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 0revision 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]

BILLING CODE 4150–36–P

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_NjI6hGOLQgmEGTNOe2zTzA.*

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