

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2026-N-0707]

GlaxoSmithKline; Withdrawal of Approval of a New Drug Application for Wellcovorin (Leucovorin Calcium) Tablets, EQ 5 mg Base and EQ 25 mg Base

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of a new drug application (NDA) for Wellcovorin (leucovorin calcium) tablets, EQ 5 mg base and EQ 25 mg base, held by GlaxoSmithKline, LLC, 2020 Walnut Street, Philadelphia, PA 19104 (GSK). GSK notified the Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of April 10, 2026.

FOR FURTHER INFORMATION CONTACT: Kimberly Thomas, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Silver Spring, MD 20993-0002, 301-796-3601, druginfo@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: GSK has informed FDA that for Wellcovorin (leucovorin calcium) tablets, EQ 5 mg base and EQ 25 mg base, is no longer marketed and have requested that FDA withdraw approval of the applications under the process in § 314.150(c) (21 CFR 314.150(c)). GSK has also, by their requests, waived their opportunity for a hearing. Withdrawal of approval of an application or abbreviated application under § 314.150(c) is without prejudice to refile.

Therefore, approval of NDA 018342, and all amendments and supplements thereto, is hereby withdrawn as of April 10, 2026. Approval of the entire application is withdrawn, including any strengths and dosage forms inadvertently missing from this notice. Introduction or delivery for introduction into interstate commerce of Wellcovorin (leucovorin calcium) tablets, EQ 5 mg base and EQ 25 mg base, without an approved NDA violates sections 505(a) and 301 (d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(a) and 331(d)). Any Wellcovorin (leucovorin calcium) tablets, EQ 5 mg base and EQ 25 mg base, that is in inventory on April

10, 2026 may continue to be dispensed until the inventories have been depleted or the drug products have reached their expiration dates or otherwise become violative, whichever occurs first.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026-06911 Filed 4-9-26; 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: Center for Scientific Review Special Emphasis Panel; Fellowships: HIV/AIDS Biological Review Panel.

Date: May 7, 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: Annie Walker-Abbey, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (240) 627-3390, aabbey@mail.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Fellowships: Chemistry, Biochemistry and Biophysics A.

Date: May 7-8, 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: John J. Laffan, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 443-7154, laffanjo@mail.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Fellowship: Infectious Disease and Immunology A.

Date: May 7, 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: Lee G. Klinkenberg, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 761-7749, lee.klinkenberg@nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Neuroimaging Technologies.

Date: May 7, 2026.

Time: 10:00 a.m. to 2:00 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: Sudhir Kumar U. Yanpallewar, MD Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 443-4577, sudhirkumar.yanpallewar@nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR Panel: Psychosocial and Interpersonal Influences Impacting Youth.

Date: May 7, 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: Janetta Lun, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 827-4588, janetta.lun@nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Program Projects: Centers and Cooperative Agreements on Substance Abuse and Aging Disorders.

Date: May 7, 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: Jasenka Borzan, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (667) 900-1640, jasenka.borzan@nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Myalgic Encephalomyelitis-Chronic Fatigue Syndrome.

Date: May 7, 2026.