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

A. JUSTIFICATION

1. Circumstances Necessitating Information Collection

On August 16, 1993, the Food and Drug Administration (FDA) issued a final rule establishing regulations for tracking certain medical devices (58 FR 43442). This regulation implemented section 519(e) of the Federal Food, Drug, and Cosmetic Act (the act), as amended by the Safe Medical Devices Act of 1990 (Public Law 101-629) (SMDA).

Under the SMDA, section 519(e) mandated that any person registered as a manufacturer of a device meeting the criteria 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 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:

§821.25(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 in 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) - Reporting - 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) - Reporting - 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) - Reporting - 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) - Reporting - 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. Inconsistencies with 5 CFR 1320.6

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

8. Consultations Outside FDA

From 2004-2006, FDA consulted the following individuals about the burden associated with this information collection. They did not recommend any changes to the regulation.

- Tara Treherne, Philips Medical Center, 2301 5th Ave., Suite 200, Seattle, WA 98121
- Robert Fleming, Mettler Electronics Corporation, 1333 South Claudina Street, Anaheim, CA 92805
- Doug Mechlenburg, Respironics, Inc., 1501 Ardmore Boulevard, Pittsburgh, PA 15221

In addition, FDA continually meets with respondents affected by this collection through its medical device inspection program and through other meetings and correspondence received. On November 2, 2007, http://www.fda.gov/cdrh/comp/guidance/169.html, FDA also issued a guidance document entitled "Guidance for Industry and FDA Staff: Medical Device Tracking."

In the Federal Register of February 5, 2008 (73 FR 6729) the FDA solicited comments on this information collection . No comments were received.

9. Explanation of Any Payment or Gift to Respondents

No payment or gift is provided to respondents.

10. Confidentiality of Information

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. 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

A. Background Facts and Assumptions:

1. Average figures. Burden estimates for information collections are based on data and methods from FDA's 1999 analysis, "Cost Assessment of Medical Device Tracking" (cost assessment), which estimates industry costs for device tracking systems from 1997-2006 and cost savings for devices no longer tracked under FDAMA. Burden hours shown in Tables 1 and 2 are average annual figures for the years 2004-2006. Numbers have been rounded up.

Table 1. - Estimated Annual Reporting Burden [1]

CFR Section	No. of Respondents	Annual Frequency of Response	Total Annual Responses	Hours per Response	Total Hours
821.25(a)	1	1	1	76	76
821.25(d)	22	1	22	2	44
821.30(a), (b)	17,000	72	1,222,725	0.1666	203,706
821.30(c)(2)	1	1	1	28	28
821.30(d)	17,000	15	259,186	0.1666	43,180
Total					247,082

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

Table 2. - Estimated Average Annual Recordkeeping Burden [1]

CFR Section	No. of Recordkeepers	Annual Frequency of Recordkeeping	Total Annual Records	Hours per Record	Total Hours
821.25(b)	229	46,260	10,593,433	0.2899	3,071,036
821.25(c)	229	1	229	63.0	14,430
821.25(c)(3)	229	1,124	257,454	0.2899	74,636
Total					3,160,102

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

2. Respondents. FDA has issued orders to 229 manufacturers who are required to track 12 types of devices intended to be implanted for more than one year (referred to as tracked implants) and 4 types of life-sustaining or life-supporting devices used outside device user facilities (referred to as tracked l/s-l/s devices).

FDA's estimate of 17,000 distributor respondents subject to tracking reporting requirements is contained in FDA's cost assessment. The number of distributors is derived from Dun and Bradstreet sources on medical equipment wholesalers, retailers, home care dealers, and equipment rental companies. The Health Forum, an American Hospital Association Company, provided statistics on hospitals.

3. Medical procedure estimates. Using implantation procedures data from the National Center for Health Statistics for 1993-1996, FDA applied a 2% annual growth rate to estimate the number of procedures for tracked implant devices from 1997-2006. See. The assessment also used unit shipment data in combination with various growth rates to estimate annual sales/distribution for the tracked l/s-l/s devices over the same time period. The average number of new tracked implants for the time period 20042-2006 is 483,497 devices. The average total number of tracked implants is 3,941,684. The average total number of tracked l/s-l/s devices is 369,612.

B. Burden Estimates- Reporting

B-2. 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. [20 hours + 56 hours = 76 hours]

B-3. Section 821.25(d). 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 22 notices in any year. FDA believes that it would take 2 hours per incident to report repeated distributor noncompliance to FDA. [22 reports x 2 hours = 44 hours]

B-4. Section 821.30(a) and (b**)** Under §821.30 (a) and (b), distributors must report specified data to manufacturers upon acquiring tracked devices as well as upon distributing the devices to patients.

Distributor reporting for tracked implants: FDA assumes that hospitals are the direct recipients of tracked implants. FDA believes most hospitals rely on manufacturer distribution records identifying initial consignees of devices, as required by the Quality System regulation (21 CFR §820.160; OMB Control No. 0910-0073), in lieu of reporting the receipt of tracked devices back to the manufacturers. Consequently, only one report is attributed to final distributors of tracked implants. FDA estimates it would take 10 minutes (0.1666 hours) for final distributors to report tracking data for each tracked implant distributed during the year. For 2004-2006, the estimated average number of new implants per year is 483,497 devices. The average annual burden for distributor reporting would be 80,551 hours. [483,497 new tracked implants x 1 final distributor per device x 1 data report per final distributor x 0.1666 hours per report = 80,551 hours]

Distributor reporting for tracked l/s-l/s devices: FDA estimates there are a median of two distributors or multiple distributors in distribution chains for tracked l/s-l/s devices. Each distributor or multiple distributor would make one data report per device received during the year. The average annual burden for distributor reporting for the tracked l/s-l/s

devices is estimated as 123,155 hours. [369,612 tracked l/s-l/s devices x 2 distributors or multiple distributors per device = 739,224 x 1 data report per distributor/multiple distributor x 0.1666 hours per report = 123,155 hours]

The total burden for Section 821.30(a) and (b) is 203,706 hours. [80,551 hours (implants) + 123,155 hours (l/s-l/s devices) = 203,706 hours]

B-6. Section 821.30(c)(2). 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, the agency estimates the multiple distributor would need 3.5 days to comply. [8 hours/day x 3.5 days/response = 28 hours]

B-7. Section 821.30(d). 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. FDA estimates that distributors will take 10 minutes (0.1666 hours) to verify data. FDA estimates that 10% of audited data might be found discrepant and would require further follow-up from distributors.

Distributor audit responses for tracked implants: The estimated percentage of database entries audited once a year for 2004-2006 is 99.2 %. The percentage of entries audited twice a year is 0.8%. The average number of total implants tracked per year is 3,941,684. The average annual burden for distributor audit responses regarding data for tracked implants audited once a year is estimated as follows:

- 3,941,684 average total tracked implants x 1 data report per device from final distributors x 1 database entry per data report x .05 (percentage of database entries audited) = 197,084 devices.
- 197,084 devices x 1 distributor audit response per audited record x .992

(percentage of entries audited once a year) = 195,507 devices.

- 195,507 devices x 0.1666 hours (10 minutes) per response = 32,571 hours.
- Adding 10% for additional responses to follow-up verification of noncompliant data increases the burden by 3,257 hours. [(195,507 x 0.1 = 19,551 devices requiring follow-up x 0.1666 hours per response = 3,257 hours].

The total number of hours for tracked implants audited once a year, including follow-up, is 35,828 hours. [32,571 hours + 3,257 hours = 35,828 total hours]

The average number of distributor audit responses for tracked implants audited twice a year is approximately 1,577. [total number of audit responses (197,084) minus distributor audit responses for tracked implants audited once a year (197,507) = 1,577]. The average annual burden for distributors is estimated as follows: [(1,577 devices x 2 times audited = 3,154) x 0.1666 (10 minutes) per response = 525 hours.] Adding 53 hours (10%) for follow-up brings the burden to 578 hours. [525 hours + 53 hours = 578 total hours]

The total burden for auditing tracked implants is 36,406 hours. [35,828 hours for implants audited once/year + 578 hours for implants audited twice/year = 36,406 hours]

Distributor audit responses for tracked l/s-l/s devices: Distributors and multiple distributors of tracked l/s-l/s devices would be asked to verify audited data for these devices. The average annual burden for distributor audit responses is estimated below:

- 369,612 devices (average number of new l/s-l/s devices distributed per year) x 2 data reports per device (based on mean number of distributors or multiple distributors in distribution chains) = 739,224 reports.
- 739,224 reports x 1 database entry per distributor data report x .05 (percentage of entries audited) = 36,961 reports.
- 36,961 reports x 1 distributor audit response per audited record x 0.1666 hours per response = 6,158 hours.
- Adding 10% for additional responses to verify noncompliant data increases the burden by 616 hours to 6,774 hours [(36,961 x 0.1 = 3,696) x 0.1666 hours per response = 616 hours].

The total burden for auditing tracked l/s-l/s devices is 6,774 hours. [6,158 hours of distributor audit responses + 616 hours of distributor audit follow-up = 6,774 total hours]

The total burden for Section 821.30(d) is 43,180 hours [36,406 hours for implant audits + 6,774 hours for l/s-l/s audits = 43,180 hours]

C. Burden Estimates- Recordkeeping

C-1. Section 821.25(b**)** Under §821.25(b) manufacturers must maintain current tracking records in accordance with standard operating procedures (SOPs). To maintain databases, manufacturers conduct transactions, such as receiving distributor data reports , registering patients, making database entries, and auditing entries against distributor data. Audit activities are estimated separately under C-3, Section 821.25(c)(3).

Database for tracked implants: In FDA's cost assessment, FDA used a consulted implant manufacturer's estimate that the representative firm conducts approximately 2.5 database transactions per tracked implant. Each transaction would take personnel approximately 17 minutes (0.2899 hour) to complete. The estimated average annual burden for database transactions for tracked implants is 2,856,735 hours. [3,941,684 devices (average number of tracked implants for 2004-2006) x 2.5 database transactions per year x 0.2899 hours (17 minutes) per transaction = 2,856,735 hours].

Database for tracked l/s-l/s devices: For tracked l/s-l/s devices, FDA assumes a similar number of database transactions per device (2.5) and time for transactions (17 minutes). The average annual burden for database transactions involving tracked l/s-l/s devices is 214,301 hours. [369,612 devices (average number of new devices distributed per year per) x 2 distributors or multiple distributors per device (based on the mean number in distribution chains) x 1 data report per distributor x 1 database transaction per report x 0.2899 hour (17 minutes) per transaction = 214,301 hours]

The total burden for Section 821.25(b) is 3,071,036 hours [2,856,735 hours for tracked implants + 214,301 hours for tracked l/s-l/s devices = 3,071,036 total hours].

C-2. Section 821.25(c**)** Under §821.25(c), manufacturers must establish SOPs for collecting, maintaining, and auditing tracking data. FDA estimates that the 20 new manufacturers would take an average of two staff months to plan and develop a tracking system, and one month to draft and implement standard operating procedures (SOPs). One month equal 22 working days at 8 hours per day. The estimated time for the new manufacturers with a one-time burden is 10,560 hours. [20 new manufacturing firms x 66 working days x 8 hours per day = 1-time burden of 10,560 hours]

Manufacturers with tracking systems in place would review and/or revise their tracking system SOPs on an annual basis, expending approximately 10 percent of the amount of time spent originally in drafting the SOPs [22 days x 8 hours per day] x 0.1 = 18 hours. From 2004-2006, approximately 215 firms would annually revise tracking SOPs. The average annual burden for revising SOPs from 2002-2004 is 3,870 hours. [215 firms x 18 hours per firm = 3,870 hours]

Section 821.25(c)(3) requires that the manufacturer's auditing SOP include a quality assurance program with procedures for statistically relevant sampling. As discussed under §821.30(d), FDA's burden estimate for manufacturer auditing assumes firms would audit 5% of records for products, based on numbers of tracked implant devices each year or distributed tracked l/s-l/s devices each year. FDA provides for 10% further follow-ups for noncompliance, i.e., to change inaccurate or update data. Burdens for auditing data for tracked implants and tracked l/s-l/s products are estimated below.

Manufacturer auditing for tracked implants: Manufacturers would audit data for total tracked implants. FDA assumes auditing transactions would take 17 minutes (0.2899 hours). For 2004-2006, the average annual burden for auditing tracked implants requiring one audit per year would be 3,941,684 devices x 1 final distributor data report per new implant upon implantation per database entry x .05 (5% of database entries

audited) (197,084) x 1.0 (average percentage of entries audited once per year) x .2899 hours (17 minutes) per audit transaction = 57,135 hours. Adding 10% for follow-up auditing (5,714) increases the burden to 62,849 hours [57,135 + 5,714 = 62,849 hours).

Manufacture auditing for tracked l/s-l/s devices The data for new l/s-l/s devices distributed each year would be audited. For 2004-2006, the average annual burden for these devices is estimated at 11,787 hours. [369,612 devices (average number of new devices distributed annually) x 2 data reports per device (based on the mean of the number of distributors or multiple distributors in distribution chains) (739,224) x 1 database entry per distributor or multiple distributor data report x .05 (percentage of entries audited) (36,961) x .2899 hours = 10,715 hours. The 10% for follow up auditing (1,072) increases the burden to 11,787 hours].

The total burden for manufacturer auditing of tracked implants (62,849) and l/s-l/s devices (11,787) is 74,636 hours.

The information collection requirements in 21 CFR 821.2 and 821.30(e) have been approved under OMB Control No. 0910-0183.

D. Annualized Cost - Estimates

Based on average annual burdens from 2004-2006, FDA estimates that respondents will expend approximately $3,165,734 ($3.2 million) to comply with reporting requirements, and approximately $102,091,359 ($102.1 million) to comply with recordkeeping requirements of the tracking regulation. Recordkeeping costs include one-time costs of approximately $562,954. Table 3 shows burden hours and costs associated with each provision in the medical device tracking regulation that requires reporting or recordkeeping.

Table 3. - Estimated Average Annual Costs[1]

Type Burden	CFR Section	Total Annual Hours	Hourly Wage Rates (Composite)	Total Annual Costs
Reporting	821.2 (including 821.30(e)): Exemption/variance requests	48	$51.65	$2,479
	821.25(a): Manufacturers provide data in 3, 10, or 10 days	76	$32.31	$2,448
	821.25(d): Manufacturers report distributor non-compliance	44	$50.75	$2,233
	821.30(a),(b): Distributors, final distributors and multiple distributors report data upon receipt and when distributed to patients.	203,706	$12.79	$2,605,400
	821.30(c)(2): Multiple distributors provide data in 5 days to manufacturers and FDA upon request.	28	$32.21	$902
	821.30(d): Distributors, final distributors, and multiple distributors provide records upon written audit requests by manufacturers (or verify data as requested during manufacturer auditing of tracking systems).	43,180	$12.79	$552,272
Total (Reporting)				$3,165,734
Recordkeeping	821.25(b): Manufacturers register patients and record and maintain current data in implementing tracking system databases	3,071,036	$32.21	$98,918,070
	821.25(c): Manufacturers develop and implement tracking systems and draft/review/revise SOPs, including audit SOP within quality assurance program	14,430	$53.31	$769,263
	821.25(c)(3): Manufacturers audit data in implementing audit SOP.	74,636	$32.21	$2,404,026
Total (Recordkeeping)				$102,091,359

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

Wage estimates used in Table 3 are based on figures found in the May 2006 National Industry-Specific Occupational Employment and Wage Estimates, U.S. Department of Labor, Bureau of Labor Statistics, at http://www.bls.gov/oes/current/naics4_339100.htm.

The composite hourly wage rate of $51.65 assumes the following participation by personnel at manufacturers and comparable personnel at various type distributors: 20%

by the general manager/top executive ($79.58 per hour); 70% by managers or supervisors ($52.54 per hour); and 10% by secretaries ($14.65 per hour).

The composite hourly wage rate of $32.21 assumes the following participation by personnel at manufacturers and comparable personnel at multiple distributors: 10% by managers/ supervisors ($48.95 per hour); 45% by computer operators ($17.61 per hour), and 45% by audit clerks ($15.91 per hour).

The composite hourly wage rate of $50.75 assumes the following participation at manufacturers: 50% by general managers ($52.54 per hour) and 50% by managers/supervisors ($48.95 per hour).

The hourly wage rate of $12.79 is for shipping, receiving, and traffic clerks at the various type distributors. (This is not a composite rate.)

The composite hourly wage rate of $53.31 assumes the following participation by manufacturing personnel: 50% by general managers/top executives ($79.58 per hour); 40% by computer programmers ($30.13 per hour); and 10% percent by secretaries ($14.65 per hour).

13. Estimates of Other Total Annual Cost Burden to Respondents

No capital and start-up, operating and maintenance, or other costs not identified in item 12 above are estimated for this information collection.

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 about $6,292. [$90,797 x 133/2080 hours (0.0693) = $6,292]

15. Explanation for Program Changes or Adjustments

There was an adjustment in the burden hours and responses due to Agency reevaluation.

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.