Proposed information collection activity; comment request

Title: Head Start Performance Standards.

OMB No.: 0970–0148.

Description: Please note that this submission does not reflect proposed changes in the Notice of Proposed Rule Making to update Head Start program performance standards published on June 15, 2015. ACF is only requesting for an extension without change of a currently approved collection.

Head Start Performance Standards are the result of a legislative mandate to administer a high quality comprehensive child development program that serves low-income pregnant women, infants and toddlers, preschoolers and their families. The information collection aspects of the Performance Standards are a part of the many actions that local agencies must take to ensure they administer quality programs for Head Start children and families. The information collection items included in the Performance Standards are almost entirely record-keeping requirements for local Head Start programs; these records are intended to act as a tool for grantees and delegate agencies to be used in their day-to-day operations. Such records are maintained by the grantees and delegate agencies and are not part of a standard information collection submitted to the Federal government. Local programs are monitored for overall compliance with the Performance Standards, including the record-keeping aspects.

Respondents: Head Start and Early Head Start program grant recipients.

ANNUAL BURDEN ESTIMATES

<table>
<thead>
<tr>
<th>Instruments</th>
<th>Number of respondents</th>
<th>Number of responses per respondent</th>
<th>Average burden hours per response</th>
<th>Total burden hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>Records</td>
<td>2,865</td>
<td>16</td>
<td>41.9</td>
<td>1,920,696</td>
</tr>
</tbody>
</table>

Estimated Total Annual Burden Hours: 1,920,696.

Cost per respondent is $10,290.64 estimated at 16 responses × 41.9 hours × $15.35 per hour. Monetary costs associated with information collection requirements for Head Start are the salaries of the staff performing the duties. These costs are assumed by the Federal Government through the provision of program operating costs.

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: infocollect@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 (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. 2016–13172 Filed 6–3–16; 8:45 am]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families
[CFDA Number: 93.568]

Reallotment of FY 2015 Funds for the Low Income Home Energy Assistance Program (LIHEAP)

AGENCY: Office of Community Services, ACF, HHS.

ACTION: Notice of determination concerning funds available for reallotment.

SUMMARY: Notice is hereby given of a preliminary determination that funds from the fiscal year (FY) 2015 Low Income Home Energy Assistance Program (LIHEAP) are available for reallocation to states, territories, tribes, and Tribal Organizations that received FY 2016 direct LIHEAP grants. No subgrantees or other entities may apply for these funds.

Section 2607(b)(1) of the Low Income Home Energy Assistance Act (the Act), (42 U.S.C. 8626(b)(1)) requires that, if the Secretary of the U.S. Department of Health and Human Services (HHS) determines that, as of September 1 of any fiscal year, an amount in excess of 10 percent of the amount awarded to a grantee for that fiscal year (excluding Leveraging, REACH, and reallocated funds) will not be used by the grantee during that fiscal year, then the Secretary must notify the grantee and publish a notice in the Federal Register that such funds may be reallocated to LIHEAP grantees during the following fiscal year. If reallocated, the LIHEAP block grant allocation formula will be used to distribute the funds. No funds may be allotted to entities that are not direct LIHEAP grantees during FY 2016.

DATES: Submit comments on or before July 6, 2016.

ADDRESSES: Comments may be submitted to: Jeannie L. Chaffin, Director, Office of Community Services, 330 C Street SW., 5th Floor, Mail Room 5425, Washington, DC 20201.

FOR FURTHER INFORMATION CONTACT: Lauren Christopher, Director, Division of Energy Assistance, Office of Community Services, 330 C Street SW.,
SUPPLEMENTARY INFORMATION: It has been determined that approximately $1,230,022 in LIHEAP funds may be available for reallocation during FY 2016. This determination is based on FY 2015 Carryover and Reallocation Reports that showed that seven grantees reported reallocation funds (Tennessee, Puerto Rico, Coyote Valley Band of Pomo Indians, Eastern Shoshone Tribe, Passamaquoddy Tribe at Pleasant Point, Poarch Band of Creek Indians, and The Klamath Tribes). Grantees submitted the FY 2015 Carryover and Reallocation Reports to the Office of Community Services (OCS), as required by regulations applicable to LIHEAP at 45 CFR 96.82. This amount, however, may increase because, as of April 1, 2016, the report for 68 grantees remains pending.

The statute allows grantees who have funds unobligated at the end of the federal fiscal year for which they are appropriated to request that they be allowed to carry over up to 10 percent of their allotments to the next federal fiscal year. Funds in excess of this amount must be returned to HHS and are subject to reallocation under section 2607(b)(1) of the Act (42 U.S.C. 8626(b)(1)). The amount described in this notice was reported as unobligated FY 2015 funds in excess of the amount that these grantees could carry over to FY 2016.

OCS contacted each of the grantees to confirm that the FY 2015 funds indicated in the chart may be reallocated. In accordance with section 2607(b)(3) of the Act (42 U.S.C. 8626(b)(3)), comments will be accepted for a period of 30 days from the date of publication of this notice.

After considering any comments submitted, the Chief Executive Officers of LIHEAP grantees will be notified of the final reallocation amount. This decision will be published in the Federal Register.

If funds are reallocated, they will be allocated in accordance with section 2604 of the Act (42 U.S.C. 8623) and must be treated by LIHEAP grantees receiving them as an amount appropriated for FY 2016. As FY 2016 funds, they will be subject to all requirements of the Act, including section 2607(b)(2) (42 U.S.C. 8626(b)(2)), which requires that a grantee obligate at least 90 percent of its total block grant allocation for a fiscal year by the end of the fiscal year for which the funds are appropriated, that is, by September 30, 2016.

### Estimated Reallocation Amounts of FY 2015 LIHEAP Funds

<table>
<thead>
<tr>
<th>Grantee name</th>
<th>FY 2015 reallocation amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tennessee</td>
<td>$271,910</td>
</tr>
<tr>
<td>Puerto Rico</td>
<td>818,566</td>
</tr>
<tr>
<td>Coyote Valley Band of Pomo Indians</td>
<td>9,025</td>
</tr>
<tr>
<td>Eastern Shoshone Tribe</td>
<td>37,413</td>
</tr>
<tr>
<td>Passamaquoddy Tribe at Pleasant Point</td>
<td>33,602</td>
</tr>
<tr>
<td>Poarch Band of Creek Indians</td>
<td>50,978</td>
</tr>
<tr>
<td>The Klamath Tribes</td>
<td>8,528</td>
</tr>
<tr>
<td>Total</td>
<td>1,230,022</td>
</tr>
</tbody>
</table>

Statutory Authority: 42 U.S.C. 8626.

Mary M. Wayland, Senior Grants Policy Specialist, Division of Grants Policy, Office of Administration.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Food and Drug Administration

[Docket No. FDA–2015–N–3432]

Organon USA et al.; Withdrawal of Approval of 67 New Drug Applications and 128 Abbreviated New Drug Applications; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the Federal Register of October 13, 2015 (80 FR 61426). The document announced the withdrawal of approval of 67 new drug applications (NDAs) and 128 abbreviated new drug applications from multiple applicants, effective November 12, 2015. The document indicated that FDA was withdrawing approval of the following two NDAs after receiving a request from the NDA holder, Merck Sharp & Dohme Corp. (Merck), 1 Merck Dr., P.O. Box 100, Whitehouse Station, NJ 08889: NDA 016096, MINTEZOL (thiabendazole) Tablets, and NDA 016097, MINTEZOL (thiabendazole) Oral Suspension. Before withdrawal of these NDAs became effective, Merck informed FDA that it did not want approval of the NDAs withdrawn. Because Merck timely requested that approval of these NDAs not be withdrawn, the approval of NDAs 016096 and 016097 is still in effect.

FOR FURTHER INFORMATION CONTACT: Florine Purdie, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6366, Silver Spring, MD 20993–0002, 301–796–3601.

SUPPLEMENTARY INFORMATION: In the Federal Register of Tuesday, October 13, 2015, appearing on page 61426 in FR Doc. 2015–25922, the following correction is made:

On page 61426, in table 1, the entries for NDAs 016096 and 016097 are removed.


Leslie Kux, Associate Commissioner for Policy.

[FR Doc. 2016–13182 Filed 6–3–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Agency Information Collection Activities; Proposed Collection; Comment Request; Human Tissue Intended for Transplantation

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, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection requirements relating to FDA regulations for human tissue intended for transplantation.

DATES: Submit either electronic or written comments on the collection of information by August 5, 2016.

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