determined that leucovorin calcium, oral solution, equivalent to (EQ) 60 milligrams (mg) base/vial, was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for leucovorin calcium, oral solution, EQ 60 mg, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Alexander Poonai, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6213, Silver Spring, MD 20993–0002, 301–796–3600, *Alexander.Poonai@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approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).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may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)).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.

Leucovorin calcium, oral solution, EQ 60 mg base/vial, is the subject of NDA 008107, held by Hospira Inc., and initially approved on January 30, 1987. Leucovorin calcium is indicated after high-dose methotrexate therapy in osteosarcoma; to diminish the toxicity and counteract the effects of impaired methotrexate elimination and of inadvertent overdosages of folic acid antagonists; and for use in combination with 5-fluorouracil to prolong survival in the palliative treatment of patients with advanced colorectal cancer

Leucovorin calcium, oral solution, EQ 60 mg base/vial is currently listed in the ''Discontinued Drug Product List'' section of the Orange Book.

Apotex, Inc. submitted a citizen petition dated January 23, 2026 (Docket No. FDA–2026–P–0749), under 21 CFR 10.30, requesting that the Agency determine whether leucovorin calcium, oral solution, EQ 60 mg base/vial, 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 leucovorin calcium, oral solution, EQ 60 mg base/vial, 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 leucovorin calcium, oral solution, EQ 60 mg base/vial 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 leucovorin calcium, oral solution, EQ 60 mg base/vial, 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. ANDAs that refer to this drug product may 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. 2026–09199 Filed 5–7–26; 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; Special Topics in Biochemistry and Biophysics.

Date: May 22, 2026.

Time: 11:00 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: Eduardo Emilio Chufan, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (240) 276–7975, *chufanee@mail.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Special: Cardiovascular and Pulmonary Research Career Development Awards.

Date: June 10, 2026.

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: Dan Yu, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 402–1081, *dan.yu@nih.gov*.

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

Date: June 11, 2026.
Time: 8:00 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: Yun Mei, MD, Scientific Review Officer, Scientific Review Branch, National Institutes of Health, 6701 Democracy Boulevard, Suite #672, Bethesda, MD 20892, 301–827–4639, *yun.mei@nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Cancer Therapeutics (R21).
Date: June 11, 2026.
Time: 9:00 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: Shree Ram Singh, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (240) 672–6175 *singhshr@mail.nih.gov*.

Name of Committee: Bioengineering Sciences & Technologies Integrated Review Group; Innovations in Nanosystems and Nanotechnology Study Section.
Date: June 11, 2026.
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: Yingli Fu, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 594–0840 *yingli.fu@nih.gov*.

Name of Committee: Applied Immunology and Disease Control Integrated Review Group; Anti-Infective Resistance and Targets Study Section.
Date: June 11, 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: Jui Pandhare, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 594–7735 *pandharej2@csr.nih.gov*.

Name of Committee: Genes, Genomes, and Genetics Integrated Review Group; Genomics, Computational Biology and Technology Study Section.
Date: June 11, 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: Methode Bacanamwo, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2200, Bethesda, MD 20892, 301–827–7088, *methode.bacanamwo@nih.gov*.

Name of Committee: Infectious Diseases and Immunology B Integrated Review Group; Mechanisms of Autoimmunity Study Section.
Date: June 11, 2026.
Time: 9:30 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: Maria Chiara G. Monaco-Kushner, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Dr., Bethesda, MD 20892, (301) 555–1212, *monaco@csr.nih.gov*.

Name of Committee: Risk, Prevention and Health Behavior Integrated Review Group; Interdisciplinary Clinical Care in Specialty Care Settings Study Section.
Date: June 11–12, 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, MD 20892.
Meeting Format: Virtual Meeting.
Contact Person: Abu Saleh Mohammad Abdullah, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 827–4043, *abuabdullah.abdullah@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: May 5, 2026.

Rosalind M. Niamke,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2026–09117 Filed 5–7–26; 8:45 am]

BILLING CODE 4167–05–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the Board of Scientific Counselors, National Cancer Institute.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting. The open session will be videocast and can be accessed from the NIH Videocast at the following link: *http://videocast.nih.gov/*.

The meeting will be closed to the public as indicated below in accordance with the provisions set forth in section 552b(c)(6), Title 5 U.S.C., as amended for the review, discussion, and evaluation of individual intramural programs and projects conducted by the National Cancer Institute, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Board of Scientific Counselors, National Cancer Institute.
Date: July 6–7, 2026.
Open: July 06, 2026, 10:00 a.m. to 10:40 a.m.
Agenda: Call to Order and the Opening Remarks.
Closed: July 06, 2026, 11:00 a.m. to 3:00 p.m., July 07, 2026, 11:00 a.m. to 2:00 p.m.
Agenda: Personnel qualifications and performance, and competence of individual investigators.
Address: National Institutes of Health, National Cancer Institute, 9609 Medical Center Drive, Rockville, MD 20850, Virtual Meeting.
Contact Person: Mehrdad M. Tondravi, Ph.D., Chief, Institute Review Office, National Cancer Institute, National Institutes of Health, 9609 Medical Center Drive, Room 2W–464 MSC 9711, Rockville, MD 20852, 240–276–5664, *tondravim@mail.nih.gov*.

Information is also available on the Institute's/Center's home page: *https://deainfo.nci.nih.gov/advisory/bsc/index.htm,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support Grants; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: May 6, 2026.

David W. Freeman,

Supervisory Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2026–09223 Filed 5–7–26; 8:45 am]

BILLING CODE 4167–05–P