

approved drugs. FDA publishes this list as part of the “Approved Drug Products With Therapeutic Equivalence Evaluations,” which is known generally as the “Orange Book.” Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug’s NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

FENOGLIDE (fenofibrate) tablets, 40 mg and 120 mg, is the subject of NDA 022118, held by Salix Pharmaceuticals, Inc., and initially approved on August 10, 2007. FENOGLIDE is indicated as an adjunct to diet to reduce triglyceride (TG) levels in adults with severe hypertriglyceridemia (TG greater than or equal to 500 mg/deciliter (dL)) and to reduce elevated low-density lipoprotein cholesterol (LDL-C) in adults with primary hyperlipidemia when use of recommended LDL-C lowering therapy is not possible.

In a letter dated September 9, 2024, Salix Pharmaceuticals, Inc. notified FDA that FENOGLIDE (fenofibrate) tablets, 40 mg and 120 mg, was being discontinued, and FDA moved the drug product to the “Discontinued Drug Product List” section of the Orange Book.

Foley & Lardner LLP submitted a citizen petition dated January 21, 2026 (Docket No. FDA-2026-P-0655), under 21 CFR 10.30, requesting that the Agency determine whether FENOGLIDE (fenofibrate) tablets, 40 mg and 120 mg, was withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that FENOGLIDE (fenofibrate) tablets, 40 mg and 120 mg, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that this drug product was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of

FENOGLIDE (fenofibrate) tablets, 40 mg and 120 mg, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have reviewed the available evidence and determined that this drug product was not withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list FENOGLIDE (fenofibrate) tablets, 40 mg and 120 mg, in the “Discontinued Drug Product List” section of the Orange Book. The “Discontinued Drug Product List” delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. FDA will not begin procedures to withdraw approval of approved ANDAs that refer to this drug product. Additional ANDAs for this drug product may also be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

**Grace R. Graham,**

*Deputy Commissioner for Policy, Legislation, and International Affairs.*

[FR Doc. 2026-08390 Filed 4-29-26; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Submission for OMB Review; 30-Day Comment Request Application and Impact of Clinical Research Training on Healthcare Professionals in Academia and Clinical Research (Office of the Director)

**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 by June 1, 2026.

**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](http://www.reginfo.gov/public/do/PRAMain). Find this particular information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by 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: Dr. Ahmed M. Gharib, Program Director, Office of Clinical Research Education and Collaboration Outreach, OD, NIH, Building 1, Room 201, 1 Center Drive, Bethesda, MD 20892, or email your request, including your address to: [ocreco-education@mail.nih.gov](mailto:ocreco-education@mail.nih.gov).

**SUPPLEMENTARY INFORMATION:** This proposed information collection was previously published in the **Federal Register** on Thursday, December 4, 2025, Volume 90, pages 55871–55873 (64 FR 16184) and allowed 60 days for public comment. One public comment was received. The purpose of this notice is to allow an additional 30 days for public comment. The Office of Clinical Research Education and Collaboration Outreach, Office of the Director, 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:* Application and Impact of Clinical Research Training on Healthcare Professionals in Academia and Clinical Research, 0925–0764-expiration date, 07/31/2027, Revision, Office of Clinical Research Education and Collaboration Outreach (OCRECO), National Institutes of Health (NIH), Office of the Director (OD).

*Need and Use of Information Collection:* The purpose of this survey is to assess the long-term impact and outcomes of clinical research training programs provided by the Office of Clinical Research Education and Collaboration Outreach located in the Office of Intramural Research (OIR), in the NIH Office of the Director (OD) over a ten-year follow-up period. The information received from respondents will provide insight on the following: impact of the courses on (a) promotion of professional competence, (b) research

productivity and independence, and (c) future career development within clinical, translational and academic research settings. These surveys will provide preliminary data and guidance in (1) developing recommendations for collecting outcomes to assess the

effectiveness of the training courses, and (2) tracking the impact of the curriculum on participants' ability to perform successfully in academic, non-academic, research, and non-research settings.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 2,725.

ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Type of respondents	Estimated number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total annual burden hours
OCRECO Learning Portal Registration (Attachment 1).	Healthcare Professionals .....	5,000	1	5/60	417
	General Public .....	15,000	1	5/60	1,250
IPPCR Lecture Evaluation (Attachment 2) ...	Healthcare Professionals .....	2,000	1	5/60	167
	General Public .....	5,000	1	5/60	417
IPPCR Final Course Evaluation (Attachment 4).	Healthcare Professionals .....	300	1	5/60	25
	General Public .....	500	1	5/60	42
PCP Lecture Evaluation (Attachment 3) .....	Healthcare Professionals .....	1,000	1	3/60	50
	General Public .....	3,000	1	3/60	150
PCP Final Course Evaluation (Attachment 5).	Healthcare Professionals .....	200	1	3/60	10
	General Public .....	400	1	3/60	20
NIH Summer Course in Clinical and Translational Research Course Evaluation (Attachment 6).	Healthcare Professionals .....	20	1	5/60	2
	General Public .....	20	1	5/60	2
Sabbatical in Clinical Research Management Course Evaluation (Attachment 7).	Healthcare Professionals .....	20	1	5/60	2
	General Public .....	20	1	5/60	2
Ethical and Regulatory Aspects of Clinical Research (Asynchronous/Online) Final Course Evaluation (Attachment 8).	Healthcare Professionals .....	500	1	5/60	25
	General Public .....	1,000	1	3/60	50
Clinical Research Curriculum Certificate Program Application (Attachment 10).	Healthcare Professionals .....	100	1	5/60	8
Radiology Research Certificate Program Application (Attachment 10).	Healthcare Professionals .....	20	1	5/60	2
Generic Lecture Evaluation (Attachment 11)	Healthcare Professionals .....	500	1	3/60	25
	General Public .....	1,000	1	3/60	50
Generic Final Course Evaluation (Attachment 12).	Healthcare Professionals .....	100	1	3/60	5
	General Public .....	150	1	3/60	8
Total .....	.....	.....	35,810	.....	2,725

Dated: April 24, 2026.  
**Matthew J. Memoli,**  
*Principal Deputy Director, National Institutes of Health.*  
 [FR Doc. 2026-08461 Filed 4-29-26; 8:45 am]  
**BILLING CODE 4167-05-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**  
**National Institutes of Health**  
**Proposed Collection; 60-Day Comment Request; NIH Office of Intramural Training & Education—Application, Registration, and Alumni Systems Office of the Director**  
**AGENCY:** National Institutes of Health, HHS.  
**ACTION:** Notice.

**SUMMARY:** In compliance with the requirement of the Paperwork Reduction Act of 1995 to provide

opportunity for public comment on proposed data collection projects, the National Institutes of Health Office of Intramural Training & Education (OITE) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

**DATES:** Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

**FOR FURTHER INFORMATION CONTACT:** To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Dr. Patricia Wagner, Program Analyst, Office of Intramural Training & Education (OITE), Office of Intramural Research (OIR), Office of the Director (OD), National Institutes of Health (NIH); 2 Center Drive: Building 2/Room

2E06; Bethesda, Maryland 20892 or call non-toll-free number 240-476-3619 or email your request, including your address to: *pat.wagner@nih.gov*. Formal requests for additional plans and instruments must be requested in writing.

**SUPPLEMENTARY INFORMATION:** Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires: written comments and/or suggestions from the public and affected agencies are invited to address one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) 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) Ways to enhance the quality, utility, and