

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Educational Developers (Health Educators)	Continuing Education (CE) Proposal	130	1	5
Public Health and Health Care Professionals (Learners).	CDC TRAIN Post-Course Evaluation ...	250,000	2	15/60
Public Health and Health Care Professionals (Learners).	CDC TRAIN Follow-up Evaluation	20,000	2	3/60

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Public Health Ethics and Regulations, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2025-16914 Filed 9-3-25; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-25-1313; Docket No. CDC-2025-0387]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other federal agencies the opportunity to comment on a continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled Distribution of Traceable Opioid Material® Kits (TOM® Kits) across U.S. and International Laboratories. The purpose of this information collection request (ICR) is for the CDC to assure that the Traceable Opioid Material® Kits (TOM® Kits) are equitably distributed to domestic and international partner laboratories, and to allow CDC to understand the types of laboratories requesting these materials and the analyses that are being conducted.

DATES: CDC must receive written comments on or before November 3, 2025.

ADDRESSES: You may submit comments, identified by Docket No. CDC-2025-0387 by either of the following methods:

- *Federal eRulemaking Portal:* www.regulations.gov. Follow the instructions for submitting comments.

- *Mail:* Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS H21-8, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to www.regulations.gov.

Please note: Submit all comments through the Federal eRulemaking portal (www.regulations.gov) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS H21-8, Atlanta, Georgia 30329; Telephone: 404-639-7570; Email: omb@cdc.gov.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

3. Enhance the quality, utility, and clarity of the information to be collected;

4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses; and

5. Assess information collection costs.

Proposed Project

Distribution of Traceable Opioid Material® Kits (TOM® Kits) across U.S. and International Laboratories (OMB Control No. 0920-1313, Exp. 3/31/2026)—Extension—National Center for Environmental Health (NCEH), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The purpose of this information collection request (ICR) is for the CDC to assure that the Traceable Opioid Material® Kits (TOM® Kits) are equitably distributed to domestic laboratory sectors (public, private, and non-profit) and to international partner laboratories. This collection will enable CDC to gather information on the types of laboratories requesting Traceable Opioid Material® Kits and to determine the types of sample analyses that are being conducted by these laboratories through use of these kits.

CDC requests OMB approval for an estimated 80 annual burden hours. There is no cost to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
U.S. Federal Laboratories	Test Kit Application and Questions for U.S. Laboratories (online).	200	1	6/60	20
State, Local, and Tribal Government Laboratories.	Test Kit Application and Questions for U.S. Laboratories (online).	200	1	6/60	20
Private or Not-for-Profit U.S. Institutions	Test Kit Application and Questions for U.S. Laboratories (online).	200	1	6/60	20
International Laboratories	Test Kit Questions for International Laboratories	300	1	5/60	20
Total	80

Jeffrey M. Zirger,
Lead, Information Collection Review Office, Office of Public Health Ethics and Regulations, Office of Science, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2025-N-0124]

Bausch & Lomb Incorporated, et al.; Withdrawal of Approval of Eight Abbreviated New Drug Applications; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** on March 14, 2025 (90 FR 49), appearing on page 12163 in FR Doc. 2025-04106. The document announced the withdrawal of approval of eight abbreviated new drug applications (ANDAs) from multiple applicants, withdrawn as of April 14, 2025. The document indicated that FDA was withdrawing approval of the ANDA 075819 for amantadine hydrochloride syrup, 50 milligrams/5 milliliters, held by CMP Pharma, Inc., 8026 East Marlboro Rd., P.O. Box 147, Farmville, NC 27828. Before FDA withdrew the approval of this ANDA, CMP Pharma, Inc., 8026 East Marlboro Rd., P.O. Box 147, Farmville, NC 27828, informed FDA that they did not want the approval of the ANDA withdrawn. Because CMP Pharma, Inc., timely requested that approval of the ANDA not be withdrawn, the approval is still in effect. This notice corrects this error.

FOR FURTHER INFORMATION CONTACT: Martha Nguyen, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New

Hampshire Ave., Bldg. 75, Rm. 1676, Silver Spring, MD 20993-0002, 301-796-3471, Martha.Nguyen@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of Friday, March 14, 2025 (90 FR 49), appearing on page 12163 in FR Doc. 2025-04106, the following correction is made:

On page 12163, in the table, the entry for ANDA 075819 is removed.

Grace R. Graham,
Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025-16905 Filed 9-3-25; 8:45 am]

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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; Program Projects: Translational Cancer Research SPORE P50.

Date: October 1-2, 2025.

Time: 9:00 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.

Meeting Format: Virtual Meeting.

Contact Person: Amr M. Ghaleb, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, 240-276-6002, amr.ghaleb@nih.gov.

Name of Committee: Musculoskeletal, Oral and Skin Sciences Integrated Review Group; Oral, Dental and Craniofacial Sciences Study Section.

Date: October 7-8, 2025.

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: Yi-Hsin Liu, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4214, MSC 7814, Bethesda, MD 20892, 301-435-1781, liuyh@csr.nih.gov.

Name of Committee: Musculoskeletal, Oral and Skin Sciences Integrated Review Group; Musculoskeletal Rehabilitation Sciences Study Section.

Date: October 9-10, 2025.

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: Richard Michael Lovering, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 1000J, Bethesda, MD 20892, 301-867-5309, loveringrm@mail.nih.gov.

Name of Committee: Surgical Sciences, Biomedical Imaging and Bioengineering Integrated Review Group; Imaging Probes and Contrast Agents Study Section.

Date: October 9-10, 2025.

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: Krystyna H. Szymczyk, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, 301-480-4198, szymczyk@csr.nih.gov.