

BURDEN ESTIMATES FOR LIHEAP RECIPIENT HOUSEHOLD ADMINISTRATIVE DATA

| Number of respondents | Number of responses per respondent | Average burden hours per response | Total burden hours |
|-----------------------|------------------------------------|-----------------------------------|--------------------|
| 49 | 1 | 24 | 1,176 |

As LIHEAP is a block grant, there is varying capacity to collect and report data among grantees. The estimated burden hours displayed above are for the average LIHEAP grantee. All LIHEAP grantees have existing data systems to collect, maintain, and analyze this data to complete annual reporting requirements.

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 Planning, Research and Evaluation, 330 C Street SW., Washington, DC 20201. Attn: ACF Reports Clearance Officer. Email 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. 2015-32242 Filed 12-22-15; 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: Native Language Preservation and Maintenance Grant Application Template Pilot (Funding Application Submission Tool (F.A.S.T. form))

OMB No.:

Description: The proposed F.A.S.T. form is intended to be used by applicants in the Administration for Native Americans' Native American Language Preservation and Maintenance grant competition in FY 2016. The F.A.S.T. form is proposed to be piloted as a consolidated and streamlined pre-formatted electronic application form that is user-friendly and has an interactive interface providing structure and clarity for applicants. The proposed F.A.S.T. form is not intended to replace the Funding Opportunity Announcement (FOAs) which will still function as the full text of all funding

opportunities for which applications are sought and considered by the Administration for Native Americans.

The proposed F.A.S.T. form will be used in a pilot capacity in just one Administration for Native Americans' discretionary program areas: Native American Language Preservation and Maintenance. All applicants applying for funding in that program area will be required to use the F.A.S.T. form during the pilot competition proposed for FY16 unless they request and receive approval to submit a paper application. By using the F.A.S.T. form no applicant will be required to provide any information beyond what is already required by the FOA. Additionally, free training and technical assistance will be available to all applicants on use of the F.A.S.T. form.

ANA intends to use the project proposals submitted via the F.A.S.T. form to make funding decisions for Native American Language Preservation and Maintenance grant awards made in the FY 2016 pilot year. In addition, ANA will solicit feedback from applicants and panel reviewers to obtain feedback on the results, outcomes, and their recommendations regarding the F.A.S.T. form as a user friendly method of applying for funding opportunities. If the pilot is successful in making it easier for applicants to apply, ANA will consider potentially expanding use of the F.A.S.T. form to all Administration for Native Americans' discretionary funding areas in subsequent years.

Respondents: 40

ANNUAL BURDEN ESTIMATES

| Instrument | Number of respondents | Number of responses per respondent | Average burden hours per response | Total burden hours |
|---------------------|-----------------------|------------------------------------|-----------------------------------|--------------------|
| F.A.S.T. form | 40 | 28 | .50 | 14 |

Estimated Total Annual Burden Hours: 560.

Additional Information

Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 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. Email 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, Email: OIRA_SUBMISSION@OMB.EOP.GOV, Attn: Desk Officer for the Administration for Children and Families.

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

Proposed Projects

Title: Head Start Grant Application and Budget Instruments.

OMB No.: 0970-0207.

Description: The Office of Head Start is proposing to renew, without changes, the Head Start Grant Application and Budget Instrument, which grantees use

to provide information that is requested from all Head Start and Early Head Start grantees applying for continuation grants. The application and budget forms are available in the Head Start Enterprise System (HSES), a secure Web-based system, which transmits completed applications to Regional and Central Offices. The Administration for Children and Families believes that this application instrument has made the process of applying for a Head Start continuation grant more efficient for applicants.

Respondents: Head Start and Early Head Start grantees.

ANNUAL BURDEN ESTIMATES

| Instrument | Number of respondents | Number of responses per respondent | Average burden hours per response | Total burden hours |
|--------------------------------------|-----------------------|------------------------------------|-----------------------------------|--------------------|
| HS grant and budget instrument | 2,000 | 1 | 33 | 66,000 |

Estimated Total Annual Burden Hours: 66,000.

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 Planning, Research and Evaluation, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. Email 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 information to be collected; and (e) 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.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA-2013-E-1433; FDA-2013-E-1435; FDA-2013-E-1437]

Determination of Regulatory Review Period for Purposes of Patent Extension; JETREA

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for JETREA and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human biological product.

DATES: Anyone with knowledge that any of the dates as published (see the **SUPPLEMENTARY INFORMATION** section) are incorrect may submit either electronic or written comments and ask for a redetermination by February 22, 2016. Furthermore, any interested person may

petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by June 20, 2016. See "Petitions" in the **SUPPLEMENTARY INFORMATION** section for more information.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <http://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").