Dallas, Texas 75201–2272. Comments can also be sent electronically to *Comments.applications@dal.frb.org:*

1. *Carpenter Bank Holdings LLC, Dallas, Texas;* to become a bank holding company by acquiring Security State Bank, Pearsall, Texas.

Board of Governors of the Federal Reserve System.

Michele Taylor Fennell,

Associate Secretary of the Board.

[FR Doc. 2026–09202 Filed 5–7–26; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10943]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments on the collection(s) of information must be received by the OMB desk officer by June 8, 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.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, please access the CMS PRA website by copying and pasting the following web address into your web browser: *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing*

FOR FURTHER INFORMATION CONTACT: William Parham at (410) 786–4669.

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. The term ''collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment.

Information Collection

1. *Type of Information Collection Request:* New collection (Request for a new OMB control number); *Title of Information Collection:* CMS Meeting Request Public Portal; *Use:* CMS is seeking approval to streamline the process for entities requesting external meetings. The proposed CMS Meeting Request Portal will gather only necessary information for representatives of the organization to meet with a representative of the federal government. This simplified approach aims to reduce administrative burden while enhancing transparency and accountability in meeting requests. By focusing on essential information, CMS ensures that the evaluation and screening process for private requests remains efficient and centered on logistics, scheduling, and conflict of interest. The proposed information collection aligns with CMS's commitment to stakeholder engagement while ensuring compliance with all applicable federal laws, regulations, and security protocols.

The information will be collected solely from organizations and third-party requestors, such as law firms or other entities acting on behalf of organizations, that seek a meeting with the Administrator. The implementation of an online portal will facilitate the ease and efficiency of submitting requests. Requestors will have the capability to securely enter their requests electronically through this portal. Information collection is voluntary, whether or not it is provided through the portal or via a letter, but no matter how it is submitted to CMS, failure to provide the requested information will result in CMS's inability to review, process, and/or act on the request.

Subsequent to submitting the 60-day notice, we decided to add the organization's mailing address to the list of data elements. Similarly, we also updated the projected number of respondents from 427 to 465 based on updated data. These changes will not have an effect on the original burden estimate of 20 minutes per request; however, we adjusted the total annual burden from 142 hours to 155 hours. *Form Number:* CMS–10943 (OMB control number: 0938–New); *Frequency:* Occasionally; *Affected Public:* Individuals, Private Sector—Business or other for-profits, Not-for-profit institutions; *Number of Respondents:* 465; *Total Annual Responses:* 465; *Total Annual Hours:* 155 hours. (For policy questions regarding this collection contact Erin Palmer at (202) 690–5943.)

William N. Parham, III,

Director, Division of Information Collections and Regulatory Impacts, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2026–09167 Filed 5–7–26; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–P–0749]

Determination That Leucovorin Calcium, Oral Solution, Equivalent to 60 Milligrams Base/Vial, 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 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.