UNITED STATES FOOD & DRUG ADMINISTRATION

Medical Device Tracking

OMB Control No. 0910-0442 – Extension

SUPPORTING STATEMENT

Terms of Clearance: n/a.

Part A: Justification:

1. Circumstances Making the Collection of Information Necessary

This information collection supports Food and Drug Administration (FDA, the agency, us or we) regulations. Section 519(e)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360i(e)(1)) provides that FDA may require by order that a manufacturer adopt a method for tracking a class II or III medical device, if the device meets one of the three following criteria: (1) the failure of the device would be reasonably likely to have serious adverse health consequences, (2) the device is intended to be implanted in the human body for more than 1 year (referred to as a "tracked implant"), or (3) the device is life-sustaining or life-supporting (referred to as a "tracked l/s-l/s device") and is used outside a device user facility. Tracked device information is collected to facilitate identifying the current location of medical devices and patients possessing those devices, to the extent that patients permit the collection of identifying information. Manufacturers and FDA (where necessary) use the data to: (1) expedite the recall of distributed medical devices that are dangerous or defective and (2) facilitate the timely notification of patients or licensed practitioners of the risks associated with the medical device. In addition, applicable regulations in 21 CFR part 821 (21 CFR 821.1 through 821.60) include provisions for: (1) exemptions and variances; (2) system and content requirements for tracking; (3) obligations of persons other than device manufacturers, e.g., distributors; (4) records and inspection requirements; (5) confidentiality; and (6) record retention requirements. The requirements in part 821 include reporting, recordkeeping, and third-party disclosure requirements.

We therefore request extension of OMB approval of the information collection requirements found in 21 CFR part 821 as discussed in this supporting statement.

2. Purpose and Use of the Information Collection

Respondents to the 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 regulations in part 821 are intended to ensure that tracked devices can be traced from the device manufacturing facility to the person for whom the device is indicated, that is, the patient. Effective tracking of devices from the manufacturing facility, through the distributor network (including distributors, retailers, rental firms and other commercial enterprises, device user facilities, and licensed practitioners) and, ultimately, to the patient is necessary for the effectiveness of remedies prescribed by the FD&C Act, such as patient notification (section 518(a) of the FD&C Act) or device recall (section 518(e) of the FD&C Act). Although these regulations

do not preclude a manufacturer from involving outside organizations in that manufacturer's device tracking effort, the legal responsibility for complying with part 821 rests with manufacturers who are subject to tracking orders, and that responsibility cannot be altered, modified, or in any way abrogated by contracts or other agreements.

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

We are unaware of duplicative information collection. Under FDA's Quality System Regulation (21 CFR 820.160; OMB control number 0910-0073), 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 do not believe the information collection imposes undue impact on small entities. We estimate that approximately 80 percent of respondents are small businesses. FDA helps to minimize the impact by aiding small businesses 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

Information collection schedule is consistent with applicable statutory and regulatory authorities administered by FDA.

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

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

We published a 60-day notice soliciting public comment on the proposed information collection in the *Federal Register* of August 8, 2023 (88 FR 53494). 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

Consistent with 5 CFR 1320.5(d)(2)(vii) and agency regulations in 21 CFR § 20.20, data will be kept private to the extent allowed by law:

The Privacy Act of 1974

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 is submitted via Form FDA 3514 (CDRH Premarket Review Submission Cover Sheet)[1] and includes point of contact name, business address, business phone number, business fax number, and business email address. FDA determined that although PII is collected, the collection is not subject to the Privacy Act of 1974 and the particular notice and other requirements of the Privacy Act do not apply. Specifically, the contractor or FDA does not use name or any other personal identifier to retrieve records from the information collected. Through appropriate form and webpage design, FDA limited submission fields and minimized the PII collected to protect the privacy of the individuals.

The Freedom of Information Act (FOIA)

Under 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.

[1] See OMB control number 0910-0120.

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

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.

Upon evaluation of the information collection, we have made no adjustment to our currently approved burden estimate of 615,380 hours annually, based on 12 tracking orders. We attribute the attendant burden to the following activities:

Under § 821.25(a) (21 CFR 821.25(a)), device manufacturers subject to FDA tracking orders must adopt a tracking method that can provide certain device, patient, and distributor information to FDA within 3 to 10 working days. Assuming one occurrence per year, we estimate 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. Based on the number of audits manufacturers conduct annually, we estimate no more than one notice will be received in any year, and that it would take 1 hour per incident.

Under § 821.30(c)(2) (21 CFR 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. Assuming one multiple distributor receives one request in a year from either a manufacturer or FDA, and that lists may be generated electronically, we estimate a burden of 1 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. We assume 5 percent of tracked devices distributed for estimating burden. Each audited database entry prompts one distributor audit response. Because lists may be generated electronically, we estimate a burden of 1 hour to comply.

12b. Annualized Cost Burden Estimate

Assuming that activities identified in *12a* are performed by labor categories consistent with that of "*Lawyer*" (occupation code 23-1011) as defined by the Bureau of Labor Statistics (BLS), we use a mean hourly wage rate of $78.74/hour for a lawyer consistent with 2022 data for our calculations.[2] We factor this figure by two to account for benefits and overhead ($157.48), multiply the total by

[2] http://www.bls.gov/oes/current/oes_nat.htm, accessed 10/11/23.

the annual burden hours and estimate annual respondent costs to be $96,910,042 (rounded) [$157.48 x 615,380 hours].

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Lawyer	615,380	$157.48	$96,910,042

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 $19,991. Based on an internal cost model, we assume a fully-loaded annual cost of $297,561 per full-time equivalent position (FTE). Our calculations assume a 40-hour work week; approximately $143 per hour (rounded). The estimate includes FDA's District office personnel as well as headquarters personnel who work with tracked device information. District office personnel spend approximately 2 hours reviewing tracked device information during each of approximately 60 inspections annually ($143 x 2 hours x 60 inspections = $17,160). Headquarters personnel spend approximately 20 minutes reviewing the tracked device information from each of the 60 inspections ($143 x 0.33 hours x 60 inspections = $2,831 (rounded)).

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.

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

The expiration date of OMB approval will be displayed as required.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.