Families, U.S. Department of Health and Human 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, Administration for Children and Families, U.S. Department of Health and Human Services, 330 C Street SW, 5th Floor, Mail Room 5425, Washington, DC 20201. Telephone: (202) 401–4870. Email: *lauren.christopher@acf.hhs.gov.*

SUPPLEMENTARY INFORMATION: It has been determined that $536,595 in LIHEAP funds may be available for reallotment during FY 2018. This determination is based on FY 2017 Carryover and Reallotment Reports which showed that fifteen grantees reported reallotment funds. These grantees were State of Alaska, Aniak Traditional Council, Association of Village Council Presidents, Bristol Bay Native Association, Colorado River Indian Tribes, Hoh Indian Tribe, Jicarilla Apache Nation, Kalispel Tribe of Indians, Little River Band of Ottawa Indians, Miami Tribe of Oklahoma, Navajo Nation, Sac and Fox Nation of Oklahoma, Samish Indian Nation, Three Affiliated Tribes, and Tyme Maidu Tribe Berry Creek Rancheria. Grantees submitted the FY 2017 Carryover and Reallotment Reports to the OCS, as required by regulations applicable to LIHEAP at 45 CFR 96.81(b).

The LIHEAP statute allows grantees who have funds unobligated at the end of the federal fiscal year for which they are awarded to request that they be allowed to carry over up to 10 percent of their full-year allotments to the next federal fiscal year. Funds in excess of this amount must be returned to HHS and are subject to reallotment under section 2607(b)(1) of the Act (42 U.S.C. 8626(b)(1)). The amount described in this notice was reported by grantees as unobligated FY 2017 funds in excess of the amount that these grantees could carry over to FY 2018.

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, all current LIHEAP grantees will be notified of the final reallotment amount redistributed to them for obligation in FY 2018. This decision will be published in a Dear Colleague Letter that gets posted to ACF's website.

If funds are reallotted, 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 2018. As FY 2018 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, 2018.

ESTIMATED REALLOTMENT AMOUNTS OF FY 2017 LIHEAP FUNDS

Grantee name	Reallotment amount
State of Alaska	$10,552
Aniak Traditional Council	840
Association of Village Council Presidents	164,654
Bristol Bay Native Association	13,605
Colorado River Indian Tribes	3,878
Navajo Nation	28,901
Tyme Maidu Tribe Berry Creek Rancheria	3
Little River Band of Ottawa Indians	62,871
Jicarilla Apache Nation	9,317
Three Affiliated Tribes	194,213
Miami Tribe of Oklahoma	77
Sac and Fox Nation of Oklahoma	35,967
Hoh Indian Tribe	4,034
Kalispel Tribe of Indians	1,211
Samish Indian Nation	6,472
Total	536,595

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

Elizabeth Leo,

Grants Policy Specialist, Division of Grants Policy, Office of Administration.

[FR Doc. 2018–11820 Filed 5–31–18; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Title: Administration for Native Americans Annual Data Report.

OMB No. 0970–0475: Renewal.

Description: The Administration for Native Americans is seeking renewal of the Annual Data Report (ADR). The ADR is an annual report to be completed at the end of every budget period of an ANA discretionary grant. The purpose of this information collection is to annually collect grantee data on outcome indicators, youth and elder engagement, partnerships, community participation, benefits and lessons learned. At the end of the project period, ANA will also collect data on beneficiaries, the overall achievement of the project goal, and project sustainability.

This information collection will be housed in the On-Line Data Collection (OLDC) with in *GrantSolutions.gov*.

Respondents: Tribal Government, Native non-profit organizations, Tribal Colleges & Universities receiving ANA discretionary funding.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
ADR	275	1	1	275

Estimated Total Annual Burden Hours: 275.

In compliance with the requirements of the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. Chap 35), 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, 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 A. Sargis,

Reports Clearance Officer.

[FR Doc. 2018–11796 Filed 5–31–18; 8:45 am]

BILLING CODE 4184–34–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–1043]

Waivers of the Single, Shared System Risk Evaluation and Mitigation Strategy Requirement; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Waivers of the Single, Shared System REMS Requirement.'' This guidance describes how FDA intends to consider granting a waiver of the requirement in the Federal Food, Drug, and Cosmetic Act (FD&C Act) that the applicant for an abbreviated new drug application (ANDA) and its reference listed drug (RLD) use a single, shared system (SSS) for a required risk evaluation and mitigation strategy (REMS) with elements to assure safe use (ETASU).

DATES: Submit either electronic or written comments on the draft guidance by August 30, 2018 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov*. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://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 *https://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'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2018–D–1043 for ''Waivers of the Single, Shared System Risk Evaluation and Mitigation Strategy Requirement; Draft Guidance for Industry; Availability.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov*. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf*.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002, or to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, 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 draft guidance document.

FOR FURTHER INFORMATION CONTACT: Elaine Lippmann, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6238, Silver Spring, MD 20993, 301–796–