ANNUAL BURDEN ESTIMATES—Continued

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
P&A: Board of Directors (Commissioners)—Chair and Members	60	1	0.75	45
P&A: Group Interview with Policymakers and Collaborators	160	1	2	320
P&A: Interview with Recipient of Community Education	100	1	0.75	75
P&A: Interview with Clients	100	1	0.75	75
P&A: Self-administered Form	20	1	8	160
UCEDD: Interview with Director	20	1	4	80
UCEDD: Telephone Interview with Current and Graduated Students	100	1	0.75	75
UCEDD: Interview with the Consumer Advisory Committee	60	1	0.75	45
UCEDD: Interview with Peer Researchers and Colleagues	100	1	0.75	75
UCEDD: Interview with Recipients of Community Services or Members of Organizations/Agencies that are Trained to Provide Community Services	100	1	0.75	75
UCEDD: Self-administered Form	20	1	8	160

Estimated Total Annual Burden Hours: 2,065.

In compliance with the requirements of Section 506(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 Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. E-mail address: *infocollection@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 4, 2009.

Janean Chambers,

Reports Clearance Officer.

[FR Doc. E9–4857 Filed 3–6–09; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

[CFDA#: 93.604]

Office of Refugee Resettlement

AGENCY: Office of Refugee Resettlement, ACF, DHHS.

ACTION: Notice of a Noncompetitive Successor Award to Utah Health and Human Rights Service for Grant Number 90ZT0059.

Legislative Authority: ''Torture Victims Relief Act (TVRA) of 1998,'' Public Law 105–320 (22 U.S.C. 2152 note), reauthorized by Public Law 109–165 in January 2006. Section 5(a) of the law provides: Assistance for Treatment of Torture Victims—The Secretary of Health and Human Services may provide grants to programs in the United States to cover the cost of the following services: (1) Services for the rehabilitation of victims of torture, including treatment of the physical and psychological effects of torture. (2) Social and legal services for victims of torture. (3) Research and training for health care providers outside of treatment centers, or programs for the purpose of enabling such providers to provide the services described in paragraph (1).

Amount of Award: Remainder of current budget period February 1, 2009 through September 29, 2009. Award $152,405. Final budget period of the originally approved three-year project period September 30, 2008 through September 29, 2009.

Project Period: February 1, 2009–September 29, 2009.

Summary: In FY 2006, ORR awarded a competitive Services for Survivors of Torture grant to the Tides Center/Utah Health and Human Rights Project in Salt Lake City, Utah. The original project period was from September 30, 2006 through September 29, 2009. The Tides Center served as fiscal sponsor and legal entity of the approved project. The Tides Center provides essential financial, human resources, and administrative services to philanthropic projects such as the Utah Health and Human Rights Project (UHHRP) while enabling them to become independent agencies. UHHRP has now completed the process of becoming an independent agency and is formally separating from the Tides Center on January 31, 2009. The Tides Center has requested permission for UHHRP to assume the grant. UHHRP has agreed to this request and will continue to function with the scope and operations of the grant remaining unchanged.

Contact for Further Information: Ronald Munia, Director, Division of Community Resettlement, Office of Refugee Resettlement, 370 L'Enfant Promenade, SW., Washington, DC 20447. Telephone: 202–401–4559. E-mail: *Ronald.Munia@acf.hhs.gov*.

Dated: March 3, 2009.

Ronald Munia,

Director, Division of Community Resettlement, Office of Refugee Resettlement.

[FR Doc. E9–4922 Filed 3–6–09; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0607]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Reclassification Petitions for Medical Devices

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 8, 2009.

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: 202–395–6974, or e-mailed to *oira_submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910–0138. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Jr., Office of Information Management (HFA–710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–796–3793.

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.

Reclassification Petitions for Medical Devices—21 CFR Section 860.123 (OMB Control Number 0910–0138)—Extension

FDA has responsibility under sections 513(e) and (f), 514(b), 515(b), and 520(l) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c(e), and (f), 360d(b), 360e(b), and 360j(l)) and part 860 (21 CFR part 860), subpart C, to collect data and information contained in reclassification petitions. The reclassification provisions of the act allow any person to petition for reclassification of a device from any one of the three classes i.e, I, II, and III, to another class. The reclassification procedure regulation requires the submission of specific data when a manufacturer is petitioning for reclassification. This includes a ''Supplemental Data Sheet,'' Form FDA 3427, and a ''Classification Questionnaire,'' Form FDA 3429. Both forms are a series of questions concerning the safety and effectiveness of the device type. Further, the reclassification content regulation (§ 860.123) requires the submission of sufficient, valid scientific evidence demonstrating that the proposed reclassification will provide a reasonable assurance of safety and effectiveness of the device type for its indications for use. Thus, the reclassification provisions of the act serve primarily as a vehicle for manufacturers to seek reclassification from a higher to a lower class, thereby reducing the regulatory requirements applicable to a particular device type, or to seek reclassification from a lower to a higher class, thereby increasing the regulatory requirements. The reclassification petitions requesting classification from class III to class II or class I, if approved, provides an alternative route to the market in lieu of premarket approval for class III devices or from class I or II, to one or the other class, which may increase requirements.

In the **Federal Register** of December 4, 2008 (73 FR 73938), FDA published a 60-day notice requesting public comment on the information collection provisions. 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	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
860.123	6	1	6	500	3,000

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

Based on the last 3 years, and actual reclassification petitions received, FDA anticipates that six petitions will be submitted each year. The time required to prepare and submit a reclassification petition, including the time needed to assemble supporting data, averages 500 hours per petition. This average is based upon estimates by FDA administrative and technical staff that: (1) Are familiar with the requirements for submission of a reclassification petition, (2) have consulted and advised manufacturers on these requirements, and (3) have reviewed the documentation submitted.

Dated: March 2, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–4829 Filed 3–6–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0098]

Agency Information Collection Activities; Proposed Collection; Comment Request; Evaluation of Potential Data Sources for the Sentinel Initiative

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 and to allow 60 days for public comment in response to the notice. This notice solicits comments on the proposed information collection through a survey designed to identify potential data sources and/or data environments that could participate in the Sentinel Initiative to create a national, electronic distributed system, strengthening FDA's ability to monitor the postmarket performance of a medical product.

DATES: Submit written or electronic comments on the collection of information by May 8, 2009.

ADDRESSES: Submit electronic comments on the collection of information to *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: Jonna Capezzuto, Office of Information