

information from students and health care professionals who are interested in becoming involved in CDRH activities. The process will reduce the time and cost of submitting written documentation to the agency and lessen the likelihood of applications being

misrouted within the agency mail system. It will assist the agency in promoting and protecting the public health by encouraging outside persons to share their expertise with CDRH.

In the **Federal Register** of November 9, 2007 (72 FR 63614), FDA published

a 60-day notice requesting public comment on the information collection provisions. No comments were received.

FDA estimate of the burden for this collection of information is as follows:

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

| 5 U.S.C. Section/<br>FDA Form No.                                   | No. of<br>Respondents | Annual Frequency<br>per Response | Total Annual<br>Responses | Hours per<br>Response | Total Hours |
|---|-----------------------|----------------------------------|---------------------------|-----------------------|-------------|
| 1104, 1302, 3301, 3304, 3320, 3361,<br>3393, 3394/<br>Form No. 3608 | 250                   | 1                                | 250                       | 1                     | 250         |

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

FDA based these estimates on the number of inquiries that have been received concerning the program and the number of requests for application forms over the past 3 years.

Dated: January 30, 2008.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. E8-2068 Filed 2-4-08; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2008-N-0048] (formerly Docket No. 2007N-0182)

#### Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Information Program on Clinical Trials for Serious and Life-Threatening Diseases: Maintaining a Databank

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Information Program on Clinical Trials for Serious and Life-Threatening Diseases: Maintaining a Databank" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

**FOR FURTHER INFORMATION CONTACT:** Jonna Capezzuto, Office of the Chief Information Officer (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4659.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of October 19, 2007 (72 FR 59295), the agency announced that the proposed information collection had been submitted to OMB for review and

clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910-0459. The approval expires on January 31, 2011. A copy of the supporting statement for this information collection is available on the Internet at <http://www.reginfo.gov/public/do/PRAMain>.

Dated: January 30, 2008.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2008-N-0050]

#### Agency Information Collection Activities; Proposed Collection; Comment Request; Medical Devices; Device Tracking

**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

information collection requirements for the tracking of medical devices.

**DATES:** Submit written or electronic comments on the collection of information by April 7, 2008.

**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 docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Denver Presley, Jr., Office of the Chief Information Officer (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301 827-1472.

**SUPPLEMENTARY INFORMATION:** Under the PRA (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (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 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 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.

**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) (Public Law 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 (the act) 21 U.S.C. 360i(e)(1) and (2) and were added by the Safe Medical Devices Act of 1990 (SMDA) (Public Law 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 which 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 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.

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

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

| 21 CFR Section      | No. of Respondents | Annual Frequency of Response | Total Annual Responses | Hours per Response | Total Hours |
|---------------------|--------------------|------------------------------|------------------------|--------------------|-------------|
| 821.2 and 821.30(e) | 4                  | 1                            | 4                      | 12                 | 48          |
| 821.25(a)           | 1                  | 1                            | 1                      | 76                 | 76          |
| 821.25(d)           | 22                 | 1                            | 22                     | 2                  | 44          |
| 821.30(a) and (b)   | 17,000             | 72                           | 1,222,725              | 0.1666             | 203,706     |
| 821.30(c)(2)        | 1                  | 1                            | 1                      | 28                 | 28          |
| 821.30(d)           | 17,000             | 15                           | 259,186                | 0.1666             | 43,180      |
| Total               |                    |                              |                        |                    | 247,082     |

<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 | No. of Recordkeepers | Annual Frequency of Recordkeeping | Total Annual Records | Hours per Record | Total Hours |
|----------------|----------------------|-----------------------------------|----------------------|------------------|-------------|
| 821.25(b)      | 229                  | 46,260                            | 10,593,433           | 0.2899           | 3,071,036   |
| 821.25(c)      | 229                  | 1                                 | 229                  | 63.0             | 14,430      |
| 821.25(c)(3)   | 229                  | 1,124                             | 257,454              | 0.2899           | 74,636      |
| TOTAL          |                      |                                   |                      |                  | 3,160,102   |

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

The annual hourly reporting burden for respondents involved with medical

device tracking is estimated to be 247,082 hours, and the annual

recordkeeping burden for these respondents is estimated to be 3,160,102

hours. These figures have been rounded up. The burden estimates cited in tables 1 and 2 of this document are based primarily upon the data and methods provided in FDA's assessment for fiscal year (FY) 1999 entitled "A Cost Assessment of Medical Device Tracking." Using implantation procedures from the National Center for Health Statistics, FDA applied a 2-percent annual growth rate to estimate the number of procedures for tracked implant devices for FY1997 through FY2006. This assessment also used unit shipment data in combination with various growth rates to estimate annual sales distribution for the tracked l/s-l/s devices over the same time period. In addition, the assessment also estimated the burden on industry for developing and maintaining tracking systems for these medical devices for FY1997 through FY2006.

For the annual recordkeeping burden, the number of respondent medical device manufacturers subject to device tracking is estimated to be 229 and is based on data from FDA's manufacturers database. FDA issued tracking orders to 20 additional medical device manufacturers during the time period for FY2002 through FY2004. Under § 821.25(c), the additional medical device manufacturers collectively bear a one-time recordkeeping burden of 10,560 hours to develop a medical device tracking system. FDA's estimate of 17,000 medical device distributor respondents contained in this assessment, are derived from Dun & Bradstreet sources on medical equipment wholesalers, retailers, home care dealers, and rental companies. Health Forum, an American Hospital Association Company, provided statistics on hospitals.

Please note that on January 15, 2008, the FDA Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic submissions will be accepted by FDA through FDMS only.

Dated: January 30, 2008.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2008N-0016]

#### Agency Information Collection Activities; Proposed Collection; Comment Request; Additional Listing Information for Medical Device Registration and Listing

**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 public comments on the reporting and recordkeeping burden associated with the paperwork requirements under § 807.31 (21 CFR 807.31), which requires device establishments to retain and, upon FDA's specific request, submit certain additional listing information.

**DATES:** Submit written or electronic comments on the collection of information by April 7, 2008.

**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 docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Denver Presley Jr., Office of the Chief Information Officer (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1472

**SUPPLEMENTARY INFORMATION:** Under the PRA (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (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 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 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.

#### Additional Listing Information for Medical Device Registration and Listing—21 CFR 80.31; (OMB Control Number 0910-0387)—Extension

The Food and Drug Administration Amendments Act of 2007 (the 2007 Amendments), enacted September 27, 2007, requires that device establishment registrations and listings under 21 U.S.C. 360(p) (including the submission of updated information), be submitted to the Secretary of Health and Human Services (the Secretary) by electronic means, unless the Secretary grants a request for waiver of the requirement because the use of electronic means is not reasonable for the person requesting the waiver. See section 224 of the 2007 Amendments. The 2007 Amendments provides for an October 1, 2007, effective date by which FDA expects approximately 30,000 establishments to begin registering. FDA is seeking OMB approval for the information collected by electronic means. Registration by electronic means for device establishments will mean replacement of FDA Forms 2891 and 2891a, "Registration of Device Establishment" and FDA Form 2892 "Medical Device Listing," with electronic versions. However, for OMB approval of the extension request for this collection of