Dated: March 23, 2011.

**Seth F. Chamberlain,**

*Reports Clearance Officer.*

[FR Doc. 2011–7340 Filed 3–29–11; 8:45 am]

**BILLING CODE 4184–37–M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2010–N–0492]**

### Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Medical Devices: Recommended Glossary and Educational Outreach To Support Use of Symbols on Labels and in Labeling of In Vitro Diagnostic Devices Intended for Professional Use

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Medical Devices: Recommended Glossary and Educational Outreach to Support Use of Symbols on Labels and in Labeling of In Vitro Diagnostic Devices Intended for Professional Use" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

**FOR FURTHER INFORMATION CONTACT:** Daniel Gittleson, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–5156, *Daniel.Gittleson@fda.hhs.gov*.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of January 7, 2011 (76 FR 1169), 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 0910–0553. The approval expires on March 31, 2014. A copy of the supporting statement for this information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain.*

Dated: March 24, 2011.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2011–7387 Filed 3–29–11; 8:45 am]

**BILLING CODE 4160–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2010–N–0606]**

### Agency Information Collection Activities; Submission for Office of Management and Budget Review; 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 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 April 29, 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 *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0387. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Daniel Gittleson, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–5156, *e-mail: Daniel.Gittleson@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.

### Additional Listing Information for Medical Device Registration and Listing—(OMB Control Number 0910–0387)—Extension

The Food and Drug Administration Amendments Act of 2007 (FDAAA), 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. The collections of information under sections 222, 223, and 224 of FDAAA have been approved under OMB control number 0910–0625. Registration by electronic means for device establishments replaced FDA Forms 2891 and 2891a, "Registration of Device Establishment," and FDA Form 2892, "Medical Device Listing," with FDA Form 3673, "Device Registration and Listing Module." The scope of this information collection addresses only the reporting and recordkeeping requirements by non-electronic means under § 807.31 (21 CFR 807.31).

Under § 807.31(a) through (d), each owner or operator is required to maintain an historical file containing the labeling and advertisements in use on the date of initial listing, and in use after October 10, 1978, but not before the date of initial listing. The owner or operator must maintain in the historical file any labeling or advertisements in which a material change has been made anytime after initial listing, but may discard labeling and advertisements from the file 3 years after the date of the last shipment of a discontinued device by an owner or operator. Section 807.31(e) requires that the owner or operator be prepared to submit to FDA copies of: (1) All device labeling, (2) all device labeling and representative advertising, or (3) only representative package inserts, depending upon whether the device is subject to the regulatory controls under sections 514 and 515 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360d and 360e), or restrictions imposed by 21 CFR 801.109 or otherwise by section 520(e) of the FD&C Act (21 U.S.C. 360j(e)).

The information collected under these provisions is used by FDA to identify: (1) Firms subject to FDA's regulations, (2) geographic distribution of firms in order to effectively allocate FDA's field resources for inspections, and (3) the class of the device that determines the frequency of inspection. As a result, when complications occur with a particular device or component, all manufacturers of similar or related devices can easily be identified.

The likely respondents to this information collection are domestic and foreign device establishments who must register and submit a device list to FDA, *e.g.,* establishments engaged in the manufacture, preparation, propagation, compounding, assembly, or processing of medical devices intended for human use and commercial distribution.

The annual respondent reporting burden for device establishment