## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2006–D–0302] (formerly Docket No. 2006D–0419)**

### Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Voluntary National Retail Food Regulatory Program Standards

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Voluntary National Retail Food Regulatory Program Standards'' 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 January 15, 2008 (73 FR 2500), 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 0910–0621. The approval expires on March 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: April 15, 2008.

**Jeffrey Shuren,**

*Associate Commissioner for Policy and Planning.*

[FR Doc. E8–8680 Filed 4–21–08; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2008–N–0050]**

### 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 May 22, 2008.

**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: 202–395–6974, or e-mailed to *baguilar@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:** 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:** 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—(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 (e)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360i(e)(1) and (e)(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.

In the **Federal Register** of February 5, 2008 (73 FR 6729), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

| CFR Sections | No. of Respondents | Annual Frequency per 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 |

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

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

| CFR Sections | No. of Recordkeepers | Annual Frequency per 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 |

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

The annual hourly reporting burden for respondents involved in 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 numbers have been rounded up. The burden estimates cited in tables 1 and 2 of this notice 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 FY 1997 through FY 2006. 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 FY 1997 through FY 2006.

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 FY 2002 through FY 2004. 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.

Dated: April 15, 2008.

**Jeffrey Shuren,**

*Associate Commissioner for Policy and Planning.*

[FR Doc. E8–8682 Filed 4–21–08; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### Joint Meeting of the Anesthetic and Life Support Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee; Amendment of Notice

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

**ACTION:** Notice.

The Food and Drug Administration (FDA) is announcing an amendment to the notice of meeting of the Anesthetic and Life Support Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee. This meeting was announced in the **Federal Register** of March 27, 2008 (73 FR 16314). The amendment is being made to reflect changes in the introductory paragraph and to add a portion entitled ''*Closed Committee Deliberations.*'' There are no other changes.

**FOR FURTHER INFORMATION CONTACT:** Teresa Watkins, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301–827–7001, FAX: 301–827–6776, e-mail: