will be current program participants. Interviews will be conducted in lieu of focus groups with program participants at secondary implementation sites (additional locations where the Tribal HPOG program are being implemented) in Year 2.

Respondents to the Employers interview will be local or regional employers at public or private companies or organizations that are partnering with the Tribal HPOG program or have employed program participants.

Respondents to the Program Completers interview will be program completers.

Respondents to the Program Non-completers interview will be individuals who did not complete the programs.

ANNUAL BURDEN ESTIMATES

Instrument	Annual number of respondents	Number of responses per respondent	Average burden hours per response	Total annual burden hours
Grantee and partner administrative staff interview	35	1	1	35
Program implementation staff interview	120	1	1.5	180
Program participant focus groups	108	1	1.5	162
Employer interview	60	1	.75	45
Program completers interview	67	1	1	67
Program non-completers interview	20	1	.30	6
Total Estimated Annual Burden				495

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.* 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: April 11, 2011.

Seth F. Chamberlain,

Reports Clearance Officer.

[FR Doc. 2011–9222 Filed 4–15–11; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

State Median Income Estimate for a Four-Person Family: Notice of the Federal Fiscal Year (FFY) 2012 State Median Income Estimates for Use Under the Low Income Home Energy Assistance Program (LIHEAP)

AGENCY: Administration for Children and Families, Office of Community Services, Division of Energy Assistance, HHS.

ACTION: Notice of State median income estimates for FFY 2012.

SUMMARY: This notice announces to LIHEAP grantees the estimated median income of four-person families in each State and the District of Columbia for FFY 2012 (October 1, 2011, to September 30, 2012). LIHEAP grantees that choose to base their income eligibility criteria on these State median income (SMI) estimates may adopt these estimates (up to 60 percent) on the estimates' date of publication in the **Federal Register** or on a later date as discussed below. This enables these grantees to implement this notice during the period between the heating and cooling seasons. However, by October 1, 2011, or the beginning of the grantees' fiscal years, whichever is later, these grantees must adjust their income eligibility criteria so that such criteria are in accord with the FFY 2012 SMI.

This listing of 60 percent of SMI provides one of the maximum income criteria that LIHEAP grantees may use in determining a household's income eligibility for LIHEAP.

LIHEAP appropriations for FFY 2009 through FFY 2010 raised this criterion from 60 percent of SMI to 75 percent of SMI for those years. The Continuing Resolutions covering FFY 2011 through the date of this publication have maintained this criterion at 75 percent of SMI. This criterion will remain at 75 percent SMI for FFY 2011 unless Congress acts otherwise after the date of this publication. This criterion will return to 60 percent of SMI for FFY 2012 unless Congress acts otherwise in providing FFY 2012 appropriations after the publication of this notice. This is because no change to the LIHEAP authorizing statute has been made.

DATES: *Effective Date:* For each LIHEAP grantee, these estimates become effective at any time between their date of publication in the **Federal Register** and the later of October 1, 2011, or the beginning of that grantee's fiscal year.

FOR FURTHER INFORMATION CONTACT: Peter Edelman, Office of Community Services, Division of Energy Assistance, 5th Floor West, 370 L'Enfant Promenade, SW., Washington, DC 20447, *Telephone:* (202) 401–5292, *E-Mail: peter.edelman@acf.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the provisions of section 2603(11) of Title XXVI of the Omnibus Budget Reconciliation Act of 1981, Public Law (Pub. L.) 97–35, as amended, HHS announces the estimated median income of four-person families for each State, the District of Columbia, and the United States for FFY 2012 (October 1, 2011, through September 30, 2012).

Section 2605(b)(2)(B)(ii) of this Act provides that 60 percent of the median income of four-person families for each State and the District of Columbia (State median income, or SMI), as annually established by the Secretary of Health and Human Services, is one of the income criteria that LIHEAP grantees may use in determining a household's eligibility for LIHEAP.

LIHEAP was last authorized by the Energy Policy Act of 2005, Public Law 109–58, which was enacted on August 8, 2005. This authorization expired on September 30, 2007, and reauthorization remains pending.

The SMI estimates that HHS publishes in this notice are three-year estimates derived from the American Community Survey (ACS) conducted by the U.S. Census Bureau, U.S. Department of Commerce (Census Bureau). HHS obtained these estimates directly from the Census Bureau. For additional information about the ACS State median income estimates, see *http://www.census.gov/hhes/www/income/data/statemedian/index.html.* For additional information about the ACS in general, *see http://www.census.gov/acs/www/* or contact the Census Bureau's Housing and Household Economic Statistics Division at (301) 763–3243.

Under the advice of the Census Bureau, HHS switched to three-year estimates rather than single-year estimates to reduce the large year-to-year fluctuations that the single-year estimates tend to generate for certain States and the District of Columbia. HHS plans to use the Census Bureau's ACS-derived SMI three-year estimates for all fiscal years after 2010. For further information about ACS one-year and three-year estimates, *see http://factfinder.census.gov/jsp/saff/SAFFInfo.jsp?_content=acs_guidance.html.*

The SMI estimates, like those derived from any survey, are subject to two types of errors: (1) Nonsampling Error, which consists of random errors that increase the variability of the data and non-random errors that consistently direct the data into a specific direction; and (2) Sampling Error, which consists of the error that arises from the use of probability sampling to create the sample. For additional information about the accuracy of the ACS SMI estimates, *see http://www.census.gov/acs/www/Downloads/data_documentation/Accuracy/MultiyearACSAccuracyofData2009.pdf.*

A State-by-State listing of SMI and 60 percent of SMI for a four-person family for FFY 2012 follows. The listing describes the method for adjusting SMI for families of different sizes as specified in regulations applicable to LIHEAP, at 45 CFR 96.85(b), which were published in the **Federal Register** on March 3, 1988, at 53 FR 6824 and amended on October 15, 1999, at 64 FR 55858.

Dated: March 22, 2011.

Yolanda J. Butler,

Acting Director, Office of Community Services.

ESTIMATED STATE MEDIAN INCOME FOR A FOUR-PERSON FAMILY, BY STATE, FOR FEDERAL FISCAL YEAR (FFY) 2012, FOR USE IN THE LOW INCOME HOME ENERGY ASSISTANCE PROGRAM (LIHEAP)

States	Estimated State median income for four-person families[1]	60 percent of estimated State median income for four-person families[2 3]
Alabama	$63,888	$38,333
Alaska	86,515	51,909
Arizona	69,119	41,471
Arkansas	56,219	33,731
California	78,666	47,200
Colorado	80,717	48,430
Connecticut	102,127	61,276
Delaware	83,602	50,161
District of Columbia	69,558	41,735
Florida	67,705	40,623
Georgia	68,908	41,345
Hawaii	87,463	52,478
Idaho	62,079	37,247
Illinois	80,607	48,364
Indiana	69,434	41,660
Iowa	73,413	44,048
Kansas	71,842	43,105
Kentucky	63,825	38,295
Louisiana	66,109	39,665
Maine	68,237	40,942
Maryland	101,997	61,198
Massachusetts	100,058	60,035
Michigan	73,433	44,060
Minnesota	86,099	51,659
Mississippi	55,809	33,485
Missouri	70,232	42,139
Montana	66,079	39,647
Nebraska	70,665	42,399
Nevada	71,230	42,738
New Hampshire	91,832	55,099
New Jersey	101,841	61,105
New Mexico	54,500	32,700
New York	82,531	49,519
North Carolina	67,966	40,780
North Dakota	74,177	44,506
Ohio	72,817	43,690
Oklahoma	61,881	37,129
Oregon	72,093	43,256

ESTIMATED STATE MEDIAN INCOME FOR A FOUR-PERSON FAMILY, BY STATE, FOR FEDERAL FISCAL YEAR (FFY) 2012, FOR USE IN THE LOW INCOME HOME ENERGY ASSISTANCE PROGRAM (LIHEAP)—Continued

States	Estimated State median income for four-person families[1]	60 percent of estimated State median income for four-person families[2 3]
Pennsylvania	78,287	46,972
Rhode Island	87,669	52,601
South Carolina	64,228	38,537
South Dakota	68,064	40,838
Tennessee	63,480	38,088
Texas	65,508	39,305
Utah	70,322	42,193
Vermont	74,877	44,926
Virginia	85,546	51,328
Washington	81,788	49,073
West Virginia	58,739	35,243
Wisconsin	77,946	46,768
Wyoming	75,998	45,599

Note: FFY 2012 covers the period of October 1, 2011, through September 30, 2012. The estimated median income for four-person families living in the United States for this period is $74,985. These estimates become effective for LIHEAP at any time between the date of this publication and October 1, 2011, or the beginning of a LIHEAP grantee's fiscal year, whichever is later.

[1] Prepared by the U.S. Census Bureau, U.S. Department of Commerce (Census Bureau), from three-year estimates from the 2007, 2008 and 2009 American Community Surveys (ACSs). These estimates, like those derived from any survey, are subject to two types of errors: (1) Non-sampling Error, which consists of random errors that increase the variability of the data and non-random errors that consistently direct the data into a specific direction; and (2) Sampling Error, which consists of the error that arises from the use of probability sampling to create the sample.

[2] These figures were calculated by the U.S. Department of Health and Human Services, Administration for Children and Families, Office of Community Services, Division of Energy Assistance (DEA) by multiplying the estimated State median income for a four-person family for each State by 60 percent.

[3] To adjust for different sizes of family, 45 CFR 96.85 calls for multiplying 60 percent of a State's estimated median income for a four-person family by the following percentages: 52 percent for one person, 68 percent for two persons, 84 percent for three persons, 100 percent for four persons, 116 percent for five persons, and 132 percent for six persons. For each additional family member above six persons, 45 CFR 96.85 calls for adding 3 percentage points to the percentage for a six-person family (132 percent) and multiply the new percentage by 60 percent of a State's estimated median income for a four-person family.

[FR Doc. 2011–8993 Filed 4–15–11; 8:45 am]

BILLING CODE 4184–24–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0214]

Guidance for Industry on How To Write a Request for Designation; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled "How to Write a Request for Designation (RFD)." This guidance is intended to clarify the type of information the Office of Combination Products (OCP) recommends that a sponsor include in a Request for Designation (RFD). This final guidance supersedes the previous RFD guidance document issued August 2005.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Office of Combination Products, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 5129, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic comments on the guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Kristina Lauritsen, Office of Combination Products, Food and Drug Administration, Bldg. 32, rm. 5132, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–8936.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled "How to Write a Request for Designation (RFD)." This guidance addresses 21 CFR 3.7 and is intended to clarify the type of information OCP recommends that a sponsor include in an RFD. The goal of this guidance is to help a sponsor understand what information FDA needs to determine the regulatory identity or classification of a product as a drug, device, biological product, or combination product, and to assign the product to the appropriate Agency component for review and regulation. This final guidance supersedes the previously issued RFD guidance document which was published on FDA's Web site on August 2005.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on how to write an RFD. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 3 have been approved under OMB control number 0910–0523.