determine whether research studies may be conducted under an FDA-approved RDRC, or whether research studies must be conducted under an investigational new drug application. It also offers answers to frequently asked questions on conducting research with radioactive drugs, and provides information on the membership, functions, and reporting requirements of an RDRC approved by FDA. All Agency guidance documents are issued consistent with our good guidance practice regulations at 21 CFR 10.115.

Under § 361.1(d)(5), each investigator will obtain the proper consent required under the regulations. Each female research subject of childbearing potential must state in writing that she is not pregnant or, based on a pregnancy test, be confirmed as not pregnant.

Under § 361.1(d)(8), the investigator will immediately report to the RDRC all adverse effects associated with use of the drug, and the committee will then report to FDA all adverse reactions probably attributed to the use of the radioactive drug.

Section 361.1(f) sets forth labeling requirements for radioactive drugs. These requirements are not in the reporting burden estimate because they are information supplied by the Federal Government to the recipient for the purposes of disclosure to the public (5 CFR 1320.3(c)(2)).

Types of research studies not permitted under the regulations are also specified and include those intended for immediate therapeutic, diagnostic, or similar purposes or to determine the safety or effectiveness of the drug in humans for such purposes (*i.e.,* to carry out a clinical trial for safety or efficacy). These studies require filing of an investigational new drug application under 21 CFR part 312, and the associated information collections, are covered in OMB control number 0910–0014.

The primary purpose of this collection of information is to determine whether the research studies are being conducted in accordance with required regulations and that human subject safety is assured. If these studies were not reviewed, human subjects could be subjected to inappropriate radiation or pharmacologic risks. Respondents to this information collection are the chairperson or chairpersons of each individual RDRC, investigators, and participants in the studies. The burden estimates are based on our experience with these reporting and recordkeeping requirements and the number of submissions we received under the regulations over the past 3 years.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section and FDA form	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (in hours)	Total hours
§ 361.1(c)(3) reports and (c)(4) approval (Form FDA 2914: Membership Summary) [2].	56	1	56	1	56
§ 361.1(c)(3) reports (Form FDA 2915: Study Summary) [3]	37	10	370	3	1,110
§ 361.1(d)(8) adverse events	10	1	10	0.5 (30 minutes)	5
Total			436		1,171

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] *https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM094979.pdf.*
[3] *https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM074720.pdf.*

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping (in hours)	Total hours
§ 361.1(c)(2) RDRC	56	4	224	10	2,240
§ 361.1(d)(5) human research subjects	37	10	370	0.75 (45 minutes)	278
Total			594		2,518

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

We have adjusted our estimate for the information collection to reflect an annual decrease of 703 hours and 158 responses since OMB's last approval. We attribute this adjustment to a decrease from 3.5 hours to 3 hours per response for public reporting burden for Form FDA–2915: Study Summary to match the burden hours reflected on the form. In addition, this adjustment is also attributable to the Agency receiving fewer submissions over the last few years.

Dated: March 13, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–05357 Filed 3–15–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–0026]

Issuance of Priority Review Voucher; Rare Pediatric Disease Product

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the issuance of a priority review voucher to the sponsor of a rare pediatric disease product application. The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Food and Drug Administration Safety and Innovation Act (FDASIA), authorizes FDA to award priority review vouchers to sponsors of approved rare pediatric disease product applications that meet certain criteria. FDA is required to publish notice of the award of the priority review voucher. FDA has determined that LAMZEDE (velmanase alfa-tycv), approved February 16, 2023, and manufactured by Chiesi Farmaceutici S.p.A., meets the criteria for a priority review voucher.

FOR FURTHER INFORMATION CONTACT: Cathryn Lee, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–1394, email: *Cathryn.Lee@fda.hhs.gov.*

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