United States Food and Drug Administration

Medical Devices; Device Tracking
OMB Control No. 0910-0442

SUPPORTING STATEMENT **Part A: Justification**

1. Circumstances Making the Collection of Information Necessary

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 FD&C 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.

The FDA Modernization Act of 1997 (Public Law 105-115) (FDAMA) amended section 519(e) of the FD&C Act, which became effective February 19, 1998. Amended section 519(e)(1), 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) provided 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.

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

2. Purpose and Use of the Information Collection

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 Improved 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 or Other Small Entities

We estimate that approximately 80 percent of respondents are 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 International and Consumer Education (DICE) and its scientific and compliance staffs.

6. Consequences of Collecting the Information Less Frequently

Respondents will respond to the data collection occasionally. 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

There are no special circumstances for this collection of information.

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.

Section 821.30(c)(2) 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. FDA has not made such a request and is not aware of any manufacturer making a request.

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.

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

In accordance with 5 CFR 1320.8(d), FDA published a 60-day notice for public comment in the FEDERAL REGISTER of November 5, 2020 (85 FR 70634). No comments were received.

9. Explanation of Any Payment or Gift to Respondents

There are no incentives, payments or gifts associated with this information collection.

10. Assurance of Confidentiality Provided to Respondents

In preparing this Supporting Statement, we consulted our Privacy Office to ensure appropriate identification and handling of information collected.

This ICR collects personally identifiable information (PII). PII is collected in the context of the subject individuals' professional capacity and the FDA-related work they perform for their employer (e.g., point of contact at a regulated entity). The PII submitted via Form FDA 3514 (CDRH Premarket Review Submission Cover Sheet) is name, address, title, phone number, fax number, and email address. All information collected is work contact information. Information collected from FDA Form 3514 is used to create the tracking order and send to the appropriate person. The manufacturer tracks their device to the patient per 21 CFR 821.25. However, FDA does not collect this information. Tracking enhances the impact of mandatory recalls or notifications when such actions concern tracked devices. Tracking information is used for purposes of recall and 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. Through appropriate form design, FDA limited submission fields and minimized the PII collected to protect the privacy of the individuals.

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 (5 U.S.C. 552(b)(1-9)). 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.

Tracking data identifying customers or patients, either reviewed by or submitted to FDA, is covered under 21 CFR part 20. Data will be kept private to the fullest extent allowed by law. 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

The collection of information does not involve sensitive questions.

12. Estimates of Annualized Burden Hours and Cost

12a. Annualized Hour Burden Estimate

Table 1.--Estimated Annual Reporting Burden					
Activity/ 21 CFR Part	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Discontinuation of business--821.1(d)	1	1	1	1	1
Exemption or variance--821.2 and 821.30(e)	1	1	1	1	1
Notification of failure to comply--821.25(d)	1	1	1	1	1
Multiple distributor data--821.30(c)(2)	1	1	1	1	1
Total					4

Table 2.--Estimated Annual Recordkeeping Burden					
Activity/ 21 CFR Part	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
Tracking information--821.25(a)	12	1	12	76	912
Record of tracking data--821.25(b)	12	46,260	555,120	1	555,120
Standard operating procedures--821.25(c)[1]	12	1	12	63	756
Manufacturer data audit--821.25(c)(3)	12	1,124	13,488	1	13,488
Multiple distributor data and distributor tracking records—821.30(c)(2) and (d)	22,000	1	22,000	1	22,000
Total					592,276
[1] One-time burden.					

Table 3.--Estimated Annual Third-Party Disclosure Burden					
Activity/ 21 CFR Part	No. of Respondents	No. of Disclosures per Respondent	Total Annual Disclosures	Average Burden per Disclosure	Total Hours
Acquisition of tracked devices and final distributor data--821.30(a) and (b)	22,000	1	22,000	1	22,000
Multiple distributor data and distributor tracking records--821.30(c)(2) and (d)	1,100	1	1,100	1	1,100
Total					23,100

Respondents to 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 total hourly burden for respondents involved with medical device tracking is estimated to be 615,380 hours per year. The burden estimates cited in tables 1 through 3 are based on the approximate number of device tracking orders, 12 annually. FDA estimates that approximately 22,000 respondents may be subject to tracking reporting requirements.

Discontinuation of business (§ 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.

Exemption or variance (§§ 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.

Tracking information (§ 821.25(a)) - Recordkeeping - 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 per 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.

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

Standard operating procedures and Manufacturer data audit (§ 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.

Notification of failure to comply (§ 821.25(d)) - Reporting - 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.

Acquisition of tracked devices (§ 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.

Final distributor data (§ 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.

Multiple distributor data (§ 821.30(c)(2)) – Reporting, Recordkeeping, and 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.

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.

Distributor tracking records (§ 821.30(d)) – Recordkeeping and Third-Party Disclosure - 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 percent 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 $72,614,840. We updated the annual cost burden estimate based on the wage rate for a Lawyer* ($118), multiplied by the total estimated burden hours (615,380).

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Lawyer	615,380	$118	$72,614,840

* The estimated wage rate for a Lawyer is based on The Bureau of Labor Statistics (BLS) hourly wage rate of $59 for a lawyer (https://www.bls.gov/ooh/legal/lawyers.htm, accessed 12-18-20). The hourly wage rate of $118 assumes a 40-hour work week and is rounded to the nearest dollar and has been doubled to account for benefits and overhead.

13. Estimates of Other Total Annual Costs to Respondents/Recordkeepers or Capital Costs

There are no capital, start-up, operating or maintenance costs associated with this information collection.

14. Annualized Cost to the Federal Government

We estimate the annualized cost to the Federal government is $17,755. The estimate includes FDA's District office personnel as well as headquarters personnel who work with tracked device information. A full time equivalent position (FTE) is estimated to cost FDA/CDRH $263,326* annually, which consists of the employee's salary and any overhead which accompanies that employee. Assuming a 40-hour work week, that equals approximately $127 per hour (rounded). District office personnel spend approximately 2 hours reviewing tracked device information during each of approximately 60 inspections annually ($127 x 2 hours x 60 inspections = $15,240). Headquarters personnel spend approximately 20 minutes reviewing the tracked device information from each of the 60 inspections ($127 x 0.33 hours x 60 inspections = $2,515(rounded)).

*Based on the FY 2020 FDA Budget Request – Executive Summary – All Table

15. Explanation for Program Changes or Adjustments*

This is a request for extension without change to the burden hour estimate. There are no adjustments or program changes.

16. Plans for Tabulation and Publication and Project Time Schedule

This information collected will not be published or tabulated. Tracking information collections are not collected as part of a statistical analysis.

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

FDA will display the expiration date of OMB approval.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.