• Indicate if individual is a ''Foreign National'' visitor

• New or Reconsidered Code(s) for which the company or organization individual is representing submitted a comment or presentation, if applicable.

Registration details may not be revised once they are submitted. If registration details require changes, a new registration entry must be submitted by the date specified in the **DATES** section of this notice. Additionally, registration information must reflect individual-level content and not reflect an organization name. Also, we request organizations register all individuals at the same time. That is, one individual may register multiple individuals at the same time. Individuals who are not registered in advance will not be permitted to enter the building (see section VI. of this notice).

After registering, a confirmation email will be sent upon receipt of the registration. The email will provide information to the attendee in preparation for the meeting. Registration is only required for stand-by speakers and members of the public attending the meeting at the CMS campus (address specified in the **ADDRESSES** section of this notice). All registration must be submitted by the deadline specified in the **DATES** section of this notice. *Note:* No registration is required for participants who plan to view the Panel meeting via webinar or listen via teleconference.

V. Panel Recommendations and Discussions

The Panel's recommendations will be posted approximately 2 weeks after the meeting on the CMS website at *https://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonClinicalDiagnosticLaboratoryTests.html.*

VI. Security, Building, and Parking Guidelines

The hybrid meeting will be held in a Federal government building; therefore, Federal security measures are applicable. In planning your arrival time, we recommend allowing additional time to clear security. We suggest that you arrive at the CMS campus and parking facilities between 9:00 a.m. and 10:00 a.m. E.D.T., so that you will be able to arrive promptly at the meeting by 10:00 a.m. E.D.T. Individuals who are not registered in advance will not be permitted to enter the building and will be unable to attend the meeting. We note that the public may not enter the CMS building earlier than 9:15 a.m. E.D.T. (45 minutes before the convening of the meeting).

Security measures include the following:

• Presentation of government-issued photographic identification to the Federal Protective Service or Guard Service personnel. Persons without proper identification may be denied access to the building.

• Interior and exterior inspection of vehicles (this includes engine and trunk inspection) at the entrance to the grounds. Parking permits and instructions will be issued after the vehicle inspection.

• Passing through a metal detector and inspection of items brought into the building. We note that all items brought to CMS, whether personal or for the purpose of demonstration or to support a demonstration, are subject to inspection. We cannot assume responsibility for coordinating the receipt, transfer, transport, storage, set-up, safety, or timely arrival of any personal belongings or items used for demonstration or to support a demonstration.

VII. Special Accommodations

Individuals attending, viewing, or listening to the meeting who are hearing or visually impaired and have special requirements, or a condition that requires special assistance, must send an email to the resource box (*CDLTPanel@cms.hhs.gov*). The deadline for submitting this request is listed in the **DATES** section of this notice.

VIII. Copies of the Charter

The Secretary's Charter for the Medicare Advisory Panel on CDLT's is available on the CMS website at *http://cms.gov/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonClinicalDiagnosticLaboratoryTests.html* or you may obtain a copy of the charter by submitting a request to the contact listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice.

IX. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

The Acting Administrator of the Centers for Medicare & Medicaid Services (CMS), Stephanie Carlton having reviewed and approved this document, authorizes Vanessa Garcia, who is the Federal Register Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Vanessa Garcia,

Federal Register Liaison, Centers for Medicare & Medicaid Services.

[FR Doc. 2025–06758 Filed 4–18–25; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–3470–N]

Medicare Program; Virtual Meeting of the Medicare Evidence Development and Coverage Advisory Committee

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice.

SUMMARY: This notice announces a virtual public meeting of the Medicare Evidence Development & Coverage Advisory Committee (MEDCAC) (''Committee'') will be held on Wednesday, June 25, 2025.

DATES:

Meeting Date: The virtual meeting will be held on Wednesday, June 25, 2025, from 10:00 a.m. until 4:00 p.m., Eastern Daylight Time (EDT).

Deadline for Submission of Written Comments: Written comments must be received at the email address specified in the **ADDRESSES** section of this notice by 5:00 p.m., EDT, on Wednesday, May 21, 2025. Once submitted, all comments are final.

Deadlines for Speaker Registration and Presentation Materials: The deadline to register as a speaker and to submit PowerPoint presentation materials and writings that will be used in support of an oral presentation, is 5:00 p.m., EDT on Wednesday, May 21, 2025. Speakers may register via email by contacting the person listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice. Presentation materials must be received at the email address specified in the **ADDRESSES** section of this notice.

Deadline for All Other Attendees Registration: Individuals who want to join the meeting may register online at: *https://cms.zoomgov.com/meeting/register/vJIsfuiuqTooHSfrDZdYHzCLsztgUqyaxvo* until 10:00 a.m., EDT on Wednesday, June 25, 2025.

Deadline for Submitting a Request for Special Accommodations: Individuals viewing or listening to the meeting who

are hearing or visually impaired and have special requirements, or a condition that requires special assistance, should send an email to the MEDCAC Coordinator as specified in the **FOR FURTHER INFORMATION CONTACT** section of this notice no later than 5:00 p.m., EDT on Wednesday, May 21, 2025.

ADDRESSES: To allow for broader public participation in the meeting, the Panel meeting will be held virtually.

Submission of Presentations and Written Comments: Presentation materials and written comments that will be presented at the meeting must be submitted via email to *MedCACpresentations@cms.hhs.gov.* All comments, presentations and articles/background materials will be posted on the MEDCAC website.

Webinar and Teleconference Meeting Information: Teleconference dial-in instructions, and related webinar details will be posted on the meeting agenda, which will be available on the CMS website *https://www.cms.gov/medicare-coverage-database/indexes/medcac-meetings-index.aspx?bc=BAAAAAAAAAAA&.* Participants in the MEDCAC meeting will require the following: a computer, laptop or smartphone where the Zoom application needs to be downloaded; a strong Wi-Fi or an internet connection and access to use Chrome or Firefox web browser and a webcam if the meeting participant is scheduled to speak or make a presentation during the meeting.

FOR FURTHER INFORMATION CONTACT: Tara Hall, MEDCAC Coordinator, via email at *medcac_registration@cms.hhs.gov* or by phone 410–786–4347.

SUPPLEMENTARY INFORMATION:

I. Background

MEDCAC, formerly known as the Medicare Coverage Advisory Committee (MCAC), is advisory in nature, with all final coverage decisions resting with CMS. MEDCAC is used to supplement CMS' internal expertise. Accordingly, the advice rendered by the MEDCAC is most useful when it results from a process of full scientific inquiry and thoughtful discussion, in an open forum, with careful framing of recommendations and clear identification of the basis of those recommendations. MEDCAC members are valued for their background, education, and expertise in a wide variety of scientific, clinical, and other related fields. (For more information on MEDCAC, see the MEDCAC Charter (*https://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/Downloads/medcaccharter.pdf*) and the CMS Guidance Document, *Factors CMS Considers in Referring Topics to the MEDCAC https://www.cms.gov/medicare-coverage-database/details/medicare-coverage-document-details.aspx?MCDId=10*).

II. Meeting Topic and Format

This notice announces the Wednesday, June 25, 2025, virtual public meeting of the Committee. The MEDCAC panel will examine which clinical endpoints in studies of devices to manage tremor in Parkinson's disease and essential tremor should be of interest to CMS. Given the increased emphasis on new and innovative medical products for difficult-to-manage conditions, some studies of new medical technologies have focused on short-term data with greater reliance on intermediate outcomes and surrogate endpoints. Furthermore, studies of new devices are often not representative of the Medicare beneficiary population in terms of demographics, comorbidity prevalence or care setting. As a result, there are more frequent evidence gaps with respect to the health outcomes that are clinically meaningful for CMS beneficiaries in assessments of medical technologies. The MEDCAC panel will consider a review of the relevant clinical research and professional guidance literature, along with expert commentary. By voting on specific questions, and by their discussions, MEDCAC panel members will advise CMS about the ideal clinical endpoints in research studies of devices to manage tremor in Parkinson's disease and essential tremor, as well as appropriate measurement instruments and follow-up durations, to help to provide clarity and transparency of National Coverage Analyses (NCAs). This meeting is open to the public in accordance with the Federal Advisory Committee Act (5 U.S.C. app. 2, section 10(a)).

Background information about this topic, including panel materials, is available at *https://www.cms.gov/medicare-coverage-database/indexes/medcac-meetings-index.aspx?bc=BAAAAAAAAAAA&.* Electronic copies of all the meeting materials, to include public comments and presentations, will be on the CMS website approximately 15 days before the meeting. We encourage the participation of organizations with expertise in the appraisal of the state of evidence for the use of device to manage tremor in Parkinson's disease and essential tremor. This meeting is open to the public. The Committee will hear oral presentations from the public for approximately 45 minutes. Time allotted for each presentation may be limited, based on the number of speakers. If the number of registrants requesting to speak is greater than what can be reasonably accommodated during the scheduled open public hearing session, we may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by June 4, 2025. Your comments must focus on issues specific to the list of topics that we have proposed to the Committee. The list of research topics to be discussed at the meeting will be available on the following website prior to the meeting: *https://www.cms.gov/medicare-coverage-database/indexes/medcac-meetings-index.aspx?bc=BAAAAAAAAAAA&.* We require that you declare at the meeting whether you have any financial involvement with manufacturers (or their competitors) of any items or services being discussed. Speakers presenting at the MEDCAC meeting must include a full disclosure slide as their second slide in their presentation for financial interests (for example, type of financial association—consultant, research support, advisory board, and an indication of level, such as minor association < $10,000 or major association > $10,000) as well as intellectual conflicts of interest (for example, involvement in a federal or nonfederal advisory committee that has discussed the issue) that may pertain in any way to the subject of this meeting. If you are representing an organization, we require that you also disclose conflict of interest information for that organization. If you do not have a PowerPoint presentation, you will need to present the full disclosure information requested previously at the beginning of your statement to the Committee.

The Committee will deliberate openly on the topics under consideration. Interested persons may observe the deliberations, but the Committee will not hear further comments during this time except at the request of the chairperson. The Committee will also allow a 15-minute unscheduled open public session for any attendee to address issues specific to the topics under consideration. At the conclusion of the day, the members will vote, and the Committee will make its recommendation(s) to CMS.

III. Registration Instructions

CMS' Coverage and Analysis Group is coordinating meeting registration. While there is no registration fee, individuals must register to attend. You may register online at *https://cms.zoomgov.com/meeting/register/vJIsfuiuqTooHSfrDZdYHzCLsztgUqyaxvo* or by email by contacting the person listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice by the deadline listed in the **DATES** section of this notice. Please provide your full name (as it appears on your state-issued driver's license), address, organization, telephone number(s), and email address. You will receive a registration confirmation with instructions for your participation at the virtual public meeting.

IV. Collection of Information

This document does not impose information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 35).

The Chief Medical Officer and Acting Director of the Center for Clinical Standards and Quality for the Centers for Medicare & Medicaid Services (CMS), Dora Hughes, having reviewed and approved this document, authorizes Chyana Woodyard, who is the Federal Register Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Chyana Woodyard,

Federal Register Liaison, Centers for Medicare & Medicaid Services.

[FR Doc. 2025–06834 Filed 4–18–25; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–P–5304]

Determination That MOBIC (Meloxicam) Tablets, 7.5 Milligrams and 15 Milligrams, Were 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 MOBIC (meloxicam) tablets, 7.5 milligrams (mg) and 15 mg, were 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: Beth Holck, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6280, Silver Spring, MD 20993–0002, 240–402–7133, *beth.holck@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 (21 CFR 314.161). FDA may not approve an ANDA that does not refer to a listed drug.

MOBIC (meloxicam) tablets, 7.5 mg and 15 mg, are the subject of NDA 020938, held by Boehringer Ingelheim Pharmaceuticals, Inc., and initially approved on April 13, 2000. MOBIC is indicated for relief of the signs and symptoms of osteoarthritis, rheumatoid arthritis, and juvenile rheumatoid arthritis in patients who weigh more than 60 kilograms.

MOBIC (meloxicam) tablets, 7.5 mg and 15 mg, are currently listed in the ''Discontinued Drug Product List'' section of the Orange Book.

Pharmobedient Consulting, LLC submitted a citizen petition dated November 8, 2024 (Docket No. FDA–2024–P–5304), under 21 CFR 10.30, requesting that the Agency determine whether MOBIC (meloxicam) tablets, 7.5 mg and 15 mg, were 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 MOBIC (meloxicam) tablets, 7.5 mg and 15 mg, were not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that MOBIC (meloxicam) tablets, 7.5 mg and 15 mg, were withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of MOBIC (meloxicam) tablets, 7.5 mg and 15 mg, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have found no information that would indicate that this drug product was withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list MOBIC (meloxicam) tablets, 7.5 mg and 15 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 these drug products. Additional ANDAs for these drug products 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 these drug products should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: April 15, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–06783 Filed 4–18–25; 8:45 am]

BILLING CODE 4164–01–P