

ANNUAL BURDEN ESTIMATES

Instrument	Annual number of respondents	Number of responses	Average burden per hours response	Total annual burden hours
First Follow-up Instrument .....	3,060	1	0.5	1,530.
<i>Estimated Total Annual Burden Hours:</i> .....				1,530.

*Additional Information:*

Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: OPRE Reports Clearance Officer. All requests should be identified by the title of the information collection. *E-mail address:* [OPREinfocollection@acf.hhs.gov](mailto:OPREinfocollection@acf.hhs.gov).

*OMB Comment:*

OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following:

Office of Management and Budget, Paperwork Reduction Project, Fax: 202-395-6974, Attn: Desk Officer for the Administration for Children and Families.

Dated: March 24, 2011.

**Seth F. Chamberlain,**

*OPRE Reports Clearance Officer.*

[FR Doc. 2011-7337 Filed 3-29-11; 8:45 am]

**BILLING CODE 4184-07-M**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Administration for Children and Families**

**Proposed Information Collection Activity: Comment Request**

*Title:* Personal Responsibility Education Program (PREP) Multi Component Evaluation—Design Survey.

*OMB No.:* New Collection.

*Description:* The Family and Youth Services Bureau (HHS/ACF/ACYF/FYSB) and the Office of Planning, Research, and Evaluation (HHS/ACF/OPRE) in the Administration for Children and Families (ACF) propose a data collection activity as part of the Personal Responsibility Education Program (PREP) Multi Component Evaluation.

In addition to other activities, the PREP Evaluation will document the

design of the PREP State grant programs via data gathered from States and selected sub-awardees funded by PREP. The findings will be of interest to the general public, federal and state policy-makers, PREP sub-awardees, community-based organizations, and other organizations interested in teen pregnancy prevention.

The proposed activity involves the collection of information through telephone conversations or in-person interviews held with administrators and program staff at the State and sub awardee level. The data collection instrument will focus on information related to program context, administration, and design. This includes, but is not limited to: Program goals and strategy/approach, program setting, population characteristics, state-level requirements and processes, program monitoring, and training and technical assistance.

*Respondents:* State Level Coordinators; Program Directors; Program Staff; General Staff; Schools and Organizations; and Community-Based Organizations.

ANNUAL BURDEN ESTIMATES DESIGN SURVEY

Instrument	Annual number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Discussion Guide for use with State Level Coordinators and State-Level Staff .....	120	1	1	120
Discussion Guide for use with Program Staff; Schools and Organizations; and Community-Based Organizations .....	120	1	1	120

Estimated Annual Burden Sub-total for Field Clearance: 240.

In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant

Promenade, SW., Washington, DC 20447, Attn: OPRE Reports Clearance Officer. *E-mail address:* [OPREinfocollection@acf.hhs.gov](mailto:OPREinfocollection@acf.hhs.gov). All requests should be identified by the title of the information collection.

The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c)

the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

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 Gittleston, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-5156, [Daniel.Gittleston@fda.hhs.gov](mailto:Daniel.Gittleston@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 [oir\\_submission@omb.eop.gov](mailto:oir_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 Gittleston, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-5156, *e-mail:* [Daniel.Gittleston@fda.hhs.gov](mailto:Daniel.Gittleston@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