requesting a waiver must submit documentation to FDA, including the number of their employees, as well as information that their application is their first human drug application, within the meaning of the FD&C Act, to be submitted to the Agency for approval.

We estimate receiving 22 requests for reconsideration annually (including small business waiver reconsiderations) and assume the average burden for preparing and submitting each request is 24 hours. In addition, we estimate receiving six requests annually for appeal of user fee waiver determinations, and assume the time needed to prepare an appeal is 12 hours. We have included in this estimate both the time needed to prepare the request for appeal to the Chief Scientist and User Fee Appeals Officer within the Office of the Commissioner, and the time needed to create and send a copy of the request for an appeal to the Director Division of User Fee Management within the Office of Management at FDA's Center for Drug Evaluation and Research.

We assume a total of 82 hours of burden for completing and submitting the 164 forms FDA 3397 (Prescription Drug User Fee Coversheet) along with submission of NDAs or BLAs. The burdens associated with submission of NDAs and BLAs are included in OMB control numbers 0910–0001 and 0910–0338, respectively.

The information collection reflects changes and adjustments. We have clarified that the scope of the collection includes provisions found in our current commitment goals letter, negotiated with industry, pertaining to the assessment of fees, waivers, refunds, and exemptions under PDUFA VII. Cumulatively these changes and adjustments have resulted in an increase of three responses and 203 burden hours annually since the prior renewal of the information collection. We attribute this to the steady state of incoming requests for waivers and reconsiderations and normal fluctuations in types of submissions or waivers received.

Dated: October 30, 2024.

Kimberlee Trzeciak,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2024–26801 Filed 11–15–24; 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: Generic Information Collection Request for Health Resources and Services Administration Hotlines, Chatlines, and Online Portals

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 January 17, 2025.

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) 443–3983.

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

Information Collection Request Title: Generic Information Collection Request for Collections Related to HRSA Hotlines, Chatlines, and Online Portals, OMB No. 0906–New.

Abstract: HRSA currently administers approximately 15 hotlines, chatlines, and online portals for use by customers, members of the public, and HRSA funding recipients. These hotlines, chatlines, and online portals are administered by HRSA or a contractor on behalf of HRSA. The purpose of information collections under this generic umbrella ICR package is to allow HRSA to collect information on the operation of such HRSA hotlines, chatlines, and online portals to assist HRSA in improving their operation and determining if these services are helpful. In addition to collecting basic demographic information, the information collections would include questions such as reasons for inquiry, topics covered by inquiry, feedback on provided guidance or the hotline/chatline/online portal user experience. No protected information, such as personal health information or trade secrets, will be disclosed unless specifically required by law.

An illustrative, but not exhaustive, list of examples of information collection activities that would fall under this collection include standardized questions that are asked during the interaction with the public; surveys about their interaction; and information collected about their experience in use of hotlines, chatlines, and online portals. This generic umbrella ICR covers responses to standardized and survey questions relating to public use of HRSA's hotlines, chatlines, and online portals, pursuant to the ''Social Media, Web-Based Interactive Technologies, and the Paperwork Reduction Act'' 2010 White House guidance memo. The memo can be found at: *https://www.whitehouse.gov/wp-content/uploads/legacy_drupal_files/omb/assets/inforeg/SocialMediaGuidance_04072010.pdf.*

Need and Proposed Use of the Information: The purpose of collections under this generic umbrella ICR is for accountability, program management, and oversight purposes. Collecting feedback from members of the public about their interaction with these services will help ensure that HRSA hotlines, chatlines, and online portals are operating to the best of their abilities. While HRSA can evaluate the general need for and the overall practical utility of such information collection in advance, HRSA is unable to determine the details of the specific individual collection methodologies until a later time. Using a generic umbrella ICR will allow HRSA to quickly and nimbly respond to public needs and efficiently provide vital services to grantees and the general public, as the standard 6 to 9 month timeline to comply with a full request under the Paperwork Reduction Act could inhibit HRSA's ability to collect information to inform these activities that involve rapid updates to be responsive to their users. The information collected is expected to be voluntary and low-burden. Therefore, a generic umbrella ICR clearance is requested to allow for quick turnaround

requests for similar information collections related to these activities.

As this generic umbrella ICR will focus on the awareness, understanding, attitudes, preferences, or experiences of customers or other stakeholders relating to HRSA-funded hotlines, chatlines, or portals, the Fast Track Process should apply to this information collection. Therefore, HRSA also requests OMB provide a response on individual information collection requests within the scope of this generic ICR within 5 business days.

Likely Respondents: The most likely respondents include users of a HRSA-funded hotline, chatline, or portal. These users may include members of the public and public or private entities who receive HRSA funding. Responses to any information collections under this generic umbrella ICR are not required to obtain or retain any benefit.

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. HRSA conducted this estimate based on reviewing hotline and chatline scripts along with online portals, in addition to reviewing the burden estimates of forms from previous HRSA customer service surveys, which were approved under other umbrella or regular packages.

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS

Instrument name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Standardized Hotline Interaction	100,000	1	100,000	0.17	17,000.00
Standardized Chatline Interaction	100,000	1	100,000	0.17	17,000.00
Online Portal Submission	10,000	1	10,000	0.067	670.00
Follow-Up Surveys	51,750	1	51,750	0.083	4,295.25
Total	261,750		261,750		38,965.25

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. 2024–26742 Filed 11–15–24; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings 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: Center for Scientific Review Special Emphasis Panel; PAR–23–137: Science Education Partnership Award (SEPA) R25.

Date: December 11–12, 2024.

Time: 9:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: James J Li, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5148, MSC 7849, Bethesda, MD 20892, 301–806–8065, *lijames@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Drug Discovery for Aging, Neurodegenerative and Neurological Disorders—Panel B.

Date: December 11, 2024.

Time: 9:00 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health Rockledge II, 6701 Rockledge Drive Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Kathryn Partlow, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 1016D, Bethesda, MD 20892 (301) 594–2138 *partlowkc@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Specialized Centers of Research Excellence (SCORE) on Sex Differences.

Date: December 11–12, 2024.

Time: 10:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Elaine Sierra-Rivera, Ph.D. IRG Chief Center for Scientific Review National Institutes of Health 6701 Rockledge Drive, Room 6182 Bethesda, MD 20892 (301) 435–2514 *riverase@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business-Anti-Infective Therapeutics.

Date: December 11–12, 2024.

Time: 10:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Marcus Ferrone, PHARMD Scientific Review Officer Center for Scientific Review National Institutes of Health 6701 Rockledge Drive Bethesda, MD 20892 (301) 402–2371 *marcus.ferrone@nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Molecular Oncology.

Date: December 11, 2024.

Time: 11:00 a.m. to 6:30 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).