Supporting Statement for
Medical Device Reporting
OMB 0910-0437 - Revision

A. JUSTIFICATION

1. Need and Legal Basis

Section 519(a)(b)&(c) of the Federal Food Drug and Cosmetic Act (the Act) Sec. 519 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 revising 21 CFR 803 implementing section 519 of the Act (60 FR 63578). FDA is proposing to amend the regulation to require electronic submission of all reports.

FDA is requesting approval for the information collections requirements contained within 21 CFR part 803.

21 CFR 803.17 – Reporting Procedures
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 – Recordkeeping Requirements
Manufacturers, user facilities, and importers must establish and maintain MDR event files.

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), 21 CFR 803.12(a) 803.30, 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 - FDA Form 3419 – Reporting
User facilities are required to annually submit the number and summary of events reported during the previous calendar year.

21 CFR 803.40 & .42 – Importer 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 – Manufacturer Reporting

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

21 CFR 803.56 – Follow-up Reporting
Manufacturers who fail to provide information required under this part because it was not known or available when the initial report was submitted, must submit the supplemental information to FDA.

2. How, by whom, how frequently, and for what purpose is the information to be used.

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. FDA makes the releasable information available to the public for downloading on its web site.

3. Improved Information Technology

Under the proposed regulation, all reports would be electronically submitted to FDA. The proposed electronic submission of reports would enhance operations for both industry and FDA. Electronic reporting can benefit industry by eliminating the costs associated with collating, copying, storing, retrieving, and mailing paper copies. FDA would benefit from a more efficient data entry process allowing for timely access to medical device adverse event information and identification of emerging public health issues. When data are provided only on paper, the information must be transcribed by hand into electronic form to review and analyze. This process is extremely time consuming, costly, and is susceptible to data entry error.

4. Duplication of Similar Information

FDA is the only Federal agency responsible for the collection of such information, and the only agency charged with the responsibility of regulating medical devices and establishments. Therefore, no duplication of data exists.

5. Small Businesses

The requirements set forth in the MDR regulation do not fall disproportionately upon small businesses.

Because the estimated incremental costs per entity are low and the CeSub software is available for free, the Agency does not believe that this proposed rule would have a significant economic impact on a substantial number of small entities.

Furthermore, 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 on the Internet with detailed guidance and instructions.

6. Less Frequent Collection

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

7. Special Circumstances

This information collection is consistent with the guidelines prescribed in 5 CFR 1320.5.

8. *Federal Register* Notice/Outside Consultation

In accordance with 5 CFR 1320.11(a) the collections of information contained in the proposed rule, and identified as such, have been submitted to OMB for review. This proposed rule will solicit comments on the information collection.

9. Payment/Gift to Respondent

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

10. Confidentiality

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. Burden Estimate (Total Hours and Wages)

. FDA is requesting approval for the revised information collection requirements contained in part 803. The total annual estimated burden imposed by this collection of information is 21,525 hours.

TABLE 1--ESTIMATED ANNUAL REPORTING BURDEN

21 CFR Section	FDA Form No.	No. of Respondents	Annual Frequency Per Response	Total Annual Responses	Hours per Response	Total Hours
803.19		55	4	220	1	220
803.30 and 809.32		411	2	822	0.33	271
803.33	3419	411	1	411	1	411
803.40 and 803.42		44	20	880	0.33	290
803.50 and 803.52		1,304	58	75,632	0.11	8,248
803.56		1,200	48	57,600	0.10	5,760
Total						15,200

TABLE 2.--ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Respondents	Frequency per Recordkeeping	Total Annual Records	Hours per Record	Total Hours
803.17	1,677	1	1,677	3.3	5,534
803.18 (a) to (d)	527	1	527	1.5	791
Total	2,204		2,204		6,325

A. Reporting Requirements

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 21 CFR 803.19 and 803.33 will take one hour. Sections 803.30, 803.32, 803.40, and 803.42 will take twenty minutes. Sections 803.50 and 803.52 will take seven minutes. Section 803.56 will take six minutes. The burden decrease in Table I for reporting requirements (hours per response), is based on the agency's estimate that electronic reporting will reduce industry total time and effort associated with data transcription from internal data management systems to paper and mailing these reports to the agency.

As previously described in the preamble to the NPRM, there are two reporting options. The first one is CeSub for low volume reporters and the second one is HL7 ICSR for high volume reporters. We are basing our hours per response for both systems on FDAs experience using the two options.

B -Recordkeeping Requirements

The number of respondents for each CFR section in Table 2 above is based upon the number of respondents entered into FDA's internal databases. 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.

C **- Cost to Respondents**

The total cost to respondents is $2,941,125. The burden cost is based on the average wage rate of $ 46.50 per hour used in the "Analysis of Impact Section "of the NPRM.

13. Total Annual Cost Burden

The total one – time capital costs and annual recurring costs is estimated to range from $58.6 million to $79.7 million The average annual cost is estimated to be $69.2 million (i.e. $58.6 million + $67.2 million / 2 = $ 69.2 million) Thus, the annual cost burden averaged over 3 years is estimated to be $23.1 million (i.e. $69.2 / 3 = $ 23.1)

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14 Cost to Federal Government

Because this rule does not require the processing of any additional reports by the government, no additional costs to the government will be incurred. However the rule will actually result in a budgetary savings. FDA's current entry data cost is 3.7 million. FDA estimates it will be able to reduce data entry cost by $1,500,000. FDA's costs will be reduced to 2.2 million.

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15 . Program or Burden Changes

The burden decrease and cost increases are associated with the proposed rule to mandate electronic reporting of medical device adverse event reporting. We estimate that the burden will decrease because electronic reporting reduces industry time and costs associated with transcribing data from internal data management system to paper and mailing them to the agency.

16. Publication and Tabulation Dates

FDA does not intend to publish the results of this information collection.

17 Display of OMB Approval Date

Currently, CDRH is not requesting an exemption for display of the OMB expiration date.

18 Exceptions to "Certification for Paperwork Reduction Act Submissions"

Currently, CDRH is not requesting an exemption to "Certification for the Paperwork Reduction Act Submissions."