Medical Device Reporting: Electronic Submission Requirements

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.

In accordance with the final rule, medical device manufacturers, importers, and user facilities submit electronic MDRs to FDA and maintain records, and may also seek exemption from these requirements. (User facilities may submit either electronic or paper MDRs.) FDA is also amending §§ 803.32, 803.42, and 803.52 by making minor revisions to reflect prior modifications to Form FDA 3500A and its instructions. Manufacturers, importers, and user facilities are currently submitting paper MDRs on Form FDA 3500A, approved under OMB control number 0910-0291. User facilities are currently submitting paper annual reports on Form FDA 3419, approved under this ICR, OMB control number 0910-0437.

FDA is requesting approval for the information collection requirements contained in part 803..

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 decision making 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 and copies of all electronic acknowledgments FDA sends you in response to electronic MDR submissions (§ 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 whichever 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

Respondents are manufacturers and importers of medical devices and device user facilities. Device user facility means a hospital, ambulatory surgical facility, nursing home, outpatient diagnostic facility, or outpatient treatment facility as defined in § 803.3, which is not a

physician's office (also defined in § 803.3). Respondents are required to report adverse events involving medical devices to the FDA.

The information that is obtained from these reports will be used to evaluate risks associated with medical devices and enable FDA to take appropriate regulatory measures to protect the public health. Complete, accurate, and timely adverse event information is necessary for the identification of emerging device problems so the Agency can protect the public health under section 519 of the FD&C Act. FDA makes the releasable information available to the public for downloading on its web site.

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. Under the final rule all respondents, except for user facilities, would be required to make electronic submissions via one of the two reporting options: eSubmitter for low-volume reporters or HL7 ICSR for high-volume reporters. User facilities have the option of electronic or paper reporting (see discussion in section 8 of this document regarding comments on the proposed rule). FDA estimates that 99 percent of the respondents will use electronic means to fulfill the information collection.

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, there is not duplication with other data sources.

5. Impact on Small Businesses or Other Small Entities

The requirements set forth in the MDR regulation do not fall disproportionately upon small businesses. Over 90 percent of registered device firms affected by the final rule are considered small entities. Because the costs per affected entity are low compared to revenues (see section VI.E of the final rule), FDA finds that although this final rule will affect a substantial number of small entities, it will not have a significant economic impact on those entities. 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.

6. Consequences of Collecting the Information Less Frequently

Respondents submit the information following an adverse event (occasionally) and as annual reports (yearly). Collecting the information less frequently would limit FDA's ability to evaluate risks associated with medical devices to protect the public health.

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

In accordance with 5 CFR 1320.8(d), FDA published a 60 day notice for public comment in the FEDERAL REGISTER of 05/07/2015 (80 FR 26278). No comments were received.

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

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

Reporting Requirements

To calculate the annual reporting burden for Table 1 of this document, the number of reporting entities that had filed MDRs during 3 years (January 1, 2006, through December 31, 2008) was identified along with the number of MDR reports filed during that time period. The rate of increase in reports and supplements filed was determined and projected for the next 3 years. The projected total annual responses were calculated by multiplying the projected number of respondents by the annual frequency per response for the reports and supplements, resulting in the estimated total that will be filed by each entity by the year 2012. The figures displayed in Table 3 of the 2009 proposed rule were based on MDRs processed during the year July 1, 2005, to June 30, 2006, but for this final rule FDA has used data for the years 2006 to 2008. One exception is the counts under exemption reporting (§ 803.19), which reflect the number of firms that had an exemption and had submitted quarterly reports in 2009. The annual burden for reporting calculated in Table 1 of this document is 37,185 hours.

The number of respondents for each applicable Code of Federal Regulations (CFR) reporting requirement in Table 1 was identified from the MDRs reported to FDA's internal databases during the period January 1, 2006, through December 31, 2008. The annual frequency per response and total annual responses shown were based on the number of MDRs reported during the same period (January 1, 2006, through December 31, 2008) with a calculated increase for the next 3 years. FDA estimates that electronic submission will decrease the burden associated with §§ 803.19, 803.30, 803.32, 803.40, 803.42, 803.50, 803.52, and 803.56.

Table 1.--Estimated Annual Reporting Burden

Activity/CFR Section	FDA Form No.	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Exemptions--803.19		56	4	224	1	224
User Facility Reporting--803.30 and 803.32		520	7	3,640	0.35	1,274
User Facility Annual Reporting--803.33	FDA Form 3419	520	1	520	1	520
Importer Reporting, Death and Serious Injury--803.40 and 803.42		1	1	1	1	1
Manufacturer Reporting--803.50 through 803.53		1,240	204	252,960	0.10	25,296
Supplemental Reports--803.56		1,050	94	98,700	0.10	9,870
Total						37,185

Recordkeeping Requirements

The number of respondents for each CFR section in Table 2 of this document was identified from the MDRs reported to FDA's internal databases during the period January 1, 2006, through December 31, 2008. The Agency believes that the majority of manufacturers, user facilities, and importers has already established written procedures and MDR files to document complaints and

information to meet the MDR requirements as part of their internal quality control system, but will need to modify their practices to address the electronic reporting process.

Table 2.--Estimated Annual Recordkeeping Burden					
Activity/21 CFR Section	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
MDR Procedures--803.17	1,820	1	1,820	3.3	6,006
MDR Files--803.18	1,820	1	1,820	1.5	2,730
Total					8,736

Third-Party Disclosure Requirements
The number of respondents for each CFR section in Table 3 of this document was identified from the MDRs reported to FDA's internal databases during the period January 1, 2006, through December 31, 2008.

Table 3.--Estimated Annual Third-Party Disclosure Burden					
Activity/21 CFR Section	No. of Respondents	No. of Disclosures per Respondent	Total Annual Disclosures	Average Burden per Disclosure	Total Hours
Importer Reporting, Death and Serious Injury--803.40 and 803.42	60	25	1,500	0.35	525

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 and recordkeeping functions described in this information collection.

Reporting:
The total amount estimated for reporting is $929,625 (37,185 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 $150,150 or $83 per entity (1,820 respondents x 3.3 Hours x $25). For those entities, a one-time burden of 3.3 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 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 $68,250 (1,820 respondents x 1.5 hours per response x $25 per hour).Total hours for this section equal 2,730 hours.

Therefore the total recordkeeping costs, at $25 per hour, are estimated at $218,400 ((6,006 hours + 2,730 hours) x $25). This cost described represents the customary and usual cost of doing business.

Third-Party Disclosure:
FDA estimates the cost to respondents for disclosing records under sections 803.40 and 803.42 to be $13,125 (525 hours x $25 per hour).

Total Annual Cost burden Estimate:
We estimate the total annual cost burden to be $1,161,150 ($929,625 reporting burden + $218,400 recordkeeping burden + $13,125 third-party disclosure burden).

Table 4 --- Estimated Annual Cost burden

	Burden Hours	Wage Rate	Total Respondent Costs
Reporting Burden	37,185	$25	$929,625
Recordkeeping Burden	8,736	$25	$218,400
Third-Party Disclosure Burden	525	$25	$13,125
Total			$1,161,150

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

The conversion from paper to electronic submissions will result in a burden to reporting entities due to both capital costs (one-time setup costs) and annual operating and maintenance costs. The one-time capital costs include the cost to develop procedures for handling adverse events and reporting MDRs, installing the eSubmitter software and/or installing gateway to gateway submission capabilities (HL7), and acquiring electronic certificates; these costs have been estimated at $14.0 million. Once the procedures have been modified, there is an operating and maintenance cost to renew the digital certificate and maintain high-speed internet access, which has been estimated at $1.5 million each year.

We based our estimates on a count of all manufacturers, importers, and user facilities that filed MDRs during the period 2006 to 2008. The estimate of capital costs included:

- Development of procedures for handling adverse events and reporting MDRs,

- Installation of eSubmitter and/or installation and validation of H7, and
- Acquiring an electronic certificate.

The maximum and minimum estimates for installation of eSubmitter and HL7 were averaged in the calculations for capital costs. The estimate of annual operating and maintenance costs included:

- Renewal of electronic certificate and
- Maintenance of high-speed Internet access.

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 Events Reports. An average full time equivalent employee is projected to cost FDA $209,632 (fully-loaded FTE for FDA/CDRH in FY 2013), 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 total estimated hour burden has been reduced as the result of program changes made in the final rule (previously approved 391,526 – estimated hour burden 46,446 = 354,080). The average burden per response/recordkeeping has decreased for all ICs, except User facility annual reporting and MDR files. Included in the reduction are adjustments to the respondents and number of responses per respondent. These adjustments are consistent with data used for the rulemaking analyses and differ from that used for the extension of the ICR. The reduction of hour burden discussed in the final rule differs from the reduction discussed here because the final rule compares the estimated hour burden to that of the estimate approved prior to the last extension of the ICR, which occurred between publication of the proposed and final rules.

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 Expiration 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.