

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Food and Drug Administration****[Docket No. FDA-2010-N-0555]****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 (the PRA).

**DATES:** Fax written comments on the collection of information by June 6, 2011.

**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 e-mailed to [oir\\_submission@omb.eop.gov](mailto:oir_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:** Daniel Gittleman, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-5156, [Daniel.Gittleman@fda.hhs.gov](mailto:Daniel.Gittleman@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 (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 (e)(2) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360i(e)(1) and (e)(2)) and 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; records and inspection requirements; (4) confidentiality; and (5) 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 604,279 hours per year. The burden estimates cited in tables 1, 2, and 3 of this document are based on the number of device tracking orders issued in the last 3 years.

This regulation also refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by Office of Management and Budget 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 0910-0183.

In the **Federal Register** of November 12, 2010 (75 FR 69447), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (in hours)	Total hours
821.1(d) .....	1	1	1	1	1
821.2 and 821.30(e) .....	1	1	1	1	1
821.25(a) .....	12	1	12	76	912
821.25(d) .....	1	1	1	1	1
Total .....					915

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

TABLE 2—ESTIMATED AVERAGE ANNUAL RECORDKEEPING BURDEN <sup>1</sup>

21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping (in hours)	Total hours
821.25(b) .....	12	46,260	555,120	1	555,120
821.25(c) <sup>2</sup> .....	12	1	12	63	756
821.25(c)(3) .....	12	1,124	13,488	1	13,488
Total .....					569,364

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

<sup>2</sup> One time burden.

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN <sup>1</sup>

21 CFR section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure (in hours)	Total hours
821.30(a) and (b) .....	17,000	1	17,000	1	17,000
821.30(c)(2) and (d) .....	17,000	1	17,000	1	17,000
Total .....					34,000

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

Dated: May 2, 2011.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

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**BILLING CODE 4160-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2011-N-0275]

#### Agency Information Collection Activities; Proposed Collection; Comment Request; Certification To Accompany Drug, Biological Product, and Device Applications or Submissions (Form FDA 3674)

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the requirements for certain FDA applications or submissions to be accompanied by a certification, Form

FDA 3674, to ensure all applicable statutory requirements have been met.

**DATES:** Submit either electronic or written comments on the collection of information by July 5, 2011.

**ADDRESSES:** Submit electronic comments on the collection of information to <http://www.regulations.gov>. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the Office of Management and Budget (OMB) control number 0910-0616. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Jonna Capezzuto, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., P150-400B, Rockville, MD 20850, 301-796-3794, [jonnalynn.capezzuto@fda.hhs.gov](mailto:jonnalynn.capezzuto@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Under the PRA (44 U.S.C. 3501-3520), Federal Agencies must obtain approval from OMB for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies

to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed extension of an existing collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed extension of the collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

#### Certification To Accompany Drug, Biological Product, and Device Applications or Submissions (Form FDA 3674)—(OMB Control Number 0910-0616)—Extension

The information required under section 402(j)(5)(B) of the Public Health Service Act (PHS Act) (42 U.S.C. 282(j)(5)(B)) is submitted in the form of