SUPPORTING STATEMENT FOR
MEDICAL DEVICE REPORTING:
MANUFACTURER REPORTING, IMPORTER REPORTING,
USER FACILITY REPORTING, DISTRIBUTOR REPORTING
0910-0437

A. JUSTIFICATION

1. Circumstances Necessitating Information Collection

Section 519(a)(b)&(c) of the Federal Food Drug and Cosmetic Act (the Act) (Attachment A) 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 rule making amending 21 CFR 803 implementing section 519 of the Act. The regulation (Attachment B) 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. (http://www.fda.gov/cdrh/mdufma/index.html) On February 28, 2005 FDA rewrote the regulation into plain language. On June 13, 2008 FDA published a Notice of Proposed Rule Making and a Direct to Final Rule eliminating 21 CFR 803.55. The rule became effective October 27, 2008.

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 No. 0910-0291.

21 CFR 803.19 – Reporting Exemptions

Allows manufacturers, importers, or user facilities of medical devices to request an exemption or variance from the Medical Device Reporting requirements (MDR), 21CFR803.30, 803.40, 803.50.

21 CFR 803.30 & .32– User Facility 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

User facilities are required to annually submit the number and summary of events reported during the previous calendar year. (Attachment C)

21 CFR 803.40 & .42 – Importer/Distributor Reporting

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 they are unknown, then the reports are submitted to FDA.

21 CFR 803.50, .52 & .53 – Manufacturer Reporting

Manufacturers of medical devices are required to submit MDR death, serious injury, and malfunction reports.

21 CFR 803.18 (c) & (d) - Recordkeeping

(Section 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

(Section 803.18 (d)) Distributors of medical devices are required to establish complaint records and to retain them for two 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.

2 By Whom and for What Purpose the Information is to be Used

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. Consideration of Information Technology

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.

4. Efforts to Identify Duplication and Similar Information Already Available

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. Small Businesses

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, on-site evaluations and other technical and non-financial 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 Less Frequent Information Collection and Technical or Legal Obstacles.

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

7. Consistency with the Guidelines in 5 CFR 1320.5

This regulation is consistent with principles in 5 CFR 1320.5.

8. Consultation 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 were 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 25, 2009, a 60-day notice for public comment on this collection was published in the Federal Register (74 FR 8547). FDA received no comments.

9. Payments or Gifts to Respondents

No payment or gifts shall be provided to respondents under this regulation.

10. Confidentiality of Information

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. Sensitive Questions

The information collection does not include questions concerning sex, behavior, attitudes, religious beliefs, or private matters.

12. Estimates of Burden Hours and Explanation

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 rule:

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

Table 1--Estimated Annual Reporting Burden[1]

CFR Section	FDA Form No.	No. of Respondents	Annual Frequency of Response	Total Annual Responses	Hours per Response	Total Hours
803.19		57	4	228	3	684
803.30 and .32		393	2	777	1	777
803.33	FDA Form 3419	393	1	393	1	393
803.40 and .42		73	37	2,682	1	2,682
803.50 and .52		1,601	104	166,271	1	166,271

803.56		1,200	63	76,186	1	76,186
Total				244,537		246,993

[1] There are no capital costs or operating and maintenance costs associated with this collection of information. Numbers are based on number of reports received Oct 1, 2007 – Sep 30, 2008.

Table 2--Estimated Annual Recordkeeping Burden[1]

21 CFR Section	No. of Record keepers	Annual Frequency of Record keeping	Total Annual Records	Hours per Recordkeeper	Total Hours
803.17	220	1	220	10	2,200
803.18 (c) & (d)	30000	1	30000	1.5	45000
Total					47,200

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

Respondents to this collection of information are businesses or other for profit and non-profit organizations including user facilities, manufacturers, and importers of medical devices.

The burden cost below 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.

The burdens are explained as follows:

Reporting Requirements

21 CFR 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, unless they are unknown, then the reports are sent to FDA.

The number of respondents for each CFR section in the reporting table above is based upon the number of respondents entered into FDA's internal databases. FDA estimates, based on its experience and interaction with the medical device

community, that all reporting CFR sections are expected to take one 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.

The total amount estimated for reporting, therefore, based on the figures above, is estimated to be $2,323,625 (92545 x $25). The cost described here represents the customary and usual cost of doing business.

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 803.18(d).

The agency has estimated that on average, 220 user facilities, importers, and manufacturers would annually be required to establish new procedures, or revise existing procedures, in order to comply with this provision.

Therefore, FDA estimates the one-time cost to respondents for establishing or revising procedures 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).

The annual cost for recordkeeping to respondents is as follows. Under Section 803.17, FDA estimates 220 respondents will spend approximately 3.3 hours to complete the requirements for this section. The number of respondents was estimated by consolidating the total of all new reporting entities together. The 3.3 hours was estimated by FDA, as this section deals with a respondent creating new MDR procedures, and is a one-time function. Total hours for this section is approximately 726 hours.

Under section 803.18, 30,000 respondents represent distributors, importers, and other respondents to this information collection. FDA estimates that it should take them approximately one and one-half hours to complete the recordkeeping requirement for this section. Total hours for this section equal 45,000 hours.

Therefore the total recordkeeping costs, at $25 per hour, are estimated at $1,143,150 ((726 hours + 45,000 hours) x $25). This cost described represents the customary and usual cost of doing business.

13. Annual Costs to Respondents

Because this rule imposes no new additional responsibilities on respondents, no capital or operational expenses are expected as a result of this rule.

14. Government Costs:

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 $113,800, which consists of the employee's salary and overhead. The burden imposed upon the government for this information collection is $3,072,600.

15. Changes in Burden

Since this collection was last approved by OMB, the number of user facilities filing reports (21 CFR 803.30 & .32) decreased from 700 to 393 and the average number of reports per facility decreased from 5 to 2. The number of importers filing reports (21 CFR 803.40 & .42) increased from 40 to 73 and the average number of reports per importer increased from 17 to 37. The number of manufacturers filing reports (21 CFR 803.50 & .52) increased from 1,465 to 1,601 and the average number of reports per manufacturer increased from 57 to 104. On June 13, 2008 FDA published a Notice of Proposed Rule Making and a Direct to Final rule deleted 21 CFR 803.55 which eliminated the need for FDA Form 3417. On September 18, 2008, FDA confirmed effective date, October 27, 2008 of the Direct to Final Rule. This eliminated 3,500 hours from the reporting burden. Other variations in the number of respondents have also led to small changes. The total increase (adjustment) in the total hourly burden estimate is 155,922 hours.

16. Statistical Reporting

No publication of information for statistical use is planned.

17. Exemption for Display of Effective Date

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

18. Exception to Certification Statement

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

List of Attachments:

Tab A- Section 519 of the Act
Tab B - 21 CFR 803
Tab C - User Facility Annual Report form FDA 3