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

registrations and listings for additional information is estimated to be 12,375 hours, and the annual respondent recordkeeping burden is estimated to be 45,000 hours. Therefore, the total burden hours for this collection are estimated to be 57,375. The estimates cited in tables 1 and 2 of this document are based primarily on fiscal year 2010 data from current systems and on conversations with industry and trade association representatives.

In the **Federal Register** of December 7, 2010 (75 FR 76008), 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 [1]

21 CFR section	No. of respondents	No. of responses per respondent	Total annual respondents	Average burden per response (in hours)	Total hours
807.31(d)(2)	2,250	1	2,250	0.5	1,125
807.31(e)	22,500	1	22,500	0.5	11,250
Total					12,375

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

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR section	No. of record-keepers	No. of records per record-keeper	Total annual records	Average burden per recordkeeping (in hours)	Total hours
807.31(a) to (c)	22,500	4	90,000	0.5	45,000
Total					45,000

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

Dated: March 24, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–7389 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–2011–N–0002]

Medical Device Epidemiology Network 2011: Second Annual Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA) is announcing a public workshop entitled "Medical Device Epidemiology Network (MDEpiNet) 2011: Second Annual Public Workshop." The purpose of the public workshop is to provide a public update on the development of MDEpiNet and to facilitate discussion among FDA and all stakeholders with expertise in epidemiology and health services research on issues related to the methodology for studying medical device performance.

DATE AND TIME: The public workshop will be held on April 25, 2011 from 8 a.m. to 5 p.m. Participants are encouraged to arrive early to ensure time for parking and security screening before the meeting. Registration will begin at 7 a.m.

LOCATION: The public workshop will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31, Rm. 1503 (the Great Room), Silver Spring, MD 20993.

CONTACTS: Mary Beth Ritchey, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Avenue, Silver Spring, MD 20993, 301–796–6638, *e-mail: MaryElizabeth.Ritchey@fda.hhs.gov;* or Ellen Pinnow, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301–796–6066, *e-mail: Ellen.Pinnow@fda.hhs.gov.*

Registration: Registration is available through April 15, 2011, at the following Web site: *http://fda-ws.s-3.net/EpiNetWSApr11/.* There is no fee to attend the workshop, but attendees must register in advance. Registration will be on a first-come, first-served basis and we ask that one person per institution be selected to represent the entity at the workshop. Non-U.S. citizens are subject to additional security screening, and they should register as soon as possible. If you need special accommodations because of a disability, please contact Mary Beth Ritchey (*see* **CONTACTS**) at least 7 days before the public workshop.

SUPPLEMENTARY INFORMATION:

I. Why are we holding this public workshop?

The purpose of the public workshop is to facilitate continuing discussion among FDA, the academic epidemiology and health services research community, and all stakeholders on issues related to the methodology of studies for medical device performance. We aim to describe and solicit feedback on the establishment of a network that works with FDA experts to determine the evidence gaps and questions, datasets and approaches for conducting robust analytic studies and improve our understanding of the performance of medical devices (including comparative effectiveness studies). We also aim to reach out to stakeholders to initiate development of scientific, methodology, and device-area priorities for MDEpiNet.

II. Who is the target audience for this public workshop? Who should attend this public workshop?

This workshop is open to all interested parties. The target audience is comprised of academic researchers with experience in epidemiology or health services research with an interest in medical device outcome and epidemiologic study methodology.