

ATSDR, regarding program goals, objectives, strategies, and priorities in fulfillment of the agencies' mission to protect and promote people's health. The Board provides advice and guidance to help NCEH/ATSDR work more efficiently and effectively with its various constituents and to fulfill its mission in protecting America's health.

Nominations are being sought for individuals who have expertise and qualifications necessary to contribute to the accomplishments of the Board's objectives. Nominees will be selected from experts having experience in preventing human diseases and disabilities caused by environmental conditions. Experts in the disciplines of toxicology, epidemiology, environmental or occupational medicine, behavioral science, risk assessment, exposure assessment, and experts in public health and other related disciplines will be considered. Balanced membership will depend upon several factors, including: (1) The committee's mission; (2) the geographic, ethnic, social, economic, or scientific impact of the advisory committee's recommendations; (3) the types of specific perspectives required, for example, those of consumers, technical experts, the public at-large, academia, business, or other sectors; (4) the need to obtain divergent points of view on the issues before the advisory committee; and (5) the relevance of State, local, or tribal governments to the development of the advisory committee's recommendations. Members may be invited to serve up to four-year terms. Nominees must be U.S. citizens.

The following information must be submitted for each candidate: Name, affiliation, address, telephone number, and current curriculum vitae. E-mail addresses are requested if available. Nominations should be sent, in writing, and postmarked by October 31, 2011 to: Sandra Malcom, Committee Management Specialist, NCEH/ATSDR, CDC, 4770 Buford Highway (MS-F61), Chamblee, Georgia 30341. (E-mail address: [sym6@CDC.GOV](mailto:sym6@CDC.GOV)). Telephone and facsimile submissions cannot be accepted.

Candidates invited to serve will be asked to submit the "Confidential Financial Disclosure Form for Special Government Employees Serving on Federal Advisory Committees at the Centers for Disease Control and Prevention." This form allows CDC to determine whether there is a statutory conflict between that person's public responsibilities as a Special Government Employee and private interests and activities, or the appearance of a lack of impartiality, as defined by Federal

regulation. The form may be viewed and downloaded at [http://www.usoge.gov/forms/oge450\\_pdf/oge450\\_accessible.pdf](http://www.usoge.gov/forms/oge450_pdf/oge450_accessible.pdf). This form should not be submitted as part of a nomination.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention, and the Agency for Toxic Substances and Disease Registry.

Dated: June 30, 2011.

**Elizabeth A. Millington,**

*Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.*

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**BILLING CODE 4163-18-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Administration for Children and Families

#### Announcement of a Grant Award

**AGENCY:** Office of Community Services, ACF, HHS.

**ACTION:** Announcement of the Award of an Assets for Independence Grant to the United Way of Abilene, Inc., Abilene, TX.

*CFDA Number:* 93.602.

**Statutory Authority:** Authorized under the Assets for Independence Act in Title IV of the Community Opportunities, Accountability, and Training and Educational Services Human Services Reauthorization Act of 1998, Public Law 105-285, as amended.

**SUMMARY:** The Administration for Children and Families (ACF), Office of Community Services (OCS), Division of Community Demonstration Programs announces the award of an Assets for Independence (AFI) demonstration grant to the United Way of Abilene, Inc. of Abilene, TX in the amount of \$61,149.

The purpose of this award is to enable the United Way of Abilene, Inc. to implement an Assets for Independence (AFI) project helping program participants save earned income in special-purpose, matched savings accounts called Individual Development Accounts (IDAs). Every dollar in savings deposited into an IDA by participants is matched, from \$1 to \$8 combined Federal and non-Federal funds, promoting savings and enabling participants to acquire a lasting economic asset. AFI project families use

their IDA savings, including the matching funds, to achieve any of three objectives: acquiring a first home; capitalizing a small business; or enrolling in postsecondary education or training.

Additionally, the United Way of Abilene, Inc. provides basic financial management training and supportive services, such as financial education on owning and managing a bank account; credit counseling and repair; guidance in accessing refundable tax credits, including the Earned Income Tax Credit and the Child Tax Credit; and specialized training in owning particular economic assets for the long term.

**DATES:** The project period for this award is November 1, 2010 through September 29, 2011.

#### FOR FURTHER INFORMATION CONTACT:

James Gatz, Program Manager, Assets for Independence, Office of Community Services, Administration for Children and Families, U.S. Department of Health and Human Services, 901 D Street, SW., 5th floor East, Washington, DC 20047. Telephone: 202-401-5284; E-mail: [james.gatz@acf.hhs.gov](mailto:james.gatz@acf.hhs.gov).

Dated: June 23, 2011.

**Lynda E. Perez,**

*Acting Director, Division of Community Demonstration Programs, Office of Community Services.*

[FR Doc. 2011-16973 Filed 7-6-11; 8:45 am]

**BILLING CODE 4184-26-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2010-D-0226]

#### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Draft Guidance for Industry, Third Parties and Food and Drug Administration Staff; Medical Device ISO 13485:2003 Voluntary Audit Report Submission Program

**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 (PRA).

**DATES:** Fax written comments on the collection of information by August 8, 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-NEW and title “Draft Guidance for Industry, Third Parties and Food and Drug Administration Staff; Medical Device ISO 13485:2003 Voluntary Audit Report Submission Program”. 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, *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.

**Draft Guidance for Industry, Third Parties and Food and Drug Administration Staff; Medical Device ISO 13485:2003 Voluntary Audit Report Submission Program—(OMB Control Number 0910)-NEW**

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 before submitting the collection to OMB for approval. To comply with this requirement, in the **Federal Register** of May 20, 2010 (75 FR 28257), FDA published a notice of availability of the draft guidance document providing a 60-day public comment period on the proposed collection of information provisions.

*Title:* Draft Guidance for Industry, Third Parties and FDA Staff: Medical Device ISO 13485:2003 Voluntary Audit Report Submission Program.

*Description:* Section 228 of the Food and Drug Administration Amendments Act of 2007 (FDAAA), amended section 704(g)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 374(g)(7)) to add the following provision: “(F) For the purpose of setting risk-based inspectional priorities, the Secretary shall accept voluntary submissions of reports of audits assessing conformance with appropriate quality system standards set by the International Organization for Standardization (ISO) and identified by the Secretary in public notice. If the owner or operator of an establishment elects to submit audit reports under this subparagraph, the owner or operator shall submit all such audit reports with respect to the establishment during the preceding 2-year periods.”

The “Draft Guidance for Industry, Third Parties and FDA Staff: Medical Device ISO 13485:2003 Voluntary Audit Report Submission Program” will describe how FDA’s Center for Devices and Radiological Health and Center for Biologics Evaluation and Research are implementing this provision of the law and providing public notice as required. The proposed collections of information are necessary to satisfy the previously mentioned statutory requirements for implementing this voluntary submission program.

Based on FDA’s experience with the founding regulatory members of the Global Harmonization Task Force (GHTF), FDA expects that the vast majority of manufacturers who will participate in the Voluntary Audit Report Submission Program will be manufacturers who are certified by Health Canada under ISO 13485:2003. In 2008, approximately 2,650 manufacturers or manufacturing sites had been certified by Health Canada. The majority of these manufacturers are also certified under ISO 13485:2003 by the European Union Notified Body accreditation system.

In addition, FDA only expects firms that do not have major deficiencies or observations in their ISO 13485:2003 audits to be willing to submit their audit reports to FDA under the Voluntary Audit Report Submission Program. FDA analyzed its inspection data from Fiscal Year (FY) 2008 (October 1, 2007 to October 1, 2008) and determined that the total number of inspections finalized in FY2008 for medical devices was 1,965. The breakdown for the 1,965 compliance decisions is as follows:

TABLE 1—COMPLIANCE DECISION BREAKDOWN

Compliance decision	Number	Approximate percentage (%)
Official Action Indicated .....	148	8
Voluntary Action Indicated .....	775	40
No Action Indicated .....	1,025	52
Pending Final Decision .....	17	1

<sup>1</sup> June 15, 2006, Compliance Program 7382.845 Inspection of Medical Device Manufacturers Part V <http://www.fda.gov/cdrh/comp/guidance/7382.845.html#p5p5.pdf>.

Because FDA only expects firms who do not have major deficiencies or observations to be willing to submit their audit reports to FDA under the Voluntary Audit Report Submission Program, FDA only expects to receive audit reports that would have been classified by FDA as No Action Indicated (NAI).

Assuming that the percentage breakdown of compliance decisions for all inspections conducted in FY2008 can be extrapolated and applied to audits of manufacturers certified under ISO 13485:2003 by Health Canada, FDA can estimate the number of Canadian establishments that would have had an inspection classified as an NAI. Because 52 percent of all compliance decisions

resulted in an NAI decision, FDA estimates that 1,378 of the facilities certified under ISO 13485:2003 by Health Canada (52 percent of the total 2,650 facilities) would have had an inspection classified as an NAI. Because FDA only expects to receive audit reports that would have been classified by FDA as NAI, FDA expects 1,378, or

approximately 1,400, audit reports to be submitted.

Because FDA expects that the vast majority of manufacturers who will participate in the Voluntary Audit Report Submission Program will be manufacturers certified by Health Canada under ISO 13485:2003, FDA expects the number of reports to be submitted from manufacturers certified by regulatory systems established by other founding GHTF members to be minimal. For purposes of calculating the reporting burden, FDA estimates that approximately 10 percent of total audit reports submitted under this program will be from these other manufacturers. Because 90 percent of the audit reports are expected to be submitted by manufacturers certified by Health Canada (approximately 1,400 audit reports as calculated previously in this document), the total number of audit reports FDA expects to receive in a year is 1,556, or approximately 1,600 audit reports.

FDA estimates from past experience with the Electronic Submission Gateway system, WebTrader, that the first year to set up the account and to receive the verification certificate takes approximately 40 hours. This burden may be minimized if the Respondent

already has an established account in WebTrader for other electronic submissions to FDA but FDA is assuming that all respondents to this new pilot program will be setting up a WebTrader account for the first time in the first year. For subsequent years, the estimate burden hours are estimated at 1 hour to renew the yearly required verification certification.

FDA further estimates that the gathering, scanning, and submission of the audit reports, certificates, and related correspondence would take approximately 2 hours utilizing the eSubmitter system.

Therefore, the first year will include 40 hours for the WebTrader system plus 2 hours for the eSubmitter submission process, resulting in 42 hours per response for the first year. For both the second and third years, it is estimated that only 1 hour will be necessary for the WebTrader system plus the 2 hours for the eSubmitter submission process, resulting in 3 hours per response each year thereafter.

The draft guidance also refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by OMB under the PRA. The collections of information in

21 CFR part 820 have been approved under OMB control number 0910-0073 and the collections of information for the Inspection by Accredited Persons Program have been approved under OMB control number 0910-0569.

In the **Federal Register** of May 20, 2010 (75 FR 28257), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received one comment which was related to the PRA reporting burden.

The comment stated that the reporting burden hours may be too low for the first submission and may take less time for subsequent submissions. In addition, this comment stated that the number of reports anticipated to be submitted may be a high estimate by a factor of 10. FDA appreciates the consideration of burden hours by the comment. The comment, however, did not provide any data to assist FDA to adjust the burden hours for the submission. Absent baseline information at this time, FDA will review the submissions during the pilot period and modify the burden to respondents accordingly.

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

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN

	No. of respondents	No. of responses per respondent per year	Total annual responses	Average burden per response (in hours)	Total hours	Capital and operating and maintenance costs
First year .....	1,600	1	1,600	142	67,200	2,016,000
Second year (recurring) .....	1,600	1	1,600	3	4,800	48,000
Third year (recurring) .....	1,600	1	1,600	3	4,800	48,000
Totals .....					76,800	2,112,000

<sup>1</sup>Respondent may already have a valid WebTrader account established for other FDA electronic submissions.

There are capital, start-up, operating, or maintenance cost associated with this information collection. The costs are \$30 per year to establish and maintain the Electronic Submission Gateway verification certificate.

Dated: July 1, 2011.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2011-N-0478]

**General and Plastic Surgery Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting**

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

**ACTION:** Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

*Name of Committee:* General and Plastic Surgery Devices Panel of the Medical Devices Advisory Committee.

*General Function of the Committee:* To provide advice and recommendations to the Agency on FDA's regulatory issues.

*Date and Time:* The meeting will be held on August 30 and 31, 2011, from 8 a.m. to 6 p.m.

*Addresses:* FDA is opening a docket for public comment on this document. The docket will open for public comment on July 7, 2011. The docket will close on August 26, 2011. Interested persons may submit electronic or written comments regarding this document. Submit electronic comments to <http://www.regulations.gov>. Submit written comments to the Division of Dockets