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

A. Justification

1. Circumstances Necessitating Information Collection

The Food and Drug Administration (FDA) has issued a final regulation (21 CFR 810) (Tab A) to implement the provisions of Section 518(e) (21 U.S.C. 360h) (Tab B) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 301 et. seq.). Section 518(e) 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, and to immediately notify health professionals and device user facilities of the order, and to instruct such professionals and facilities to cease use of such device, if FDA finds that there is a reasonable probability that the device intended for human use would cause serious adverse health consequences or death.

FDA is requesting approval from the Office of Management and Budget (OMB) for the collection of information required by 21 CFR Part 810 promulgated under the statutory mandate of section 518(e) of the act. Below is a description of the information collection requirements in 21 CFR part 810:

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 a 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 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.

Section 518(e) 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

In the **Federal Register** of March 20, 1997 (62 FR 13430) (Tab C), FDA issued a final rule that would, under certain circumstances, permit the agency to accept electronic records, electronic signatures, and handwritten signatures executed to electronic records as generally equivalent to paper records and handwritten signatures executed on paper. These regulations would apply to records when submitted in electronic form that are called for in Title 21 of the Code of Federal Regulations (CFR). 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.

4. Identification of 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 the 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 Assistance, 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.

6. Consequences of Less Frequent Information Collection

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 November 20, 1996 (61 FR 59004) (Tab A), FDA published a final rule to implement the medical device recall authority provisions of section 518(e) of the act. The final rule, among other things, revised and clarified certain provisions of the June 14, 1994 (59 FR 30656) proposed rule (Tab D) and established procedures for implementing the medical device recall authority to protect the public health by removing dangerous devices from the market promptly.

In the preamble to the final rule (61 FR 59018), the agency requested comments on the information collection provisions of the new regulation. The 60- day comment period closed January 21, 1997. The agency received two comments. The comments stated that: (1) the information collection requirements in this regulation are redundant and time and resource consuming, and (2) FDA should provide for the use of electronic media for reporting.

FDA disagrees with the comment that the information collection requirements for the medical

device recall authority are redundant and time and resource consuming. Almost all recalls are carried out under the voluntary recall procedures in part 7 (21 CFR part 7) (Tab E). As discussed in the final rule of November 1996, for cease distribution and notification orders and recall orders, FDA interprets the standard in §§ 810.10(a) and 810.13 to match closely to the elements of a class I voluntary recall under part 7, subpart C (21 CFR, subpart C), for which the agency has a long record of experiences. FDA will initiate a mandatory recall under section 518(e) 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 November 1996 final rule 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 of 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.

As discussed elsewhere in this supporting statement, the regulation for electronic records and electronic signatures became effective March 20, 1997. Part 11 (21 CFR part 11) sets forth the criteria under which FDA will accept documents and signatures in electronic form in lieu of paper.

9. Payments or Gifts to Respondents

FDA will not provide payment or gifts to respondents.

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 (Tab G).

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 of Response	Total Annual Response	Hours per Response	Total Hours

ESTIMATED ANNUAL REPORTING BURDEN[1]					
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)-(d)	2	1	2	16	32
810.15(e)	10	1	10	1	10
810.16	2	12	24	40	960
810.17	2	1	2	8	16
Total					1082

[1]There are no capital costs or operating and maintenance cost 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.

810.10(d)

FDA estimates that it will take approximately 8 hours for the person named in a cease distribution and notification order to gather and submit the information required by this section. The total annual burden is 16 hours (2 recalls X 8 hours per recall)

810.11(a)

Based on its experience in similar situations, FDA expects that there will be only one request for a regulatory hearing per year and that it will take approximately one staff day (8 hours) to prepare this request.

810.12(a)-(b)

Based on its experience in similar situations, FDA expects that there will be only one written request for a review of a cease distribution and notification order per year and that it will take approximately one staff day (8 hours) to prepare this request.

810.14

Based upon its experience with voluntary recalls, FDA estimates that it will take approximately two staff days (16 hours) to develop a strategy for complying with the order.

810.15(a)-(d)

Based upon its experience with voluntary recalls, FDA estimates that it will take approximately two staff days (16 hours) to notify each health professional, user facility, or individual of the order.

810.15(e)

Based upon its experience with voluntary recalls, FDA estimates that there will be approximately 5 consignees per recall (10 per year) who will be required to notify their consignees of the order.

FDA estimates that it will take them about 1 hour to do so.

810.16

FDA estimates that it would take no more than one staff week (40 hours) to assemble and prepare a written status report required by a recall ('810.16). The status reports are prepared by manufacturers 6-12 times each year. Therefore, each manufacturer would spend no more than 480 hours each year preparing status reports (40 X 12). If there were two FDA invoked recalls each year, the total burden hours estimated would be 960 hours each year (480 X 2).

810.17

Based on its experience with similar procedures, FDA estimates that it would take one staff day (8 hours) to draft a written request for termination of a cease distribution and notification or mandatory recall order ('810.17).

13. Estimated Annual Cost To Respondents

The agency does 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. The agency does not have a cost figure for a recall, but it is likely that the cost would be under $2 million (a ten-year old figure for a nation-wide Class I recall of ten million cans of mushrooms was $2 million). Therefore, if this regulation were used twice a year to order a recall, the cost would not be expected to exceed $4 million.

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 $58,027 (the

agency's average cost of an FTE, including benefits) per position at the GS-13 grade level, plus an estimated $60,000 the federal government will spend to educate health professionals and industry concerning patient notification, the total estimated annual cost to the government is $118,027.

15. Changes in Burden

This is a new information collection.

16. Publication of Results

No tabulation of the data is planned or anticipated.

17. Exemption For Display of Effective Date

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-I.

B. Collection of Information Using Statistical Methods

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

Tabs

A. Federal Register Notice of November 20, 1996 (61 FR 59004)

B. FD&C Act section 518e (21 U.S.C. 360h)

C. Federal Register Notice of March 20, 1997 (62 FR 13430)

D. June 14, 1994 Proposed Rule (59 FR 30656)

E. 21 CFR Part 7