SUPPORTING STATEMENT FOR
MEDICAL DEVICES; DEVICE TRACKING
OMB Control Number 0910-0442

A. JUSTIFICATION

1. Circumstances Necessitating Information Collection

Under the Safe Medical Devices Act of 1990 (Public Law 101-629) (SMDA), section 519(e) of the Federal Food, Drug, and Cosmetic Act (the act) was amended to require that any person registered as a manufacturer of a device meeting the criteria described in section 519(e)(1) must track that device. Section 519(e)(1) describes the types of devices that manufacturers must track: (1) A device the failure of which would be reasonably likely to have serious adverse health consequences and which is (a) a permanently implantable device or (b) a life-sustaining or life- supporting device used outside a device user facility, or (2) any other device which the Secretary may designate. In implementing the SMDA provisions, the regulations established requirements for manufacturer tracking systems and distributor reporting.

Effective February 19, 1997, section 519(e) was amended by the FDA Modernization Act of 1997 (Public Law 105-115) (FDAMA). Amended section 519(e)(1) http://www.fda.gov/opacom/laws/fdcact/fdcact5a2.htm#sec519, provided FDA with discretionary authority to issue orders that require a manufacturer to track a class II or class III device if its failure would be reasonably likely to have serious adverse health consequences, or it is intended to be implanted in the human body for more than one year, or it is life-sustaining or life-supporting ("l/s-l/s") and used outside a device user facility. Amended section 519(e)(2) provides that patients may refuse permission to release, their names, addresses, social security numbers, or other identifying information for tracking purposes. On February 8, 2002, FDA issued a final rule (67 FR 5943) to conform existing tracking regulations (21 CFR 821) to changes in tracking provisions effected by FDAMA. Currently, 16 device types are tracked per orders issued by FDA.

FDA is requesting an extension of OMB approval for the information collection requirements in 21 CFR Part 821.

A description of the information collection requirements are as follows:

§821.1(d) – Reporting – Requires persons subject to device tracking regulations to report permanent discontinuation of business and provide FDA with a complete set of its tracking records.

§§821.2 and 821.30(e) – Reporting – Provides mechanism for obtaining an exemption or variance from existing medical device tracking regulations under this part through agency petition process.

§821.25(a) - Reporting - Requires manufacturers of tracked devices to adopt a tracking method which can provide certain information to FDA within defined timeframes.

§821.25(b) - Recordkeeping - Requires manufacturers of tracked devices to keep current records of tracking data according to their standard operating procedures (SOPs).

§821.25(c) and (c)(3) - Recordkeeping- Requires manufacturers to establish SOPs for collecting, maintaining, and auditing tracking data and to incorporate a quality assurance program, procedures for auditing devices twice annually for the first three years of tracking, and annually thereafter.

§821.25(d) - Reporting - Requires manufacturers to notify FDA of distributors, final distributors, or multiple distributors not maintaining or reporting required information.

§821.30(a) – Third Party Disclosure - Requires distributors, final distributors, and multiple distributors, upon acquiring tracked devices, to provide manufacturers with data about the distributors, the devices, receipt, and other usage.

§821.30(b) – Third Party Disclosure - Requires that final distributors of tracked devices intended for single patient use, upon distribution to patients, provide manufacturers with data about patient identities (if permitted), the devices, use dates, physicians, and other information.

§821.30(c)(2) – Third Party Disclosure - Requires multiple distributors to provide data on current users of tracked devices, current device locations, and other information, within 5 working days of a manufacturer's request or within 10 working days of FDA's request.

§821.30(d) – Third Party Disclosure - Requires all distributors to make required tracking information records available for auditing, upon a manufacturer's written request.

2. Purpose and Use of the Information

Tracking information is collected to facilitate identifying the current location of tracked devices, and patients (or end-users) possessing the devices, to the extent that patients permit the collection of identifying information (see item 10). Manufacturers and, as necessary, FDA use the data to expedite recalling distributed devices that are dangerous or defective, and to facilitate the timely notification of patients or licensed practitioners of risks associated with the devices. So far FDA has not found it necessary to utilize tracking information for these purposes.

3. Use of Information Technology and Burden Reduction

Respondents have complete flexibility to use tracking system procedures, computer

technology, and automation that reduce the time needed to compile tracking information. Based on inspections conducted to date, FDA believes that manufacturers and distributors keep at least 90% of these records in electronic format. If FDA requests submission of reports, FDA expects that manufacturers will also submit at least 90% of these reports in electronic format.

4. Efforts to Identify Duplication and Use of Similar Information

FDA is the only agency requiring an information collection that tracks devices to patients and distributors. Legal impediments prevent using Social Security and Internal Revenue Service data that might help locate patients with tracked implants lost to follow-up.

Under FDA's Quality System Regulation, (OMB Control No. 0910-0073; 21 CFR §820.160), manufacturers must maintain distribution records identifying initial consignees of devices. Under §821.30(a), some device distributors might report to manufacturers tracking data already contained in initial consignee records. In practice, FDA believes many final distributors, such as hospitals receiving tracked implants directly from manufacturers, rely on manufacturer records identifying initial consignees as fulfilling the intent of §821.30(a). They only report, under §821.30(b), when tracked implants are implanted in patients and not when they are received. Also, many distributors and multiple distributors of tracked life-sustaining or life-supporting devices do not receive the devices directly from manufacturers. Consequently, duplicative reporting is minimal.

5. Impact on Small Businesses

FDA helps to minimize the impact by aiding small business in dealing with tracking through guidance provided by the Center for Devices and Radiological Health's Division of Small Manufacturers, International, and Consumer Assistance (DSMICA) and its scientific and compliance staffs.

6. Consequence of Collecting the Information Less Frequently

FDA does not require a specific collection frequency, because the agency reviews tracking data during an FDA inspection or upon FDA request. Failure of manufacturers to record, and of distributors to report, data upon the distribution and patient receipt of tracked devices could delay the expeditious recall of distributed devices that are dangerous or defective.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

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

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

Notice has been published in the Federal Register of November 12, 2010 (75 FR 69,447) soliciting 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). No comments were posted to the docket.

9. Explanation of Any Payment or Gift to Respondents

No payment or gift is provided to respondents.

10. Assurance of Confidentiality Provided to Respondents

Tracking data identifying customers or patients, either reviewed by or submitted to FDA, is treated as confidential in accordance with 21 CFR Part 20. Although patients are not respondents, patients receiving tracked devices may refuse to provide personal identifying data under §821.55(a).

11. Justification for Sensitive Questions

Required tracking information does not include questions pertaining to sexual behavior, attitude, religious beliefs, or to other matters commonly considered private or sensitive in nature.

12. Estimates of Burden Hours, Explanation, and Annualized Costs to Respondents

12a. Annualized Hour Burden Estimate

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

Table 1. - Estimated Annual Reporting Burden

21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Respondents	Average Burden per Response (in hours)	Total Hours
821.1(d)	1	1	1	1	1
821.2 and 821.30(e)	1	1	1	1	1
821.25(a)	12	1	12	76	912
821.25(d)	1	1	1	1	1
821.30	17,000	1	17,000	1	17,000
Total					17,915

Table 2. - Estimated Average Annual Recordkeeping Burden

CFR Section	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping (in hours)	Total Hours
821.25(b)	12	46,260	555,120	1	555,120
821.25(c)[1]	12	1	12	63	756
821.25(c)(3)	12	1,124	13,488	1	13,488
Total					569,364

[1.] One time burden.

Table 3 - Estimated Annual Third-Party Disclosure Burden[1]

21 CFR Section	No. of Respondents	No. of Disclosures per Respondent	Total Annual Disclosures	Average Burden per Disclosure (in hours)	Total Hours
821.30(a) and (b)	17,000	1	17,000	1	17,000
821.30(c)(2) and (d)	17,000	1	17,000	1	17,000
Total					34,000

Respondents for this collection of information are medical device manufacturers, importers, and distributors of tracked implants or tracked l/s-l/s devices used outside a device user facility. Distributors include multiple and final distributors, including hospitals.

The annual hourly burden for respondents involved with medical device tracking is estimated to be 621,279 hours per year. The burden estimates cited in Tables 1, 2, and 3 are based upon the fact that FDA has issued 36 tracking orders over the past three years, resulting in an average of 12 tracking orders annually. Also, although the estimated 17,000 distributor respondents are required to report directly to manufacturers, the Agency believes that including these respondents in the estimated reporting burden is appropriate under the PRA. FDA's estimate of 17,000 distributor respondents subject to tracking reporting requirements is contained in an FDA cost assessment of medical device tracking prepared in 1999, however, the agency believes this number has remained fairly constant.

Section 821.25(a). Under §821.25(a), device manufacturers subject to FDA tracking orders must adopt a tracking method which can provide certain device, patient, and distributor information to FDA within 3-10 working days. Assuming one occurrence a year, FDA estimates it would take a firm 20 hours to provide FDA with location data for all tracked devices and 56 hours to identify all patients and/or multiple distributors possessing tracked devices.

Under §821.25(d) manufacturers must notify FDA of distributor noncompliance with reporting requirements. FDA is unaware of receiving any such notices and assumes only repeated noncompliances would be reported. Based on the number of audits

manufacturers conduct annually, FDA estimates it would receive no more than one notice in any year, and that it would take 1 hour per incident.

Under §821.30(c)(2), multiple distributors must provide data on current users of tracked devices, current device locations, and other information, upon request from a manufacturer or FDA. FDA has not made such a request and is not aware of any manufacturer making a request. Assuming one multiple distributor receives one request in a year from either a manufacturer or FDA, and that lists may be generated electronically, the agency estimates a burden of one hour to comply.

Under §821.30(d) distributors must verify data or make required records available for auditing, if a manufacturer provides a written request. FDA's estimate of the burden for distributor audit responses assumes that manufacturers audit database entries for 5% of tracked devices distributed. Each audited database entry prompts one distributor audit response. Because lists may be generated electronically, FDA estimates a burden of one hour to comply.

12b. Annualized Cost Burden Estimate.

The estimated annual reporting cost to respondents for device tracking is $20,139,973. This figured was derived by multiplying the total reporting burden hours from Table 1 and Table 3 by an hourly rate of $55. This hourly rate is based on 2,080 annual work hours and an annual salary rate of $116,000. This health care professional salary rate includes salary, benefits, overhead, technical staff, support staff, etc. and was determined by the agency's current estimates of staff expenses.

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Healthcare professionals	34,915	$55	1,920,325
Recordkeepers	569,364	$32	18,219,648
Total			$20,139,973

Using the same data, FDA estimates that the recordkeeping costs for respondents is $18,219,648. This figure was determined by multiplying the total number of hours estimated for recordkeeping (569,364) by $32.00. Historical submissions, trend analysis, and estimates for annual cost of living increases determined the hourly rate.

13. Estimates of Other Total Annual Cost Burden to Respondents

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

14. Annualized Cost to the Federal Government

The 229 manufacturers will be inspected once every two years under FDA's Quality System (Q/S) inspection program. The field force will spend one hour per inspection to check tracking systems. Headquarters will spend about 10 minutes reviewing results. Total hours would be 133 hours (114 firms inspected per year x 1 hour/inspection = 114 hours) + (114 checklist results x 0.1666 hour/headquarters review per checklist = 19).

Based on an average wage estimate for involved FDA employees of $90,797 per full time equivalent (FTE) position (40 hours per week x 52 weeks per year), the annualized cost to FDA would be $6,292. [$90,797 x 133/2080 hours (0.0693) = $6,292]

15. Explanation for Program Changes or Adjustments

The burden hours and responses have been adjusted as the result of re-estimating and re-evaluating submissions and tracking data by the agency. There was a decrease of 2,785,905 burden hours, and a decrease of 241,262 annual responses. The new total is 621,279 burden hours and 17,915 annual responses. FDA attributes this reduction to the decreased number of tracking orders issued since original estimates were provided. More specifically, while the Safe Medical Devices Act of 1990 required tracking by all manufacturers of certain devices, FDAMA (enacted in 1997) provides that devices subject to tracking would be determined at the Agency's discretion and only upon order by FDA.

16. Plans for Tabulation and Publication and Project Time Schedule

Tracking information collections are not collected as part of a statistical analysis.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

FDA is not seeking approval to not display the OMB expiration date for OMB approval.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

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