SUPPORTING STATEMENT FOR
MEDICAL DEVICE RECALL AUTHORITY
21 CFR PART 810
OMB NUMBER 0910-0432

A. Justification

1. Circumstances Necessitating Information Collection

The Food and Drug Administration (FDA) promulgated **21 CFR PART 810** to implement the provisions of Sec. 518 [**21 U.S.C. 360h**] of the Federal Food, Drug, and Cosmetic Act (the Act). If FDA finds that there is a reasonable probability that a device intended for human use would cause serious adverse health consequences or death, Sec. 518 of the Act gives FDA the authority to issue an order requiring the appropriate person; including manufacturers, importers, distributors, and retailers of a device to: immediately cease distribution of such device; notify health professionals and device user facilities of the order; and instruct those professionals and device user facilities to cease use of the device.

FDA is requesting approval from the Office of Management and Budget (OMB) for the extension of collection of information required by 21 CFR PART 810 promulgated under the statutory mandate of section Sec. 518 [21 U.S.C. 360h] of the Act. Below is a description of the information collection requirements in 21 CFR PART 810 Subpart B:

21 CFR 810.10(d) – Reporting
FDA may require the person named in the cease distribution and notification order to submit certain information to the agency.

21 CFR 810.11(a) – Reporting
A request for regulatory hearing regarding the cease distribution and notification order must be submitted in writing to FDA.

21 CFR 810.12 (a) and (b) – Reporting
In lieu of requesting a regulatory hearing under §810.11, the person named in the cease distribution and notification order may submit a written request to FDA asking that the order be modified or vacated. A written request for review of a cease distribution and notification order shall identify each ground upon which the requestor relies in asking that the order be modified or vacated, address an appropriate cease distribution and notification strategy, and address whether the order should be amended to require a recall of the device that was the subject of the order and the Actions required by such a recall order.

21 CFR 810.14 – Reporting
The person named in the cease distribution and notification order or a mandatory recall order must develop and submit a strategy for complying with the order that is appropriate for the individual circumstances.

21 CFR 810.15 (a) – (d) – Notification
The person named in a cease distribution and notification order or a mandatory recall order must promptly notify each health professional, user facility, consignee, or individual of the order.

21 CFR 810.15 (e) – Notification
Health professionals, device user facilities, and consignees should immediately notify their consignees of the order.

21 CFR 810.16 – Reporting
The person named in a cease distribution and notification order or a mandatory recall order must submit periodic status reports to FDA to enable the agency to assess the person's progress in complying with the order. The frequency of such reports and the agency official to whom such reports must be submitted will be specified in the order.

21 CFR 810.17 – Reporting
The person named in a cease distribution and notification order or a mandatory recall order may request termination of the order by submitting a written request to FDA. The person submitting a request must certify that he or she has complied in full with all the requirements of the order and most current status report submitted to the agency.

2. How, By Whom, And for What Purpose Information is Used

The information collected under the recall authority will be used by FDA to ensure that all devices entering the market are safe and effective, to accurately and immediately detect serious problems with medical devices, and to remove dangerous and defective devices from the market.

Almost all recalls are carried out under the voluntary recall procedures PART 7 (**21 CFR PART 7**). FDA interprets the standard in 810.10(a) and 810.13 to match closely with the elements of a class I voluntary recall under 21 CFR Part 7, Subpart C, for which the agency has a long record of experiences. FDA will initiate a mandatory recall under section Sec. 518 [21 U.S.C. [360h] of the Act when FDA finds that there is a reasonable probability that a device would cause serious, adverse health consequences or death. A firm may initiate a voluntary recall of a violative device without FDA intervention; however, if FDA determines that such a voluntary recall is not effective in remedying a violation and there remains a reasonable probability that the violative device would cause serious

adverse health consequences or death, FDA will invoke the medical device recall authority in addition to the voluntary efforts that the manufacturer has already undertaken. FDA will not order a mandatory recall if a voluntary recall has been effective in addressing the problems.

FDA believes that the regulation provides sufficient flexibility so as to minimize the burden on those required to take action consistent with the determination that the device presents a risk or serious adverse health consequences or death. FDA expects that at most, one or two recalls per year would be ordered that would not have occurred without this regulation.

Sec. 518 [21 U.S.C. 360h] of the Act sets out a three-step procedure for the issuance of a mandatory device recall order. First, after finding that there is a reasonable probability that a device intended for human use would cause serious, adverse health consequences or death, FDA may issue a cease distribution and notification order requiring the appropriate person to immediately: (1) cease distribution of the device; (2) notify health professionals and device user facilities of the order, and (3) instruct these professionals and facilities to cease use of the device. Second, FDA will provide the person named in the cease distribution and notification order with the opportunity for an informal hearing on whether the order should be modified, vacated, or amended to require a mandatory recall of the device. Third, after providing the opportunity for an informal hearing, FDA may issue a mandatory recall order if the agency determines that such an order is necessary.

3. Consideration of Information Technology

The intended effect of the final rule is to permit the use of electronic technologies in a manner that is consistent with FDA's overall mission and that preserves the integrity of the agency's enforcement activities. Reports and records concerning recalls may be submitted to FDA in electronic format or retained in electronic files provided that they comply with **21 CFR PART 11**. concerning electronic records and electronic signatures. Also, FDA currently allows respondents involved in recall actions to submit data to district offices electronically.

4. Efforts to Identify Duplication and Similar Information Already Available

FDA is the only agency responsible for the collection of this information. Therefore, no duplication of data exists. In addition, no data exists from any other source that can be used to recall devices subject to final regulation.

5. Small Business

FDA aids small businesses in dealing with the requirements of the regulations by providing guidance and information through the Division of Small Manufacturers and International Assistance (DSMICA), and through the scientific and administrative staff within the Center for Devices and Radiological Health. These efforts help to assure that the burden on small manufacturers is minimized. FDA also provides all manufacturers uniform device reporting criteria to avoid confusion and minimize burden to the respondent.

6. Consequences of Less Frequent Information Collection and Technical or Legal Obstacles

Manufacturers are required to submit periodic progress reports to FDA only if FDA requires a cease distribution and notification order or a mandatory recall order. If this information is collected less frequently, FDA will be unable to monitor the progress of such orders.

7. Inconsistencies with 5 CFR 1320.6

This collection of information is consistent with the guidelines prescribed in 5 CFR 1320.6

8. Consultation Outside FDA

In the Federal Register of December 19, 2008 (73 FR 77719), FDA solicited 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)**. There were no comments received on the information collection

Over the past three years, FDA has delivered three presentations relating to Medical Device Recalls; AdvaMed-February 22, 2006, AMDN-July 24, 2007 and ADVAMED-November 19, 2008. Each of these programs included information on FDA's mandatory recall authority for medical devices.

9. Payments or Gifts to Respondents

FDA will not provide payment or gifts to respondents of this collection of information.

10. Confidentiality of Information

Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), the public has broad access to government documents. However, FOIA provides certain exemptions from mandatory public disclosure of government records (21 U.S.C. 552(b) (I-90)). FDA will make the fullest possible disclosure of records to the public, consistent with the rights of individuals to privacy, the property rights of persons in trade and confidential commercial or financial information. Recalls and other information submitted to FDA under 21 CFR Part 810 are releasable under **21 CFR Part 20**.

11. 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 Burden Hours and Explanation

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours Per Response	Total Hours
810.10(d)	2	1	2	8	16
810.11(a)	1	1	1	8	8
810.12(a-b)	1	1	1	8	8
810.14	2	1	2	16	32
810.15(a-c)	2	1	2	12	24
810.15(d)	2	1	2	4	8
810.15(e)	10	1	10	1	10
810.16(a-b)	2	12	24	40	960
810.17(a)	2	1	2	8	16
Total Hours					**1,082**

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

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours Per Record	Total Hours
810.15(b)	**2**	**1**	**1**	**8**	**8**

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

Explanation of Reporting Burden Estimates:
The following estimates are based on FDA's experience with voluntary recalls under 21 CFR Part 7. FDA expects no more than 2 mandatory recalls per year, as most recalls are done voluntarily.

Cost to Respondents

The agency has issued one mandatory recall over the past three years. For burden determination purposes, we used the expectation that we would not expect to order more than two recalls per year. The cost of a recall varies widely depending upon the number of products involved, the number of persons using the device, and the ease in finding these persons. Because we have not issued many mandatory recall orders in recent years, it is virtually impossible to even guess what the cost of a recall would be to industry associated.

13. Estimated Annual Cost to Respondents

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

14. Estimated Annual Cost to Government

FDA anticipates the Federal government will use 1 FTE to implement the Medical Device Recall authority regulation required by section 518(e) of the Act. Based on a cost of $120,000 (the agency's average cost of an FTE, including benefits) per position at the GS-13 grade level, plus an estimated $66,000 the Federal government will spend to educate health professionals and industry concerning patient notification, the total estimated annual cost to the government is $186,000.

15. Changes in Burden

In the 2006 submission, FDA did not include the recordkeeping burden. With the inclusion of the recordkeeping burden the total burden has increased by 8 hours.

16. Publication of Results

No publication of the data is planned or anticipated by FDA**.**

17. Exemption for Display of Effective Data

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

18. Exception to Certification Statement

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

19. Certification for Paperwork Reduction Act Submissions

B. Collection of Information Using Statistical Methods

The use of statistical methods is not applicable to this information collection.