

SUPPLEMENTARY INFORMATION: FDA is announcing the issuance of a priority review voucher to the sponsor of an approved rare pediatric disease product application. Under section 529 of the FD&C Act (21 U.S.C. 360ff), which was added by FDASIA, FDA will award priority review vouchers to sponsors of approved rare pediatric disease product applications that meet certain criteria. FDA has determined that LAMZEDE (velmanase alfa-tycv), manufactured by Chiesi Farmaceutici S.p.A., meets the criteria for a priority review voucher. LAMZEDE (velmanase alfa-tycv) injection is for the treatment of non-central nervous system manifestations of alpha-mannosidosis.

For further information about the Rare Pediatric Disease Priority Review Voucher Program and for a link to the full text of section 529 of the FD&C Act, go to <http://www.fda.gov/ForIndustry/DevelopingProductsforRareDiseasesConditions/RarePediatricDiseasePriorityVoucherProgram/default.htm>. For further information about LAMZEDE (velmanase alfa-tycv), go to the “Drugs@FDA” website at <http://www.accessdata.fda.gov/scripts/cder/daf/>.

Dated: March 13, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023-05355 Filed 3-15-23; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency Information Collection Request; 60-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

DATES: Comments on the ICR must be received on or before May 15, 2023.

ADDRESSES: Submit your comments to Sherrette.Funn@hhs.gov or by calling (202) 795-7714.

FOR FURTHER INFORMATION CONTACT:

When submitting comments or requesting information, please include the document identifier 0990-0473-60D and project title for reference, to Sherrette A. Funn, email: Sherrette.Funn@hhs.gov, PRA@HHS.gov, or call (202) 795-7714 the Reports Clearance Officer.

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information

collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Title of the Collection: HHS Subpart C Certification Form.

Type of Collection: Revision.

OMB No.: 0990-0473.

Abstract: The Office for Human Research Protections (OHRP) is requesting a three-year approval on a Orevision of OMB No. 0990-0473, the HHS Subpart C Certification Form. The purpose of this form is to provide a simplified, standardized procedure for institutions to submit subpart C research certifications to OHRP in order to obtain authorization to include prisoners in HHS-conducted or supported human subjects research. The form also simplifies the internal process used by OHRP to review and record such certifications, resulting in faster processing while reducing unnecessary and burdensome staff time.

Likely Respondents: Institutions or Organizations operating Institutional Review Boards (IRBs) that have enrolled or are planning to enroll prisoners in human subjects research conducted or supported by HHS.

ANNUALIZED BURDEN HOUR TABLE

Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
Subpart C Certification Form	25	2	1.0	50
Subpart C Certification Form	5	3	1.0	15
Total	65

Sherrette A. Funn,

Paperwork Reduction Act Reports Clearance Officer, Office of the Secretary.

[FR Doc. 2023-05345 Filed 3-15-23; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended, notice is hereby given of a

meeting of the Sleep Disorders Research Advisory Board.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

Name of Committee: Sleep Disorders Research Advisory Board Sleep Disorders Research Advisory Board.

Date: April 6-7, 2023.

Open: April 06, 2023, 1:00 p.m. to 5:00 p.m.

Agenda: The purpose of this meeting is to update the Advisory Board and public

stakeholders on the progress of sleep and circadian research activities across NIH, and the activities of Federal stakeholders and interested organizations.

Place: Virtual-Teleconference, ZoomGov and In-Person.

Virtual: The event is free and open to the public, however, registration is required. Please use this link to register: https://nih.zoomgov.com/webinar/register/WN_Njl6hGOLQgmEGTNOe2zTzA.

In Person: Two Rockledge Centre, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20817.

Open: April 07, 2023, 9:00 a.m. to 2:00 p.m.

Agenda: The purpose of this meeting is to update the Advisory Board and public stakeholders on the progress of sleep and circadian research activities across NIH, and

the activities of Federal stakeholders and interested organizations.

Place: Virtual-Teleconference, ZoomGov and In-Person.

Virtual: The event is free and open to the public, however, registration is required. Please use this link to register: https://nih.zoomgov.com/webinar/register/WN_Njl6hGOLQgmEGTNOe2zTzA.

In Person: Two Rockledge Centre, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20817.

Contact Person: Marishka Brown, Ph.D., SDRAB Executive Secretary, Director, National Center on Sleep Disorders Research, National Institutes of Health, National Heart, Lung, and Blood Institute, Division of Lung Diseases, 6705 Rockledge Drive, Suite 407B, Bethesda, MD 20892, 301-435-0199, ncsdr@nih.gov.

Any member of the public interested in presenting oral comments to the committee may notify the Contact Person listed on this notice at least 10 days in advance of the meeting. Interested individuals and representatives of organizations may submit a letter of intent, a brief description of the organization represented, and a short description of the oral presentation. Only one representative of an organization may be allowed to present oral comments and if accepted by the committee, presentations may be limited to five minutes. Both printed and electronic copies are requested for the record. In addition, any interested person may file written comments with the committee by forwarding their statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the Institute's/Center's home page: www.nhlbi.nih.gov/meetings/index.htm, where an agenda updates and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: March 13, 2023.

David W. Freeman,
Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023-05400 Filed 3-15-23; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Fiscal Year (FY) 2023 Notice of Supplemental Funding Opportunity

AGENCY: Substance Abuse and Mental Health Services Administration,

Department of Health and Human Services (HHS).

ACTION: Notice of intent to award supplemental funding.

SUMMARY: This notice is to inform the public that the Substance Abuse and Mental Health Services Administration (SAMHSA) is supporting an administrative supplement (in scope of the parent award) up to \$157,674,392 (total costs) available until the budget period end date (09/29/2023) to the 988 Suicide and Crisis Lifeline Cooperative Agreement recipient, Mental Health Association of New York City, Inc. (DBA Vibrant Emotional Health). This grant was funded in FY 2021 under the Cooperative Agreement for National Suicide Prevention Lifeline and Disaster Distress Helpline Cooperative Agreement, Notice of Funding Opportunity (NOFO), SM 21-005, with a project end date of September 2026. The supplemental funding will be used to maintain 988 operations and services, both at local levels and across all backup, chat, text, LGBTQ+ youth, Spanish language, and videophone based services. This funding will ensure continuation of all 988 services and supports.

FOR FURTHER INFORMATION CONTACT:

James Wright, LPC, Division Director, Crisis Operations, Substance Abuse and Mental Health Services Administration, 5600 Fishers Lane, Rockville, MD 20857, telephone 240-276-1615; email: james.wright@samhsa.hhs.gov.

SUPPLEMENTARY INFORMATION:

Funding Opportunity Title: FY 2021 988 Suicide and Crisis Lifeline Cooperative Agreement SM-21-005.

Assistance Listing Number: 93.243.

Authority: Section 520E-3 [42 U.S.C. 290bb-36c] of the Public Health Service Act, as amended.

Justification: The 988 Suicide and Crisis Lifeline Cooperative Agreement (988 Lifeline) manages, enhances, and strengthens the 988 Lifeline network that routes individuals in the United States to a network of certified crisis centers that links to local emergency, mental health, and social services resources. The 988 Lifeline is a 24/7 confidential suicide and crisis hotline providing phone, chat, and text services for anyone in the United States experiencing a suicidal crisis or in emotional distress. This supplemental funding will ensure continuation of all active services, expand access for high-risk populations, improve access to services, and infrastructure support to ensure stability, safety, privacy, and connection of service. This is not a formal request for application.

Assistance will only be provided to the 988 Suicide and Crisis Lifeline Cooperative Agreement recipient, Mental Health Association of New York City, Inc. (DBA Vibrant Emotional Health). Since 2005, Vibrant Emotional Health has provided oversight and management of the Suicide Prevention Lifeline and its local call centers, backup centers, Spanish network, and chat/text functions with a network of over 200 centers in all fifty states. Vibrant Emotional Health has the infrastructure, experience, and national reach to work with the backup centers, language services, and chat/text organizations to address the increased contact volumes expected in 2023 and beyond. With the transition to 988 accomplished, greater services, such as expanding access to the local and national Lifeline backup centers, language services, system evaluation and data reporting, and access to specialized care for populations to be known at higher risk for suicide, are required to fully realize the potential impact to 988 contact service. Through this supplemental funding, SAMHSA and Vibrant can expand capacity to address increased call, chat and text volume following 988 implementation, further develop connection and support for individuals at higher risk of suicide and strengthen the efficiency and customer experience of the network through unified technology.

Alicia Broadus,

Public Health Advisor.

[FR Doc. 2023-05408 Filed 3-15-23; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Office of the Secretary

[Docket No. DHS-2023-0014]

Homeland Security Advisory Council

AGENCY: Office of Partnership and Engagement, Department of Homeland Security (DHS).

ACTION: Committee management; notice of committee charter renewal.

SUMMARY: The Secretary of Homeland Security has determined that the renewal of the Homeland Security Advisory Council is necessary and in the public interest. This determination follows consultation with the Committee Management Secretariat, General Services Administration.

DATES: The committee's charter is effective March 11, 2023 and expires March 11, 2025.