TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR part 60—Patent term restoration	Number of respondents	Number of responses per respondent	Total responses (2016–2018)	Average burden per response	Total hours (2016–2018)	Average annual burden hours
60.24; revision of regulatory review period determinations	12	1.333	16	100	1,600	533.33
60.30; due diligence petitions	1	1	3	50	150	50
60.40; due diligence hearings	1	1	1	10	10	3.3
Total						586.63

[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 a small increase (+7 responses) associated with submissions received under § 60.24 in previous years.

Dated: January 16, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–01084 Filed 1–22–20; 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 VYONDYS 53 (golodirsen), manufactured by Sarepta Therapeutics, Inc., meets the criteria for a priority review voucher.

FOR FURTHER INFORMATION CONTACT: Althea Cuff, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–4061, Fax: 301–796–9856, email: *althea.cuff@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 VYONDYS 53 (golodirsen), manufactured by Sarepta Therapeutics, Inc., meets the criteria for a priority review voucher. VYONDYS 53 (golodirsen) is indicated for the treatment of Duchenne muscular dystrophy (DMD) in patients who have a confirmed mutation of the DMD gene that is amenable to exon 53 skipping.

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 *https://www.fda.gov/ForIndustry/DevelopingProductsforRareDiseasesConditions/RarePediatricDiseasePriorityVoucherProgram/default.htm.* For further information about VYONDYS (golodirsen), go to the ''Drugs@FDA'' website at *https://www.accessdata.fda.gov/scripts/cder/daf/.*

Dated: January 16, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–01059 Filed 1–22–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request Information Collection Request Title: Sickle Cell Disease Treatment Demonstration Regional Collaborative Program, OMB No. 0906–xxxx–New

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this ICR should be received no later than March 23, 2020.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 14N136B, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer at (301) 443–1984.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information request collection title for reference.

Information Collection Request Title: Sickle Cell Disease Treatment Demonstration Regional Collaborative Program.

OMB No.: 0906–xxxx–New.

Abstract: The Sickle Cell Disease Treatment Demonstration Regional Collaborative Program (SCDTDRCP) was reauthorized and amended in 2018 by the Sickle Cell Disease and Other Heritable Blood Disorders Research, Surveillance, Prevention, and Treatment Act (Pub. L. 115–327), 42 U.S.C. 300b–5. The purpose of the proposed data collection is to monitor the progress of the SCDTDRCP in improving health outcomes in individuals living with sickle cell disease.

The goals of the program are to improve health outcomes in individuals with sickle cell disease; reduce morbidity and mortality caused by

sickle cell disease; reduce the number of individuals with sickle cell receiving care only in emergency departments; and improve the quality of coordinated and comprehensive services to individuals with sickle cell and their families. The program funds five grantees to establish regional networks to provide leadership and support for regional and statewide activities in sickle cell disease. The grantees develop and establish systemic mechanisms to improve the treatment of sickle cell disease, by: (1) Increasing the number of providers treating individuals with sickle cell disease using the National Heart, Lung and Blood Institute (NHLBI) Evidence-Based Management of Sickle Cell Disease Expert Panel Report; (2) using tele-mentoring, telemedicine and other provider support strategies to increase the number of providers administering evidence-based sickle cell care; and (3) developing and implementing strategies to improve access to quality care with emphasis on individual and family engagement/partnership, adolescent transitions to adult life, and care in a medical home. The SCDTDRCP is designed to improve access to services for individuals with sickle cell disease, improve and expand patient and provider education, and improve and expand the continuity and coordination of service delivery for individuals with sickle cell disease and sickle cell trait. Per the statutory requirement, the data collected will be used to evaluate the program and will be published in a report to Congress.

Need and Proposed Use of the Information: The purpose of the proposed data collection is to monitor the progress of the SCDTDRCP in improving care and health outcomes for individuals living with sickle cell disease/trait and monitor grantee progress in meeting the goals of the program. Each regional grantee will conduct one quality improvement initiative for hydroxyurea utilization among individuals with sickle cell disease. Grantees must conduct an additional quality improvement initiative on one of these topics: (1) Pneumococcal vaccinations, (2) Transcranial Doppler Ultrasound (TCD) screening, or (3) transition planning. Grantees are encouraged to conduct additional clinical outcome quality improvement (QI) initiatives according to their ability. The regional grantees will also survey providers annually to assess provider comfort with treating individuals with sickle cell disease, awareness of the guidelines and involvement in Project ECHO (Extension of Community Health Outcomes) and other program activities. Pursuant to 42 U.S.C. 300b–5(b)(3)(B), the Sickle Cell Disease Treatment Demonstration Regional Collaborative Program's National Coordinating Center (NCC) will work with the grantees to gather data and prepare a Report to Congress at the conclusion of the program. Additional information regarding the data collection activities is below:

Provider Survey

Regional grantees will administer the Provider Survey annually to providers within their region. The Provider Survey is a 13 item questionnaire that collects information on the provider type, their utilization of telementoring, and aggregate de-identified patient-level data. The number of states participating within a region may range from 5 to 17 states. Data from the Provider Survey will be aggregated by the regional grantee and submitted to the NCC.

Quality Improvement

As part of the requirement for funding under the grant, each regional grantee is required to conduct at least two quality improvement initiatives within their region. All grantees are required to conduct a quality improvement initiative on increasing the use of hydroxyurea. Grantees must conduct an additional quality improvement initiative on one of these topics: (1) Pneumococcal vaccinations, (2) TCD screening, or (3) transition planning. Each regional grantee will collect QI data from participating providers and medical centers within their region and aggregate the data for submission to the NCC. Specific quality improvement data will be extracted from patients' charts quarterly, either manually or via electronic health records (EHR). This will require an initial set-up time in year 1 to develop data collection and reporting protocols for manual or electronic collection for the quality improvement project(s) that each regional grantee decides to measure. This initial set-up time has been included in the burden estimates listed in the chart.

Likely Respondents: Providers who treat individuals with sickle cell disease will complete the Provider Survey. The five regional grantees will aggregate these data and submit to the NCC. The grantees will also aggregate data from medical record extraction for the quality improvement initiatives.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purposes of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the tables below:

Provider Survey and QI Measures

TOTAL ANNUAL BURDEN ESTIMATE HOURS

Form name	Number of respondents	Number of responses per respondent per year	Total responses per year	Average burden per response (hrs/yr)	Total burden hours per year
SCDTDP Provider Survey, participant responses	70	1	70	1	70
SCDTDP QI Measures*	50	4	200	22	4,400
Total	120	.....	270	.....	4,470

* **Note:** Total burden hours per year shown represents the maximum number of estimated hours. Actual hours may be lower since many teams will not be assessing all four QI initiatives.

HRSA specifically requests comments on (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.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2020–01075 Filed 1–22–20; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Complementary & Integrative Health; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Center for Complementary and Integrative Health Special Emphasis Panel; Exploratory Clinical Trials of Mind and Body Interventions (MB).

Date: March 10–11, 2020.

Time: 11:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, One Democracy Plaza, 6701 Democracy Boulevard, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Pamela Jeter, Ph.D., Scientific Review Officer, Office of Scientific Review, Division of Extramural Activities, NCCIH, NIH, 6707 Democracy Boulevard, Suite 401, Bethesda, MD 20892–547, 301–435–2591, *pamela.jeter@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.213, Research and Training in Complementary and Alternative Medicine, National Institutes of Health, HHS)

Dated: January 16, 2020.

Ronald J. Livingston, Jr., Program Analyst,

Office of Federal Advisory Committee Policy.

[FR Doc. 2020–01014 Filed 1–22–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director, National Institutes of Health Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Council of Councils, January 24, 2020, 8:15 a.m. to 4:00 p.m., National Institutes of Health, John E. Porter Neuroscience Research Center, Building 35A, Rooms 620/630, 35 Convent Drive, Bethesda, MD 20892 which was published in the **Federal Register** December 16, 2019, 84 FR 68467.

This meeting notice is amended to change the open and closed session meeting times. The morning open session will now be held from 8:15 a.m. to 11:55 a.m.; the closed session will be held from 12:25 p.m.–1:15 p.m.; and the afternoon open session will be held from 1:15 p.m. to 4:00 p.m.

Dated: January 16, 2020.

Ronald J. Livingston, Jr.,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–01028 Filed 1–22–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Environmental Health Sciences; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Advisory Environmental Health Sciences Council.

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.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Advisory Environmental Health Sciences Council.

Date: February 11–12, 2020.

Closed: February 11, 2020, 8:30 a.m. to 9:00 a.m.

Agenda: To review and evaluate grant applications.

Place: Durham Convention Center, Durham Marriott City Center, 301 W Morgan Street, Durham, NC 27701.

Open: February 11, 2020, 9:15 a.m. to 5:00 p.m.

Agenda: Discussion of program policies and issues.

Place: Durham Convention Center, Durham Marriott City Center, 301 W Morgan Street, Durham, NC 27701.

Open: February 12, 2020, 8:30 a.m. to 11:00 a.m.

Agenda: Discussion of program policies and issues.

Place: Durham Convention Center, Durham Marriott City Center, 301 W Morgan Street, Durham, NC 27701.

Contact Person: Patrick Mastin, Ph.D., Chief, Cellular, Organs, and Systems Pathobiology Branch, Division of Extramural Research and Training, National Institute of Environmental Health Sciences, Research Triangle Park, NC 27709, 984–287–3285, *mastin@niehs.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.niehs.nih.gov/dert/c-agenda.htm,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.115, Biometry and Risk Estimation—Health Risks from Environmental Exposures; 93.142, NIEHS Hazardous Waste Worker Health and Safety Training; 93.143, NIEHS Superfund Hazardous Substances—Basic Research and Education; 93.894, Resources and Manpower Development in the Environmental Health Sciences; 93.113, Biological Response to