

Commissioner of Food and Drugs will enter summary judgment against the person who requests the hearing, making findings and conclusions, and denying a hearing.

If you choose to submit confidential information under this notice of opportunity for a hearing, it must be a paper submission filed in two copies. Except for data and information prohibited from public disclosure under 21 U.S.C. 331(j) or 18 U.S.C. 1905, the submissions may be seen at the Dockets Management Staff (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <https://www.regulations.gov>.

This notice is issued under section 505(e) of the FD&C Act, 21 CFR part 314, and under authority delegated to the Director of CDER by the Commissioner of Food and Drugs.

III. References

The following references marked with an asterisk (*) are on display at the Dockets Management Staff (see **ADDRESSES**¹) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at <https://www.regulations.gov>. References without asterisks are not on public display at <https://www.regulations.gov> because they have copyright restriction. Some may be available at the website address, if listed. References without asterisks are available for viewing only at the Dockets Management Staff. Although FDA verified the website addresses in this document, please note that websites are subject to change over time.

1. Jayne, D., P. Merkel, T. Schall, et al., 2021, "Avacopan for the Treatment of ANCA-Associated Vasculitis," *NEJM*, 384(7): 599–609, available at <https://pubmed.ncbi.nlm.nih.gov/33596356/> (accessed Apr. 24, 2026).
2. * FDA, "Arthritis Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments," 86 FR 16227 (Mar. 26, 2021), available at <https://www.federalregister.gov/documents/2021/03/26/2021-06265/arthritis-advisory-committee-notice-of-meeting-establishment-of-a-public-docket-request-for-comments> (accessed Apr. 24, 2026).
3. * Expert Report of Marc Walton, MD Ph.D., Sept. 25, 2024, *Homyk v. ChemoCentryx, Inc.*, Case No. 4:21-cv-03343 (N.D. Ca).
4. * Amgen, Inc., "Response to FDA Requests Dated Jul. 23, 2025." NDA 214487, Aug. 22, 2025.
5. * ChemoCentryx, Inc., "Protocol" CL010_168, Amendment 4.0, Jan. 18, 2016, available at https://cdn.clinicaltrials.gov/large-docs/27/NCT02994927/Prot_000.pdf (accessed Apr. 24, 2026).
6. * ChemoCentryx, Inc., "Statistical Analysis Plan," version 2.0, Oct. 28, 2019, available at https://cdn.clinicaltrials.gov/large-docs/27/NCT02994927/SAP_001.pdf (accessed Apr. 24, 2026).
7. * ChemoCentryx, Inc., "Clinical Study Report CL010_168." NDA 214487, Jun. 1, 2020.
8. * ChemoCentryx, Inc., "BVAS and VDI Adjudication Committee Charter," Protocol CL010_168, version 4.0, NDA 214487, Jun. 21, 2019.
9. * FDA, Memorandum of Meeting Minutes (IND 120784), Nov. 1, 2016.
10. Love, S., V. Yorke-Edwards, et al., 2021, "Making a Distinction Between Data Cleaning and Central Monitoring in Clinical Trials," *Clin Trials*, 18(3): 386–388, available at <https://pmc.ncbi.nlm.nih.gov/articles/PMC8174009/> (accessed Apr. 24, 2026).
11. * FDA, ICH guidance for industry "E6(R3) Good Clinical Practice," (September 2025), available at <https://www.fda.gov/media/169090/download> (accessed Apr. 24, 2026).
12. * FDA, International Council for Harmonisation (ICH) guidance for industry "E9 Statistical Principles for Clinical Trials," (September 1998), available at <https://www.fda.gov/media/71336/download> (accessed Apr. 24, 2026).
13. * ChemoCentryx, Inc., Study CL010_168, Week 52 Primary Analysis Topline Tables, Table 14.2.2.1 (Nov. 7, 2019).
14. * ChemoCentryx, Inc., "Clinical: Response to Information Request #4." NDA 214487, Sept. 25, 2020.
15. * FDA, TAVNEOS (avacopan). "Information Request 11." NDA 214487, Dec. 9, 2020.
16. * ChemoCentryx, Inc., "Response to Information Request #11: Clinical & Statistics." NDA 214487, Dec. 29, 2020.
17. * FDA, Arthritis Advisory Committee Meeting, Transcript, May 6, 2021, available at <https://web.archive.org/web/20230330025701/https://www.fda.gov/advisory-committees/advisory-committee-calendar/may-6-2021-meeting-arthritis-advisory-committee-meeting-announcement-05062021#event-materials> (accessed Feb. 24, 2026).
18. * FDA, TAVNEOS (avacopan). "Multi-Discipline Review." NDA 214487, Oct. 12, 2018, available at https://www.accessdata.fda.gov/drugsatfda_docs/nda/2021/214487Orig1s000MultidisciplineR.pdf (accessed Apr. 24, 2016).
19. * FDA, "Approval Letter—TAVNEOS (avacopan) (NDA 214487)." Letter to ChemoCentryx, Inc., Oct. 7, 2021, available at https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2021/214487Orig1s000ltr.pdf (accessed Apr. 24, 2026).
20. FDA, ICH guideline for industry "Structure and Content of Clinical Study Reports," (July 1996), available at <https://www.fda.gov/media/71271/> download (accessed Apr. 24, 2026).

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Tracy Beth Høeg,

Acting Director, Center for Drug Evaluation and Research.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–P–0655]

Determination FENOGLIDE (Fenofibrate) Tablets, 40 Milligrams and 120 Milligrams, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) has determined that FENOGLIDE (fenofibrate) tablets, 40 milligrams (mg) and 120 mg, was not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) that refer to this drug product, and it will allow FDA to continue to approve ANDAs that refer to the product as long as they meet relevant legal and regulatory requirements.

FOR FURTHER INFORMATION CONTACT: Heather Dorsey, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6269, Silver Spring, MD 20993–0002, 301–796–3600, Heather.Dorsey@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(j)) allows the submission of an ANDA to market a generic version of a previously approved drug product. To obtain approval, the ANDA applicant must show, among other things, that the generic drug product: (1) has the same active ingredient(s), dosage form, route of administration, strength, conditions of use, and (with certain exceptions) labeling as the listed drug, which is a version of the drug that was previously approved, and (2) is bioequivalent to the listed drug. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

Section 505(j)(7) of the FD&C Act requires FDA to publish a list of all

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.

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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. 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.

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