

include 2 states and 10 tribes, which are listed in the table below. Grantees submitted the FY 2019 Carryover and Reallotment Reports to the OCS, as required by regulations applicable to LIHEAP at 45 CFR 96.81(b). After publication of this notice DEA will redetermine the final reallotment amounts and make adjustments where necessary.

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 Low Income

Home Energy Assistance Act, (42 U.S.C. 8626(b)(1)). The amount described in this notice was reported by grantees as unobligated FY 2019 funds in excess of the amount that these grantees could carry over to FY 2020. In accordance with section 2607(b)(3) of the Act (42 U.S.C. 8626(b)(3)), HHS has notified each grantee of any balance that will be de-obligated for purpose of this anticipated reallotment and has given 30 days to provide comments directly to HHS. Public comments will be accepted for a period of 30 days from the date of publication of this notice.

All current LIHEAP grantees will be notified of the final reallotment amount redistributed to them for obligation in FY 2020. This decision will also be published in the **Federal Register** and in

a Dear Colleague Letter that is posted to ACF's website at <https://www.acf.hhs.gov/ocs/resource/dear-colleagues>.

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 2020. As FY 2020 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, 2020.

ESTIMATED REALLOTMENT AMOUNTS OF FY 2019 LIHEAP FUNDS

Grantee name	Grantee reported reallotment amount	Amount available for redistribution
Ohio	\$206,951	\$206,951
Utah	540,516	540,516
Chippewa Cree Tribe	13,302	13,302
Coeur d'Alene Tribe	1,328	1,328
Colorado River Indian Tribes	595	595
Hoh Indian Tribe	2,472	0
Karuk Tribe	9,337	9,337
Little River Band of Ottawa Indians	32,069	3,247
Northern Cheyenne Tribe	5,704	5,704
Paiute Tribe of Utah	95,125	95,125
Quinault Indian Nation	1,285	7
Sac and Fox Nation of Oklahoma	30,768	30,767
Sitka Tribe	41,606	41,606
Total	981,058	948,485

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

Karen Shields,

Senior Grants Policy Specialist, Office of Grants Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-N-1095]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Electronic Submission Process for Voluntary Allegations to the Center for Devices and Radiological Health

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by October 5, 2020.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to <https://www.reginfo.gov/public/do/PRAMain>. Find this particular information collection by selecting "Currently under Review—Open for Public Comments" or by using the search function. The OMB control number for this information collection is 0910-0769. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-7726, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Electronic Submission Process for Voluntary Allegations to the Center for Devices and Radiological Health

OMB Control Number 0910-0769—Extension

This information collection request collects information voluntarily submitted to the Center for Devices and Radiological Health (CDRH) on actual or potential health risk concerns about a medical device or radiological product or its use. Because, prior to the

establishment of the electronic submission process for voluntary allegations to CDRH, there had been no established guidelines or instructions on how to submit an allegation to CDRH, allegations often contained minimal information and were received via phone calls, emails, or conversationally. CDRH has established a consistent format and process for the submission of device allegations that enhances our timeliness in receiving, assessing, and evaluating voluntary allegations. The information provided in the allegations received by CDRH may be used to clarify the recurrence or emergence of significant device-related risks to the

general public and the need to initiate educational outreach or regulatory action to minimize or mitigate identified risks.

In the **Federal Register** of February 10, 2020 (85 FR 7562), we published a 60-day notice requesting public comment on the proposed collection of information. FDA received two comments.

The first comment was not relevant to the information collection.

The second comment stated that the rule does not state whether people submitting allegations of regulatory misconduct are required to redact their contact information.

We disagree with the comment. Anyone may file a complaint reporting an allegation of regulatory misconduct. FDA encourages people submitting allegations to include supporting information and contact information in case additional information is needed for FDA to understand the allegation and act on the report; however, you can choose to submit a report anonymously. FDA will not share your identity or contact information with anyone outside FDA unless required to do so by law, regulation, or court order.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN¹

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Electronic submission of voluntary allegations to CDRH.	1,600	1	1,600	0.25 (15 minutes)	400

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

Our estimated burden for the information collection reflects an overall increase of 225 hours and a corresponding increase of 900 responses/records. We attribute this adjustment to an increase in the number of submissions we received over the last few years.

Dated: August 26, 2020.

Lauren K. Roth,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–1767]

Joint Meeting of the Psychopharmacologic Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of a public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Joint Meeting of the Psychopharmacologic Drugs Advisory Committee and the Drug Safety and Risk

Management Advisory Committee. The general function of the committees is to provide advice and recommendations to FDA on regulatory issues. The meeting will be open to the public. FDA is establishing a docket for public comment on this document.

DATES: The meeting will be held on October 8, 2020, from 8 a.m. Eastern Time to 5 p.m. Eastern Time.

ADDRESSES: Please note that due to the impact of this COVID–19 pandemic, all meeting participants will be joining this advisory committee meeting via an online teleconferencing platform. Answers to commonly asked questions about FDA advisory committee meetings may be accessed at: <https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm>.

FDA is establishing a docket for public comment on this meeting. The docket number is FDA–2020–N–1767. The docket will close on October 7, 2020. Submit either electronic or written comments on this public meeting by October 7, 2020. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before October 7, 2020.

The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of October 7, 2020. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service

acceptance receipt is on or before that date.

Comments received on or before September 25, 2020, will be provided to the committees. Comments received after that date will be taken into consideration by FDA. In the event that the meeting is cancelled, FDA will continue to evaluate any relevant applications or information, and consider any comments submitted to the docket, as appropriate.

You may submit comments 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>.