ingredients) meet certain ''time and extent'' criteria outlined in the regulations. The regulations in § 330.14 allow a sponsor to submit certain information to the Agency in a time and extent application (TEA) for use to determine eligibility of a condition for consideration in the OTC monograph system.

We developed the final guidance document entitled ''Time and Extent Applications for Nonprescription Drug Products'' (September 2011) (available from our website at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/time-and-extent-applications-nonprescription-drug-products*) to assist respondents with the information collection provisions found in the regulations. The guidance was issued consistent with our good guidance practice regulations at 21 CFR 10.115, which provide for comment at any time. The guidance explains what information an applicant should submit to the Agency to request that a drug product be included in the OTC drug monograph system. The guidance also discusses format and content elements, and the process for submitting information, consistent with the applicable regulations.

II. OTC Monograph Reform in the Coronavirus Aid, Relief, and Economic Security Act

The Coronavirus Aid, Relief, and Economic Security Act (CARES Act (Pub. L. 116–136, Stat. 281)) signed March 27, 2020, included provisions that govern the way certain OTC drugs are regulated in the United States. The CARES Act added section 505G to the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355h), which reforms and modernizes the OTC drug review process, including establishing new procedures for consideration of additions or changes to conditions covered in OTC monographs. As a result of these revised statutory provisions, we anticipate no submissions under § 330.14. Our OTC Monographs@FDA portal (*https://dps.fda.gov/omuf*) provides additional information about OTC monograph drugs and the OTC drug review process.

Consistent with section 505G(k)(3) of the FD&C Act, we plan to withdraw the regulations supporting the TEA provisions in part 330 and discontinue the related guidance document. When these actions occur, we will also request discontinuation of the information collection approved under OMB control number 0910–0688.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section; activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
§ 330.14(c) and (d); Time and extent application and submission of information.	1	~1.29	1.29	861.78 hours (861 hours and 47 minutes).	1,112
§ 330.14(f) and (i); Submission of safety and effectiveness data, including data and information listed in § 330.10(a)(2), a listing of all serious adverse drug experiences that may have occurred (§ 330.14(f)(2)), and an official or proposed compendial monograph (§ 330.14(i)).					
§ 330.14(j) and (k); Submitter correspondence with FDA.					

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

As previously stated, as a result of the CARES Act statutory provisions described above, we anticipate no TEA submissions. For purposes of burden calculation, we assume one respondent as a placeholder. The burden we attribute to reporting activities is assumed to be distributed among the individual elements.

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–12884 Filed 6–25–26; 8:45 am]

BILLING CODE 4164–01–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: Population Sciences and Epidemiology Integrated Review Group; Population based Research in Infectious Disease Study Section.

Date: July 21, 2026.

Time: 9:30 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.

Meeting Format: Virtual Meeting.

Contact Person: James T. Snyder, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, 301–443–7414, *snyderji@csr.nih.gov.*

Name of Committee: Risk, Prevention and Health Behavior Integrated Review Group; HIV/AIDS Intra- and Interpersonal Determinants and Behavioral Interventions Study Section.

Date: July 21–22, 2026.

Time: 9:30 a.m. to 5:30 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, M.D. 20892.

Meeting Format: Virtual Meeting.
Contact Person: Xinli Nan, M.D., Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, 301–594–6295, *Xinli.Nan@nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Cellular to Systems Neuroscience of Learning, Decision-Making, and Cognitive Dysfunction.
Date: July 21, 2026.
Time: 9:30 a.m. to 7:30 p.m.
Agenda: To review and evaluate grant applications.
Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.
Meeting Format: Virtual Meeting.
Contact Person: Rekha Dhanwani, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, 301–451–1323, *rekha.dhanwani@nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Drug and Therapy Development in Neurological Disorders.
Date: July 21, 2026.
Time: 9:30 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.
Meeting Format: Virtual Meeting.
Contact Person: Milene Lara Brownlow, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, 301–480–7449, *milene.brownlow@nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; RFA Panel: Topics in HIV and Substance Use Disorder, SCORCH, Data Mining and Functional Validation, Mitochondria, Neuropathology and Immunodeficient Aging.
Date: July 21–22, 2026.
Time: 10:00 a.m. to 6:00 p.m.
Agenda: To review and evaluate grant applications.
Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.
Meeting Format: Virtual Meeting.
Contact Person: Kristina S. Wickham, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, 301–594–2490, *kristina.wickham@nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Skeletal Muscle and Rehabilitation Sciences.
Date: July 21, 2026.
Time: 10:00 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.
Meeting Format: Virtual Meeting.
Contact Person: Richard Ingraham, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4116, MSC 7814, Bethesda, MD 20892, 301–496–8551, *ingrahamrh@mail.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Immune Mechanisms of Rheumatology.
Date: July 21–22, 2026.
Time: 10:00 a.m. to 6:00 p.m.
Agenda: To review and evaluate grant applications.
Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.
Meeting Format: Virtual Meeting.
Contact Person: Lindsey M. Pujanandez, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, 301–594–2861, *lindsey.pujanandez@nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Molecular, Cellular Sciences and Bioanalytical Technologies.
Date: July 21, 2026.
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.
Meeting Format: Virtual Meeting.
Contact Person: John Harold Laity, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, 301–402–8254, *laityjh@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR Panel: Maximizing Investigators' Research Award.
Date: July 21–22, 2026.
Time: 10:00 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.
Meeting Format: Virtual Meeting.
Contact Person: Laureen Elizabeth Connell, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 710K, Bethesda, MD 20892, 301–480–3629, *connelle@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Virology.
Date: July 21, 2026.
Time: 10:00 a.m. to 4:00 p.m.
Agenda: To review and evaluate grant applications.
Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.
Meeting Format: Virtual Meeting.
Contact Person: Seyhan Boyoglu Barnum, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, 301–480–1446, *seyhan.boyoglu-barnum@nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Fellowships: Neural Basis of Substance Use, Reward, and Motivated Behavior.
Date: July 21–22, 2026.
Time: 10:00 a.m. to 6:00 p.m.
Agenda: To review and evaluate grant applications.
Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.
Meeting Format: Virtual Meeting.
Contact Person: Caitlin Elizabeth Angela Moyer, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, 301–594–7880, *caitlin.moyer@nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR Panel: Musculoskeletal, Oral, and Rehabilitation Sciences.
Date: July 22, 2026.
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.
Meeting Format: Virtual Meeting.
Contact Person: Yi-Hsin Liu, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, 301–435–1781, *liuyh@csr.nih.gov.*

Name of Committee: Aging and Neurodegeneration Integrated Review Group Cognitive Disorders and Brain Aging Study Section.
Date: July 22, 2026.
Time: 9:00 a.m. to 6:00 p.m.
Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Simone Chebabo Weiner, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 1011K, Bethesda, MD 20892, 301–594–3694, *weinersc@csr.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: June 23, 2026.

Rosalind M. Niamke,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2026–12877 Filed 6–25–26; 8:45 am]

BILLING CODE 4167–05–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Submission for Office of Management and Budget Review (OMB); Comment Request

AGENCY: Substance Abuse and Mental Health Services Administration (SAMHSA), Department of Health and Human Services.

ACTION: Notice.

Proposed Project: Evaluation of the Projects for Assistance in Transition from Homelessness (PATH) Program (OMB No. 0930–0381)—Reinstatement

Periodically, SAMHSA will publish a summary of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these documents, email the SAMHSA Reports Clearance Officer at: *samhsapra@samhsa.hhs.gov.*

SAMHSA is conducting the federally mandated Evaluation of the PATH program. The PATH grant program, created as part of the Stewart B. McKinney Homeless Assistance Amendments Act of 1990, is administered by SAMHSA's Center for Mental Health Services' Division of State and Community Systems Development. The PATH program is authorized under Section 521 *et seq.* of the Public Health Service (PHS) Act, as amended. The SAMHSA PATH program funds each fiscal year the 50 states, the District of Columbia, Puerto Rico, and four U.S. Territories (the U.S. Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands). The PATH grantees make grants to local, public and non-profit organizations to provide PATH-allowable services.

The SAMHSA Assistant Secretary is required under Section 528 of the PHS Act to evaluate the expenditures of PATH grantees at least once every 3 years to ensure they are consistent with legislative requirements and to recommend changes to the program design or operations.

The primary task of the PATH evaluation is to meet the mandates of Section 528 of the PHS Act. The second task of the PATH evaluation is to conduct additional data collection and analysis to further investigate the sources of variation in key program output and outcome measures that are important for program management and policy development. The PATH evaluation builds on the previous evaluation which was finalized in 2016 and was conducted as part of the National Evaluation of SAMHSA Homeless Programs. Previously, the data collections activities also included PATH Intermediary Web Survey, a PATH Provider Web Survey, and a PATH Telephone Interview Guide. The current PATH evaluation will be limited to the State PATH Contact (SPC) Web Survey and PATH Site Visit Discussion Guides to facilitate the collection of information regarding the structures and processes in place at the grantee and provider level. The current PATH evaluation will use web surveys and site visits to facilitate the collection of information regarding the structures and processes in place at the grantee and provider level. Data regarding the outputs and outcomes of the PATH program will be obtained from grantee applications, providers' intended use plans and from PATH annual report data, which is also required by Section 528 of the PHS Act and is approved under OMB No. 0930–0205.

Web Surveys will be conducted with all SPCs. The Web Surveys will capture detailed and structured information in the following topics: selection, monitoring, and oversight of PATH providers; populations served; the PATH services provided; provision of training and technical assistance; implementation of Evidence Based Practices and innovative practices including the Supplemental Security Income/Social Security Disability Insurance Outreach, Access, and Recovery program; data reporting, use of data and the Homeless Management Information System; and collaboration, coordination and involvement with Continuums of Care and other organizations. The SPCs for all grantees (56) will be contacted to complete the web surveys. The Web Surveys will be administered once per triennial evaluation cycle.

Site Visits will be conducted with a purposive sample of PATH grantees and providers to collect more nuanced information than will be possible with the web survey. Semi-structured discussions will take place with the SPCs, grantee staff, PATH provider staff, outreach workers, case managers and other clinical treatment staff, and consumers. Five grantees will be selected for Site Visits and visited within each grantee will be one to two PATH providers. The Site Visits will be utilized to collect information on: provider and state characteristics; practices and priorities; context within which the grantees and providers operate; and services available within the areas the providers operate. The successes, barriers, and strategies faced by PATH grantees and providers will also be discussed. Focus groups will be held with current or former consumers of the PATH program to obtain consumer perspectives regarding the impact of the programs. The Site Visits will be conducted once per triennial evaluation cycle.

The estimated burden for the reporting requirements for the PATH evaluation is summarized in the table below.

ANNUAL BURDEN TABLE

Instrument/activity	Number of respondents	Responses per respondent	Total responses	Hours per response	Total hour burden	Hourly wage rate ($)	Total hour cost ($)
Web Surveys:	.....	.....	.....	.....	.....	.....	.....
SPC Web Survey ..	56	1	56	1	56	$37.61	$2,106.16
Site Visit Interviews:							