

Household Water Assistance Program (LIHWAP) program. The information collection is essential to the mission of the agency for this emergency assistance effort and the use of normal clearance procedures is reasonably likely to disrupt and prevent the collection of information.

**DATES:** *Comments due within 60 days of publication.* In compliance with the requirements of the Paperwork Reduction Act of 1995, ACF is soliciting public comment on the specific aspects of the information collection described in this notice.

**ADDRESSES:** Copies of the proposed collection of information can be obtained and comments may be submitted by emailing [infocollection@acf.hhs.gov](mailto:infocollection@acf.hhs.gov). All requests should identify the title of the information collection.

**SUPPLEMENTARY INFORMATION:**

*Description:* ACF is requesting that OMB grant a 180-day approval for this request under procedures for expedited processing. A request for review under normal procedures will be submitted

within 180 days of the approval for this request. The LIHWAP effort was authorized under two separate appropriations as part of an emergency effort to prevent and respond to COVID-19: The Consolidated Appropriations Act, 2021 (Pub. L. 116-260) and the American Rescue Plan Act of 2021 (Pub. L. 117-2). As a result of the emergency nature, the timeline to implement the program was very short and the time to develop and submit related performance measures is similarly short. The proposed LIHWAP Quarterly Performance and Management Report and the LIHWAP Annual Report are conducted in accordance with the LIHWAP statute (Pub. L. 116-260) and will provide ACF and Congress information necessary for oversight of recipients' performance in administering the LIHWAP program. The completeness, accuracy, consistency, and timeliness of responses to data collections are needed for the agency to do the following:

- Ensure that LIHWAP, an emergency and temporary program, is implemented effectively and efficiently;
- Provide reliable and complete fiscal and household data for OCS analysis and reporting to Congress and the public; and
- Respond to questions from the Congress, Department, OMB, White House, and other interested parties in a timely and accurate manner.

This information collection package also includes a burden estimate related to the information collected from households. While grant recipients will collect necessary information from households using a variety of intake systems and local forms, OCS is providing technical assistance in this area and has included a sample application template in supplementary materials. This is a sample template; there will be no mandated household application format and OCS will not receive or analyze copies of individual household application materials.

*Respondents:* LIHWAP grant recipients.

**ANNUAL BURDEN ESTIMATES**

Instrument	Total number of respondents	Total number of responses per respondent	Average burden hours per response	Total burden hours	Annual burden hours
Quarterly Report .....	157	4	13	8,164	8,164
Annual Report .....	157	2	211	66,254	33,127
Household Application .....	1,200,000	1	.5	600,000	200,000

*Estimated Total Annual Burden Hours:* 241,291 (for first year with Quarterly reports), 233,127 (for subsequent years without Quarterly reports).

*Comments:* 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. Comments will be considered and any necessary updates to materials made prior to, and responses provided in, the submission to OMB that will follow this public comment period.

*Authority:* Public Law 116-260 and LIHWAP Terms and Conditions Section 10 (<https://www.acf.hhs.gov/sites/>

[default/files/documents/LIHWAP%20Terms%20and%20Conditions%20for%20States.pdf](https://www.acf.hhs.gov/sites/default/files/documents/LIHWAP%20Terms%20and%20Conditions%20for%20States.pdf)).

**Mary B. Jones,**  
*ACF/OPRE Certifying Officer.*  
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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2021-N-0008]

**Neurological Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Neurological Devices

Panel of the Medical Devices Advisory Committee. The general function of the committee is to provide advice and recommendations to the Agency on FDA's regulatory issues. The meeting will be open to the public.

**DATES:** The meeting will take place virtually on December 10, 2021, from 9 a.m. to 6 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 including information regarding special accommodations due to a disability may be accessed at: <https://www.fda.gov/advisory-committees/about-advisory-committees/common-questions-and-answers-about-fda-advisory-committee-meetings>.

**FOR FURTHER INFORMATION CONTACT:** James Swink, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5214, Silver Spring,

MD 20993-0002, *James.Swink@fda.hhs.gov*, 301-796-6313, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's website at <https://www.fda.gov/AdvisoryCommittees/default.htm> and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before the meeting.

**SUPPLEMENTARY INFORMATION:**

*Agenda:* The meeting presentations will be heard, viewed, captioned, and recorded through an online teleconferencing platform. On December 10, 2021, the committee will discuss, make recommendations, and vote on information regarding the premarket approval application (PMA) for the BrainsGate Ischemic Stroke System (ISS500) by BrainsGate Ltd. The proposed indications for use, submitted by the sponsor, as stated in the PMA, are as follows: The ISS500 is indicated to increase cerebral blood flow and reduce disability in adult patients with acute ischemic stroke with confirmed cortical involvement in the anterior circulation who are ineligible or have no access to IV-tPA and endovascular thrombectomy. Treatment is to be initiated between 8 and 24 hours from stroke onset (last known well).

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available on FDA's website at the time of the advisory committee meeting, and the background material will be posted on FDA's website after the meeting. Background material and the link to the online teleconference meeting room will be available at <https://www.fda.gov/advisory-committees/medical-devices-advisory-committee/neurological-devices-panel>. Select the link for the 2021 Meeting Materials. The meeting will include slide presentations with audio components to allow the presentation of materials in a manner that most closely resembles an in-person advisory committee meeting.

*Procedure:* Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written

submissions may be made to the contact person on or before November 29, 2021. Oral presentations from the public will be scheduled on December 10, 2021, between approximately 1 p.m. and 2 p.m. Eastern Time. Those individuals interested in making formal oral presentations should notify the contact person (see **FOR FURTHER INFORMATION CONTACT**). The notification should include a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before November 18, 2021. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by November 19, 2021.

For press inquiries, please contact the Office of Media Affairs at *fdaoma@fda.hhs.gov* or 301-796-4540.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Artair Mallett at *Artair.Mallett@fda.hhs.gov* or 301-796-9638 at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at <https://www.fda.gov/advisory-committees/about-advisory-committees/public-conduct-during-fda-advisory-committee-meetings> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: October 19, 2021.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Request for Information and Notice of Listening Session on Efforts To Advance Health Equity Among Native Hawaiian and Pacific Islander Populations**

**AGENCY:** Office of Minority Health, Office of the Secretary, Department of Health and Human Services.

**ACTION:** Request for information (RFI) and notice of a listening session on efforts to advance health equity among Native Hawaiian and Pacific Islander populations.

**SUMMARY:** The U.S. Department of Health and Human Services (HHS) Office of Minority Health (OMH) seeks input from Native Hawaiian and Pacific Islander (NHPI) communities, NHPI-serving organizations, and other interested parties regarding efforts of the new Center for Indigenous Innovation and Health Equity (Center). The Center is tasked with supporting education, service and policy development, and research related to advancing sustainable solutions, to address health disparities and advance health equity among NHPI and American Indian/Alaska Native (AI/AN) populations. This is NOT a solicitation for proposals or proposal abstracts.

*Please Note:* This RFI and notice of a listening session is for planning purposes only. It is not a notice for a proposal and does not commit the federal government to issue a solicitation, make an award, or pay any costs associated with responding to this announcement. All submitted information shall remain with the federal government and will not be returned. All responses will become part of the public record and will not be held confidential. The federal government reserves the right to use the information provided by respondents for purposes deemed necessary and legally appropriate. Respondents are advised that the federal government is under no obligation to acknowledge receipt of the information received or provide feedback to respondents concerning any information submitted. Responses will not be accepted after the due date.

**DATES:** The virtual listening session will be held on Tuesday, November 2, 2021, from 3:30 p.m.-4:30 p.m. EDT. To register for the listening session, visit <https://www.zoomgov.com/meeting/register/vJlsc-6qj4tGrQwQx2vdmoUfMZmRWXZNds>. Written comments also may be submitted and must be received at the address provided below,