

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.

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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.