Ave., Bldg. 51, Rm. 6226, Silver Spring, MD 20993, 301–796–3137, *Kimberly.Lehrfeld@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: On June 30, 1999, FDA approved ANDA 075286 for pemoline tablets, 18.75 mg, 37.5 mg, and 75 mg, for the conditions of use in the labeling of new drug application (NDA) 016832, the reference listed drug on which it relied. On October 24, 2005, the Agency issued a Postmarket Drug Safety Information for Patients and Providers communication entitled ''Information for Healthcare Professionals: Pemoline Tablets and Chewable Tablets (Marketed as CYLERT)'' which concluded the overall liver toxicity risk of CYLERT (pemoline) (NDAs 016832 and 017703) and generic pemoline products outweighed the benefits of these products (*https://wayback.archive-it.org/7993/20171114124349/https://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm126461.htm*).

All holders of approved applications for pemoline products, including Fosun, ceased marketing the products at that time. On April 22, 2019, Fosun requested that FDA withdraw approval of ANDA 075286, pursuant to § 314.150(d) (21 CFR 314.150(d)) and waived its opportunity for a hearing.

For the reasons discussed above, and in accordance with the applicant's request, approval of ANDA 075286 for pemoline tablets, 18.75 mg, 37.5 mg, and 75 mg, and all amendments and supplements thereto, is withdrawn under § 314.150(d). Distribution of pemoline tablets, 18.75 mg, 37.5 mg, and 75 mg, into interstate commerce without an approved application is illegal and subject to regulatory action (see sections 505(a) and 301(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(a) and 331(d))).

Dated: March 1, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–04564 Filed 3–6–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; Rural Health Network Development Planning Program

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

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, HRSA submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period. OMB may act on HRSA's ICR only after the 30-day comment period for this notice has closed.

DATES: Comments on this ICR should be received no later than April 6, 2023.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email Samantha Miller, the HRSA Information Collection Clearance Officer, at *paperwork@hrsa.gov* or call (301) 594–4394.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: The Rural Health Network Development Planning Performance Improvement and Measurement System Database OMB No. 0915–0384—Revision.

Abstract: The purpose of the Rural Health Network Development Planning Program (Network Planning Program) is to promote the planning and development of integrated health care networks to address the following legislative aims: (i) achieve efficiencies; (ii) expand access to, coordinate, and improve the quality of basic health care services and associated health outcomes; and (iii) strengthen the rural health care system. This program supports 1 year of planning and brings together key parts of a rural health care delivery system, particularly those entities that may not have collaborated in the past, to establish and/or improve local capacity in order to strengthen rural community health interventions and enhance care coordination. HRSA collects information from the Network Planning Program award recipients using approved performance measures. HRSA seeks to revise its approved information collection by increasing the total estimated annual burden hours, due to an increase in the number of program award recipients.

A 60-day notice was published in the **Federal Register** on December 9, 2022, vol. 87, No. 236; pp. 75638–39. There were no public comments.

Need and Proposed Use of the Information: Performance measures for the Network Planning Program serve the purpose of quantifying awardee-level data that conveys the successes and challenges associated with the grant award. These measures and aggregate data substantiate and inform the focus and objectives of the grant program. The approved measures encompass the following principal topic areas: network infrastructure, network collaboration, sustainability, and network assessment. The burden is increasing by 2 hours from the previously approved collection due to an increase in the number of award recipients from 21 to 23.

Likely Respondents: The respondents for these measures are Rural Health Network Development Planning Program award recipients.

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	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Rural Health Network Development Planning Program Performance Improvement Measurement System	23	1	23	1	23
Total	23		23		23

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. 2023–04585 Filed 3–6–23; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; 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 Institute on Aging Special Emphasis Panel; Dementia Care.

Date: March 28, 2023.

Time: 9:00 a.m. to 12:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Dario Dieguez, Ph.D., Scientific Review Officer, National Institutes of Health, National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Bethesda, MD 20892, (301) 827–3101, *dario.dieguez@nih.gov*.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: March 2, 2023.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023–04621 Filed 3–6–23; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; 30-Day Comment Request; NCI Genomic Data Commons (GDC) Data Submission Request Form (National Cancer Institute)

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below.

DATES: Comments regarding this information collection are best assured of having their full effect if received within 30 days of the date of this publication.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or using the search function.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Jean Claude Zenklusen, Ph.D., Scientific Program Director, Center for Cancer Genomics (CCG), National Cancer Institute, Building 31 Room 3A20, 31 Center Drive, Bethesda MD 20814 or call the non-toll-free number 301–781–3409 or Email your request, including your address to: *Jean.Zenklusen@nih.gov.*

SUPPLEMENTARY INFORMATION: This proposed information collection was previously published in the **Federal Register** on November 7, 2022, page 67049 (Vol. 87 No. 215 FR 67049 and allowed 60 days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment.

The National Cancer Institute (NCI), National Institutes of Health, may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

In compliance with Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below.

Proposed Collection: NCI Genomic Data Commons (GDC) Data Submission Request Form, 0925–0752, Expiration Date 3/31/2023, EXTENSION, National Cancer Institute (NCI), National Institutes of Health (NIH).

Need and Use of Information Collection: The purpose of the NCI Genomic Data Commons (GDC) Data Submission Request Form is to provide a vehicle for investigators to request the submission of their cancer genomic data into the GDC in support of data sharing. The purpose is also to provide a mechanism for the GDC Data Submission Review Committee to review and assess the data submission request for applicability to the GDC mission. The scope of the form involves obtaining information from investigators that: (1) would like to submit data about their study into the GDC, (2) are affiliated with studies that adhere to GDC data submission conditions. The benefits of the collection are that it provides the needed information for investigators to understand the types of