comments and suggestions submitted within 60 days of this publication.

Robert Sargis,

Reports Clearance Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Title: Objective Work Plan (OSP), Objective Progress Report (OPR) and Project Abstract.

OMB No. 0980–0204.

Description: Content changes are being made to the OPR and OWP only. The information in the OPR is being collected on a quarterly basis to monitor the performance of grantees and better gauge grantee progress. The OWP is utilized by applications when they submit their proposals and then by grantees to monitor their projects once awarded. ANA has reworded and renumbered the OPR questions to allow for better flow and clarity. The majority of content being requested from the grantees is the same and has not changed.

OPR: Following are content changes being made:

Objective Work Plan Update: Content is the same. Questions 1 and 2 were originally questions 3 and 4 on the previous OPR. ANA has also reduced the number of objectives under this section to 3. ANA is also separating out the current status of expected results and the current status of expected benefits. This will match ANA's revised OWP.

Partnerships and Leveraged Resources: Content is the same. Questions 3 and 4 were originally part of questions 11–13. The leveraged resources table under question 4 has been reformatted to allow for easier data collection.

Impact indicator: The content requested in this section is similar to the previous OPR with some additional information being requested. Question 5 was originally captured under question 11 of the previous OPR. ANA has added additional fields to this section: Tracking mechanism, pre-grant status, and three-year target to align with ANA's funding opportunity announcement. Questions 5a and 5b are new and ask the grantee for the status of the impact indicator at the end of each budget period. This information was captured quantitatively in the previous OPR.

Native American Youth and Elder Opportunities: Content is the same. Questions 6 and 6a were originally questions 14 and 14a on the previous OPR.

Staffing: Content is the same. Questions 7 and 7a were originally question 16 on the previous OPR. Question 7b was originally question 15 on the previous OPR. ANA has added one field to this table: Type of position.

Challenges: Content is the same. Questions 8 and 9 were originally questions 1 and 5 on the previous OPR. For question 9 ANA has added a table to capture information that was previously provided in a narrative format. Questions 10 and 11 were originally questions 2 and 6 on the previous OPR.

Project Sustainability: Content is the same. Questions 12 and 13 were originally questions 18 and 17 on the previous OPR.

Financial: The content requested in this section is similar to the previous OPR with some additional information being requested. Questions 14 and 16a were originally questions 9, 10, and 7 on the previous OPR. Question 17 is a new question. This question will not require the grantee to conduct additional work as they will be able to respond to this question utilizing the required OPR and 425 forms. Question 18 was originally question 8 on the previous OPR.

Four additional questions have been added that are specific to a special initiative ANA is funding this year. These questions are only to be filled out by the Asset for Independence Grantees.

OWP: ANA has reformatted the OWP (content is same). ANA has added a field for applicants to include problem statement identified in grant application; has separated the results and benefits expected to align with ANA's funding opportunity announcement. ANA is no longer requesting data on non-personnel hours. On the previous OWP ANA requested applicants to provide the position responsible for each activity. This title has changed to 'position performing the activity' and applicants will be asked to identify the lead person in one cell and other support in a second cell.

Project Abstract: ANA is no longer managing this form. Grants.gov has taken control of this form and will submit any additional requests for this submission.

Respondents: Tribal Government, Native non-profit organizations, Tribal Colleges & Universities.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
OWP	500	1	3	1,500
OPR	275	4	1	1,100

Estimated Total Annual Burden Hours: 2,600.

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 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.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2011–20646 Filed 8–12–11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Application Requirements for the Low Income Home Energy Assistance Program (LIHEAP) Residential Energy Assistance Challenge Program (REACH) Model Plan.

OMB No.: 0970–0348.

Description: States, including the District of Columbia, Tribes, Tribal organizations and Territories applying for LIHEAP REACH funds must Submit an annual application prior to receiving Federal funds. The Human Services Amendments of 1994 (Pub. L. 103–252) amended the LIHEAP statute to add Section 2607B, which established the REACH program. REACH was funded for the first time in FY 1996 and is intended to: (1) Minimize health and safety risks that result from high energy burdens on low-income Americans; (2) reduce home energy vulnerability and prevent homelessness as a result of the inability to pay energy bills; (3) increase the efficiency of energy usage by low-income families, helping them achieve energy self-sufficiency; and (4) target energy assistance to individuals who are most in need. The REACH Model Plan clarifies the information being requested and ensures the submission of all the information required by statute. The form facilitates our response to numerous queries each year concerning the information that should be included in the REACH application. Submission of a REACH application and use of the REACH Model Plan is voluntary. Grantees have the option to use another format.

Respondents: State Governments, Tribal governments, Insular Areas, the District of Columbia, and the Commonwealth of Puerto Rico.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Reach model plan	51	1	72	3,672

Estimated Total Annual Burden Hours: 3,672.

Additional Information: Copies of the proposed collection may be obtained 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. All requests should be identified by the title of the information collection. *E-mail address: infocollection@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:* 202–395–7285, *E-mail: OIRA_SUBMISSION@OMB.EOP.GOV, Attn:* Desk Officer for the Administration for Children and Families.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2011–20613 Filed 8–12–11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0577]

Draft Guidance for Industry and Food and Drug Administration Staff; Factors to Consider When Making Benefit-Risk Determinations in Medical Device Premarket Review; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance document entitled ''Factors to Consider When Making Benefit-Risk Determinations in Medical Device Premarket Review.'' The recommendations in this guidance are intended to provide greater clarity on FDA's decisionmaking process with regard to benefit-risk determinations in the premarket review of medical devices. This draft guidance is not final nor is it in effect at this time.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit electronic or written comments on the draft guidance by November 14, 2011.

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled ''Factors to Consider When Making Benefit-Risk Determinations in Medical Device Premarket Review'' to the Division of Small Manufacturers, International, and Consumer Assistance, Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4613, Silver Spring, MD 20993–0002; or to the Office of Communication, Outreach and Development (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301–847–8149. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit electronic comments on the draft 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. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: *For Devices Regulated by CDRH:* Rachel Turow, Center for Devices and