Justification for Sensitive Questions

The information collection does not include questions concerning sexual behavior and attitudes, religious beliefs, or other matters that are commonly considered private.

12. Estimates of Annualized Burden Hours and Costs

12a. Annualized Hour Burden Estimate

The following is a summary of the estimated annual burden hours for medical device manufacturers, importers, and user facilities to report, as well as distributors to maintain records, in compliance with the provisions imposed by this regulation. The number of respondents and annual responses per respondent for each CFR section in the burden tables below is an average based on FDA's experience with the MDR program and on data in FDA's internal databases for the years 2009 through 2011.

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

Reporting Requirements

21 CFR part 803 requires user facilities to report incidents where a medical device caused or contributed a death or serious injury to the device manufacturer and to FDA in the case of a death. 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 (see third-party disclosure burden table), unless the manufacturers are unknown, then the reports are sent to FDA.

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 21 CFR 803.19. Section 803.19 is expected to take approximately 3 hours to complete, but is only required to report 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.

Table 1.--Estimated Annual Reporting Burden

CFR Section	FDA Form No.	No. of Respondents	Annual Frequency of Response	Total Annual Responses	Hours per Response	Total Hours
Exemptions--803.19		57	4	228	3	684
User Facility Reporting--803.30 and 803.32		544	9	4,896	1	4,896
User Facility Annual Reporting--803.33	FDA Form 3419	195	1	195	1	195
Importer Reporting, Death and Serious Injury--803.40 and 803.42		1	1	1	1	1
Manufacturer Reporting--803.50, through 803.53		1,239	243	301,077	1	301,077
Supplemental Reports--803.56		124	302	37,448	1	37,448
Total						344,301

Recordkeeping Requirements

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 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 21 CFR 803.18(d). We estimate that it will take each respondent 1.5 hours annually to maintain the records.

The agency has estimated that on average, 220 user facilities, importers, and manufacturers would annually be required, under 21 CFR 803.17, to establish new procedures, or revise

existing procedures, in order to comply with this provision. We estimate that it will take each respondent 10 hours annually to establish new procedures, or revise existing procedures.

Table 2.--Estimated Annual Recordkeeping Burden

21 CFR Section	No. of Recordkeepers	Annual Frequency of Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
MDR Procedures--803.17	220	1	220	10	2,200
MDR Files--803.18	30,000	1	30,000	1.5	45,000
Total					47,200

Third-Party Disclosure Burden

Under 21 CFR 803.40 and 803.42, 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. We estimate that it will take respondents 1 hour annually to report the information.

Table 3.--Estimated Annual Third-Party Disclosure Burden

21 CFR Section	No. of Respondents	No. of Disclosures per Respondent	Total Annual Disclosures	Average Burden per Disclosure	Total Hours
Importer Reporting, Malfunctions--803.40 and 803.42	1	25	25	1	25

12b. Annualized Cost Burden Estimate

Respondents to this collection of information are businesses or other for-profit and not-for-profit organizations including user facilities, manufacturers, and importers of medical devices.

The annual cost burden is based on an average wage rate of $25 per hour. FDA estimates, based on its experience and interaction with industry, that the group of workers represented by this wage rate will be doing most of the reporting, recordkeeping, and disclosure functions described in this information collection.

Reporting:
The total amount estimated for reporting is $8,607,525 (344,301 x $25). The cost described here represents the customary and usual cost of doing business.

Recordkeeping:
FDA estimates the one-time cost to respondents for establishing or revising procedures, under 21 CFR 803.17, to be $55,000, or $250 per entity (220 respondents x 10 hours x $25). For those entities, a one-time burden of 10 hours is estimated for establishing written MDR procedures. Establishing MDR procedures is a normal cost for new manufacturers, user facilities, and importers. 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).

FDA estimates the cost to respondents for establishing and retaining records under section 803.18 to be $1,125,000 (30,000 respondents x 1.5 hours per response x $25 per hour). Total hours for this section equal 45,000 hours.

Therefore the total recordkeeping costs, at $25 per hour, are estimated at $1,180,000 ((2,200 hours + 45,000 hours) x $25). This cost described represents the customary and usual cost of doing business.

Third-Party Disclosure:
Under 21 CFR 803.40 and 803.42, device importers report deaths and serious injuries to the manufacturers and FDA (included in reporting burden). Importers report malfunctions only to the manufacturers, unless the manufacturers are unknown, then the reports are sent to FDA. We estimate that it will take respondents 25 hours annually to send information to the manufacturers under 21 CFR 803.40 and 803.42, resulting in an estimated annual cost burden of $625 (25 hours x $25 per hour).

Total Annual Cost Burden Estimate:
We estimate the total annual cost burden to be $_____ ($8,607,525 reporting burden + $1,180,000 recordkeeping burden + $625 third-party disclosure burden).

Table 4.--Estimated Annual Cost Burden

	Burden Hours	Wage Rate	Cost Burden
Reporting Burden	344,301	$25	$8,607,525
Recordkeeping Burden	47,200	$25	$1,180,000
Third-Party Disclosure Burden	25	$25	$625
Total Estimated Annual Cost Burden			$9,788,150

13. Estimates of Other Total Annual Costs to Respondents and/or Recordkeepers/Capital Costs

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

14. Annualized Cost to the Federal Government

FDA estimates that it spends an average of 27 full time equivalents (FTEs) reviewing and processing Medical Device Adverse Event Reports. An average full time equivalent employee is projected to cost FDA $209,632 (fully-loaded FTE for FDA/CDRH in FY 2012), which consists of the employee's salary and overhead. The burden imposed upon the government for this information collection is $5,660,064.

15. Explanation for Program Changes or Adjustments

The estimated annual reporting burden has changed because of adjustments to the number of respondents and the annual responses per respondent for the following activities: User Facility Reporting (§§ 803.30 and 803.32) increased from 777 to 4,896 hours due to an increase in the number of respondents and the annual responses per respondent; User Facility Annual Reporting (§ 803.33) decreased from 393 to 195 hours due to a decrease in the number of respondents; Importer Reporting, Death and Serious Injury (§§ 803.40 and 803.42) decreased from 2,682 to 1 hour due to a decrease in the number of respondents and due to a shift of part of the burden from reporting to third-party disclosure (see explanation below); Manufacturer Reporting (§§ 803.50 through 803.53) increased from 166,271 to 301,077 hours due to a decrease in the number of respondents and an increase in the annual responses per respondent; and Supplemental Reports (§ 803.56) decreased from 76,186 to 37,448 hours due to a decrease in the number of respondents and an increase in the annual responses per respondent. As a result of these adjustments, the total estimated annual reporting burden has increased from 246,993 to 344,301 hours.

After a review under the PRA, a portion of the burden to device importers has been changed from reporting to third-party. FDA feels that regarding part of the burden as third-party disclosure is more appropriate because, under 21 CFR 803.40 and 803.42, device importers report deaths and serious injuries to manufacturers as well as to FDA and when the manufacturer is known, they report malfunctions only to the manufacturers.

Therefore the new total burden hours of this collection are 391,526 burden hours and 374,090 annual responses. This is an increase of 97,332 hours and 129,553 annual responses from the currently approved 294,194 hours and 244,537 annual responses.

FDA also separated the IC's in ICRAS to make it easier to read. The IC's are not new just broken out from the previous approval, which had the entire burden grouped in one IC.

16. Plans for Tabulation and Publication and Project Time Schedule

Publication of information for statistical use is not planned.

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

FDA is not seeking an exemption of display of effective date.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

Attachment A: User Facility Annual Report Form FDA 3419