has verified the applicant's claims that the new drug application (NDA) for ROZLYTREK CAPSULES (NDA 212726) was initially submitted on December 18, 2018.''

Dated: November 14, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–25489 Filed 11–16–23; 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: Scientific Registry of Transplant Recipients Information Collection Effort for Potential Donors for Living Organ Donation, OMB No. 0906–0034—Extension

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

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 January 16, 2024.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 14N39, 5600 Fishers Lane, Rockville, Maryland 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 Joella Roland, the HRSA Information Collection Clearance Officer, at (301) 945–0232.

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

Information Collection Request Title: Scientific Registry of Transplant Recipients Information Collection Effort for Potential Donors for Living Organ Donation, OMB No. 0906–0034—Extension.

Abstract: The Scientific Registry of Transplant Recipients (SRTR) is administered under contract with HRSA, an agency within HHS. HHS is authorized to establish and maintain mechanisms to evaluate the long-term effects associated with living organ donations (42 U.S.C. 273a) and is required to submit to Congress an annual report on the long-term health effects of living donation (42 U.S.C. 273b). In 2018, the SRTR contractor implemented a pilot living donor registry in which transplant programs registered all potential living organ donors who provided informed consent to participate in the pilot registry. The Organ Procurement and Transplantation Network final rule, 42 CFR part 121, requires organ procurement organizations and transplant hospitals, ''as specified from time to time by the Secretary,'' to submit to the SRTR, as appropriate, information regarding ''donors of organs'' and ''other information that the Secretary deems appropriate.'' 42 CFR 121.11(b)(2).

In 2018, a pilot living donor registry was implemented by the SRTR, and each participating transplant program registered all potential candidates for living donation who provided informed consent to enroll. In 2019, an updated version of the data collection instrument was approved, followed by the latest data collection forms which were approved on February 26, 2021. These data collection modifications were intended to improve the quality of the data and reduce the administrative burden for respondents. This **Federal Register** notice requests an extension of the last approved data collection forms (February 2021) with no changes to the total estimated annualized burden hours.

Need and Proposed Use of the Information: The transplant programs submit health information collected at the time of donation evaluation through a secure web-based data collection tool developed by the SRTR contractor. The SRTR contractor maintains contact with registry participants and collects data on long-term health outcomes through surveys. The data collection includes outcomes of evaluation, including reasons for non-donation. The living donor registry is an ongoing effort, and the goal is to continue to collect data on living organ donor transplant programs in the United States over time. Monitoring and reporting of long-term health outcomes of living organ donors post-donation will continue to provide useful information to transplant programs for their future donor selection process and to aid potential living organ donors in their decision to pursue living donation.

Likely Respondents: Potential and actual living donors, transplant programs, medical and scientific organizations, and public organizations, including patient advocacy groups.

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 purpose 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 table below.

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Average number of responses per respondent	Total number of responses	Average burden per response (in minutes)	Total burden hours
Potential Living Donor Registration form	[a] 16	112	1,792	0.27	484
Potential Living Donor Follow-up form	[b] 754	1	754	0.50	377
Reasons Did not Donate form (liver or kidney)	[a] 16	106	1,696	0.23	390

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Form name	Number of respondents	Average number of responses per respondent	Total number of responses	Average burden per response (in minutes)	Total burden hours
Total	786		4,242		1,251

[a] Number of respondents is based on the current number of transplant programs and is likely to increase as additional programs decide to participate.
[b] Number of living organ donor candidates submitting follow-up forms in 2019.

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. 2023–25368 Filed 11–16–23; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Announcement of Intent To Establish Federal Advisory Committee on Long COVID

AGENCY: Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: The Department of Health and Human Services announces the intent to establish an Advisory Committee on Long COVID and invites nominations for the Committee.

DATES: Nominations must be submitted by 11:59 p.m. eastern time on January 16, 2024.

ADDRESSES: Nominations may be submitted by email to *LongCOVID@hhs.gov* and addressed to Allison O'Donnell. 202–690–7694.

FOR FURTHER INFORMATION CONTACT: Allison O'Donnell at 202–690–7694 or *LongCOVID@hhs.gov*.

SUPPLEMENTARY INFORMATION: The Committee is authorized under 42 U.S.C. 217a, section 222 of the Public Health Service Act, as amended. The Committee is governed by the provisions of the Federal Advisory Committee Act, Public Law 92–463, as amended (5 U.S.C. chapter 10), which sets forth standards for the formation and use of advisory committees.

The April 5, 2022, Memorandum (*https://www.whitehouse.gov/briefing-room/presidential-actions/2022/04/05/memorandum-on-addressing-the-long-term-effects-of-covid-19/*) on Addressing the Long-term Effects of COVID–19 charged the Secretary of Health and Human Services (Secretary) with coordinating a Government-wide response to the longer-term effects of COVID–19. The Secretary named the Assistant Secretary for Health to coordinate the U.S. Government response to Long COVID. The Memorandum specified development and publication of two reports that were published August 3, 2022. One of the reports, the National Research Action Plan on Long COVID (*https://www.covid.gov/assets/files/National-Research-Action-Plan-on-Long-COVID-08012022.pdf*), called for the establishment of a Secretary's Advisory Committee on Long COVID. The Committee will bring perspectives from outside the Government to help inform action of the Executive Branch on Long COVID and associated conditions, with a focus on health equity. Numerous entities across the U.S. Government fund and conduct research and use external advisory bodies. This Federal Advisory Committee does not replace or supersede the ongoing work of these advisory bodies.

Structure: The Committee will consist of up to 20 members, including any Chair, Vice Chair, or Co-Chairs. Factors to be considered in selecting individuals to serve on the Committee include expertise in the issues to be examined by the Committee, as well as statutory obligations under FACA and desire for a balanced and diverse membership. To the extent possible, composition of the Committee will reflect the experience of an inclusive and diverse cross-section of persons with Long COVID and multidisciplinary expertise of those supporting and caring for those affected as well as specific clinical, medical, public health, behavioral health, human services, employment, data science, and research expertise. The membership of the Committee will reflect diverse individuals or organizations including underserved populations, with a focus on health equity.

The following areas of expertise will be considered in selecting the voting members with the goal of achieving a balanced membership in terms of points of view, expertise, and groups represented and functions to be performed by the Committee.

Long COVID and related groups: Representation from individuals living with Long COVID and organizations directly engaged in supporting people living with Long COVID.

Professional Associations: Representation from medical professional, behavioral health and human services associations representing practitioners caring for people with Long COVID, including those representing the primary healthcare system.

Disability and Chronic Illness Groups: Representation from associations, researchers, or organizations focused on disability and chronic illness, and their possible interplay with Long COVID.

Public Health and related groups: Representation from public health groups supporting communities in addressing the impacts of Long COVID.

Healthcare and Social Care Providers: Clinical care settings and health systems involved in providing care for patients with Long COVID, including in underserved areas, such as rural communities and communities disproportionately impacted by Long COVID.

Employee and Employer Related Groups: Representation from employee and employer experts, attorneys, or organizations involved in addressing the impacts of Long COVID in the workplace, including discrimination.

Research: Researchers and research institutions involved in Long COVID and associated conditions research.

Non-voting Industry Representatives: Those involved in, or representing those involved in, Long COVID research and development, including prevention, diagnostics, and treatment will be designated to represent the interests of this sector.