4161-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-N-5569]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Medical Devices; Device Tracking

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to https://www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under Review--Open for Public Comments" or by using the search function. The OMB control number for this information collection is 0910-0442. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-3794, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Medical Devices; Device Tracking--21 CFR Part 821

OMB Control Number 0910-0442--Extension

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.

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. We currently estimate 22,000 potential respondents.

In the *Federal Register* of August 8, 2023 (88 FR 53494), we published a 60-day notice soliciting comment on the proposed collection of information. No comments were received.

We estimate the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden[1]

Activity; 21 CFR Section	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

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

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

Activity; 21 CFR Section	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)[2]	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] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] One-time burden.

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

Activity; 21 CFR Section	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

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

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), 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), 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.

Dated: November 30, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

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