

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

Administration for Children and Families

[CFDA Number: 93.568]

Reallotment of FY 2013 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) 2013 Low Income Home Energy Assistance Program (LIHEAP) are available for reallotment to States, Territories, Tribes, and Tribal Organizations that receive FY 2014 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), Title XXVI of the Omnibus Budget Reconciliation Act of 1981 (42 U.S.C. 8621 *et seq.*), as amended, 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 certain levels allotted to a grantee for any fiscal year will not be used by the grantee during the fiscal year, the Secretary must notify the grantee and publish a notice in the **Federal Register** that such funds may be reallotted to LIHEAP grantees during the following fiscal year. If reallotted, 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 2014.)

It has been determined that \$2,192,230 may be available for reallotment during FY 2014. This determination is based on revised Carryover and Reallotment Reports from the State of Nebraska, Salt River Pima-Maricopa Indian Community, and the Delaware Tribe of Indians, which were submitted to the Office of Community Services as required by 45 CFR 96.82.

The 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 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. The amount described in this notice was reported as unobligated FY 2013 funds in excess of the amount that the State of Nebraska, Salt River Pima-Maricopa Indian Community, and the Delaware Tribe of Indians could carry over to FY 2014.

Each of the grantees mentioned above were notified and confirmed that the FY 2013 funds indicated in the chart below may be reallotted. In accordance with section 2607(b)(3), the Chief Executive Officers of the grantees referenced in the chart below have 30 days from the date of this publication to submit comments to: Jeannie L. Chaffin, Director, Office of Community Services, 370 L'Enfant Promenade, SW., Washington, DC 20447.

After considering any comments submitted, the Chief Executive Officers will be notified of the final reallotment amount, and this decision also will be published in the **Federal Register**. If funds are reallotted, they will be allocated in accordance with section 2604 of the Act and must be treated by LIHEAP grantees receiving them as an amount appropriated for FY 2014. As FY 2014 funds, they will be subject to all requirements of the Act, including section 2607(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, 2014.

ESTIMATED REALLOTMENT AMOUNTS OF FY 2013 LIHEAP FUNDS

Grantee name	FY 2013 reallotment amount
State of Nebraska	\$2,180,356.00
Delaware Tribe of Indians ..	9,793.00
Salt River Pima-Maricopa Indian Community	2,081.00
Total	2,192,230.00

DATES: The comment period expires February 13, 2014.

FOR FURTHER INFORMATION CONTACT: Lauren Christopher, Energy Program Operations Branch Chief, Division of Energy Assistance, Office of Community Services, 370 L'Enfant Promenade, SW., Washington, DC, 20447; telephone (202) 401-4870; email: lauren.christopher@acf.hhs.gov.

Statutory Authority: 45 CFR 96.81 and 42 U.S.C. 8621 *et seq.*

Lynda Pérez,

Acting Director, Office of Community Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-D-1601]

Custom Device Exemption; Draft Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled "Custom Device Exemption." FDA has developed a draft guidance to provide guidance to industry and FDA staff about implementation of the custom device exemption contained in the Food, Drug, and Cosmetic Act (the FD&C Act). The intent of this guidance is to provide draft definitions of terms used in the custom device exemption, explain how to interpret the "five units per year of a particular device type" language contained in the FD&C Act, describe what information FDA proposes manufacturers should submit in the custom device annual report, and provide recommendations on how to submit an annual report for devices distributed under the custom device exemption. 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 of this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by March 17, 2014.

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled "Custom Device Exemption" to the Division of Small Manufacturers, International, and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4613, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301-847-