

beneficiaries on a mandatory basis into managed care entities without section 1115 or 1915(b) waiver authority; *Frequency*: On occasion; *Affected Public*: State, local, or tribal government; *Number of Respondents*: 56; *Total Annual Responses*: 10; *Total Annual Hours*: 100.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS' Web Site address at <http://www.cms.hhs.gov/PaperworkReductionActof1995>, or e-mail your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov, or call the Reports Clearance Office on (410) 786-1326.

To be assured consideration, comments and recommendations for the proposed information collections must be received at the address below, no later than 5 p.m. on October 30, 2007.

CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development—A, Attention: Melissa Musotto, Room C4-26-05, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Dated: August 24, 2007.

Michelle Shortt,

Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. E7-17351 Filed 8-30-07; 8:45 am]

BILLING CODE 4120-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Notice of Award of Non-Competitive Grant

AGENCY: Administration on Children, Youth, and Families (ACYF), ACF, DHHS.

ACTION: Notice.

CFDA No.: 93.010, Community-Based Abstinence Education.

Legislative Authority: Title XI, Section 1110 of the Social Security Act.

Amount of Award: \$2,500,000.

Project Period: September 30, 2007–March 30, 2009 (18 months).

Justification for the Exception to Competition: ACYF will award service grant funds without competition to the Prevention Research Center at the University of Texas Health Science Center at Houston to build on a longitudinal study they are currently

conducting of adolescent pregnancy approaches. They are the only research group currently conducting a study of size and scope that provides for access to schools and study participants for the collection of additional data needed. Building on the existing study already underway saves the cost of initiating a study from the ground up.

FOR FURTHER INFORMATION CONTACT: Stan Koutstaal, Ph.D., Director, Division of Abstinence Education, Family and Youth Services Bureau, ACYF, ACF, DHHS. Portals Building, Suite 800, 1250 Maryland Avenue, SW., Washington, DC 20024; 202-401-6959.

Dated: August 24, 2007.

Joan E. Ohl,

Commissioner, Administration on Children, Youth and Families.

[FR Doc. E7-17216 Filed 8-30-07; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007N-0325]

Agency Information Collection Activities; Proposed Collection; Comment Request; 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 an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing information collection, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the reporting requirements for the collection "Recommended Glossary and Educational Outreach to Support Use of Symbols on Labels and in Labeling of In Vitro Diagnostic Devices Intended for Professional Use."

DATES: Submit written or electronic comments on the collection of information by October 30, 2007.

ADDRESSES: Submit electronic comments on the collection of information to: <http://www.fda.gov/dockets/ecomments> or <http://www.regulations.gov>. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Jr., Office of Chief Information Officer (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1472.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

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—Section 502 of the Federal Food, Drug and Cosmetic Act/Section 351 of the Public Health Service Act (OMB Control Number 0910–0553)—Extension

Section 502 of the Federal Food, Drug and Cosmetic Act (FFD&C Act) (21 U.S.C. 352), among other things, establishes requirements for the label or labeling of a medical device so that it is not misbranded. Section 351 of the Public Health Service Act (the PHS Act) (42 U.S.C. 262), establishes requirements that manufacturers of biological products must submit a license application for FDA review and approval prior to marketing a biological product for introduction into interstate commerce.

In the **Federal Register** of November 30, 2004 (69 FR 69606), FDA published a notice of availability of the guidance

entitled “Use of Symbols on Labels and in Labeling of In Vitro Diagnostic Devices Intended for Professional Use.” The guidance document provides guidance for the voluntary use of selected symbols in place of text in labeling. It provides the labeling guidance required for: (1) In vitro diagnostic devices (IVDs), intended for professional use under 21 CFR 809.10, FDA’s labeling requirements for IVDs and (2) FDA’s labeling requirements for biologics, including IVDs under 21 CFR parts 610 and 660. Under section 502(c) of the FFD&C Act, a drug or device is misbranded, “If any word, statement, or other information required by or under authority of this Act to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions

of purchase and use.” The guidance document recommends that a glossary of terms accompany each IVD to define the symbols used on that device’s labels and/or labeling. Furthermore, the guidance recommends an educational outreach effort to enhance the understanding of newly introduced symbols. Both the glossary and educational outreach information will help to ensure that IVD users will have enough general familiarity with the symbols used, as well as provide a quick reference for available materials, thereby further ensuring that such labeling satisfies the labeling requirements under section 502(c) of the act and section 351 of the PHS Act.

The likely respondents for this collection of information are IVD manufacturers who plan to use the selected symbols in place of text on the labels and/or labeling of their IVDs.

FDA estimates the burden for this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

Section 502 of the FFD&C Act/Section 351 of the PHS Act	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Glossary	1,742	1	1,742	4	6,968 ²
Educational Outreach	1,742	1	1,742	6	27,872
Total					34,840

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

² One time burden.

The glossary and educational outreach activities are inclusive of both domestic and foreign IVD manufacturers. The Center for Devices and Radiological Health’s “Information Retrieval System’s Registration and Listing Information” database listed the total number of IVD manufacturers as 1,742. From this total, 1,206 of the IVD manufacturers were listed as domestic and 536 were listed as foreign manufacturers. Consequently, FDA has based its burden estimate on the maximum possible number of manufacturers choosing to implement the use of symbols in labeling. The number of hours per response for the glossary and educational outreach activities were derived from consultation with a trade association and FDA personnel. The 4-hour estimate for a glossary is based on the average time necessary for a manufacturer to modify the glossary for the specific symbols used in labels or labeling for the IVDs manufactured. The 16-hour estimate for educational outreach is inclusive of activities

manufacturers used to educate the various professional users of IVDs regarding the meaning of the IVD symbols. Further, this estimate is based on FDA’s expectation that IVD manufacturers will jointly sponsor many more educational outreach activities.

Dated: August 23, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–17217 Filed 8–30–07; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007N–0330]

Presidential Interagency Working Group on Import Safety; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Interagency Working Group on Import Safety (Working Group) is announcing a public meeting to identify actions the public and private sectors can take to promote the safety of products imported into the United States. The Working Group was created by the Executive order on July 18, 2007.

DATES: The public meeting will be held on October 1, 2007, from 8 a.m. to 6 p.m. Persons interested in attending the meeting in person or by teleconference must register by September 17, 2007. See section III.B of the **SUPPLEMENTARY INFORMATION** section of this document for details on how to register. Submit written or electronic comments by October 1, 2007.

ADDRESSES: The public meeting will be held in the Jefferson Auditorium, U.S. Department of Agriculture, 1400 Independence Ave., SW., South Bldg., Washington, DC 20090. The public may