4164-01-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: Fax written comments 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 faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202-395-7285, or emailed to oira_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0442. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-8867, 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 211 of the Food and Drug Administration Modernization Act of 1997 (FDAMA) (Pub. L. 105-115) became effective on February 19, 1998. FDAMA amended the previous medical device tracking provisions under section 519(e)(1) and (2) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360i(e)(1) and (2)) that were added by the Safe Medical Devices Act of 1990 (SMDA) (Pub. L. 101-629). Unlike the tracking provisions under SMDA, which required tracking of any medical device meeting certain criteria, FDAMA allows FDA discretion in applying tracking provisions to medical devices meeting certain criteria and provides that tracking requirements for medical devices can be imposed only after FDA issues an order. In the *Federal Register* of February 8, 2002 (67 FR 5943), FDA issued a final rule that conformed existing tracking regulations to changes in tracking provisions effected by FDAMA under part 821 (21 CFR part 821).

Section 519(e)(1) of the FD&C Act, as amended by FDAMA, 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, the regulations 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 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 615,380 hours per year. The burden estimates cited in tables 1 through 3 are based on the number of device tracking orders issued in the last 3 years, an average of 12 tracking orders annually. FDA estimates that approximately 22,000 respondents may be subject to tracking reporting requirements.

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, 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. 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 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. 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 1 hour to comply.

In the *Federal Register* of October 18, 2017 (82 FR 48516), FDA published a 60-day notice requesting public comment on the proposed collection of information. Although one comment was received, it was not responsive to the four collection of information topics solicited and therefore will not be discussed in this document.

FDA estimates 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

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
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.

The burden estimate for this information collection has not changed since the last OMB approval.

This document also refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by OMB under the PRA

(44 U.S.C. 3501-3520). The collections of information found in §§ 821.2(b), 821.25(e), and 821.30(e) have been approved under OMB control number 0910-0191.

Dated: January 9, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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