

**POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:**

In accordance with the National Archives and Records Administration General Records Schedule 2.8 Employee Ethics Records, these records are generally retained for a period of six years after filing, or for such other period of time as is provided for in that schedule for certain specified types of ethics records. In cases where records are filed by, or with respect to, a nominee for an appointment requiring confirmation by the Senate when the nominee is not appointed and Presidential and Vice-Presidential candidates who are not elected, the records are generally destroyed one year after the date the individual ceased being under Senate consideration for appointment or is no longer a candidate for office. However, if any records are needed in an ongoing investigation, they will be retained until no longer needed in the investigation. Destruction is by shredding or electronic deletion.

**ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:**

These records are maintained in file cabinets which may be locked or in specified areas to which only authorized personnel have access. Access to the data in the Executive branch-wide Integrity public financial disclosure information system and OGE electronic systems is protected by electronic controls, such as multifactor authentication and password protection. Access to the systems is controlled based on user roles and responsibilities. Executive branch agencies control their users' access to information in Integrity and are responsible for properly safeguarding the records maintained in their systems.

**RECORD ACCESS PROCEDURES:**

Individuals wishing to request access to their records should contact the appropriate office as shown in the Notification Procedures section below. Individuals must furnish the following information for their records to be located and identified:

- a. Full name.
- b. Department or agency and component with which employed or proposed to be employed.
- c. Dates of employment.
- d. A reasonably specific description of the record content being sought.

Individuals requesting access to records maintained at OGE must also follow OGE's Privacy Act regulations regarding verification of identity and access to records (5 CFR part 2606).

**CONTESTING RECORD PROCEDURES:**

Because the information in these records is updated on a periodic basis, most record corrections can be handled through established administrative procedures for updating the records. However, individuals can obtain information on the procedures for contesting the records under the provisions of the Privacy Act by contacting the appropriate office shown in the Notification Procedures section below.

**NOTIFICATION PROCEDURES:**

Individuals wishing to inquire whether this system of records contains information about them should contact, as appropriate:

- a. For records filed directly with OGE by non-OGE employees, contact the General Counsel, Office of Government Ethics, at the agency's address as set forth in the System Location section;
- b. For records filed with a Designated Agency Ethics Official (DAEO) or the head of a department or agency, contact the DAEO at the department or agency concerned; and
- c. For records filed with the FEC by candidates for President or Vice President, contact the FEC General Counsel, Federal Election Commission, 999 E Street NW, Washington, DC 20463.

Individuals wishing to make such an inquiry must furnish the following information for their records to be located and identified:

- a. Full name.
- b. Department or agency and component with which employed or proposed to be employed.
- c. Dates of employment.

Individuals seeking to determine if an OGE system of records contains information about them must also follow OGE's Privacy Act regulations regarding verification of identity (5 CFR part 2606).

**EXEMPTIONS PROMULGATED FOR THE SYSTEM:**

None.

**HISTORY:**

84 FR 47303 (Sept. 9, 2019).

Approved: March 5, 2024.

**Shelley K. Finlayson,**

*Acting Director, U.S. Office of Government Ethics.*

[FR Doc. 2024-05083 Filed 3-8-24; 8:45 am]

**BILLING CODE 6345-03-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Food and Drug Administration**

[Docket No. FDA-2024-N-0948]

**Blood Products Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments—Strategies for Testing Blood Donations for Malaria Infection**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of meeting; establishment of a public docket; request for comments.

**SUMMARY:** The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Blood Products Advisory Committee (the Committee). The general function of the Committee is to provide advice and recommendations to FDA on regulatory issues regarding blood and blood products. At this meeting the Committee will consider strategies to reduce the risk of transfusion-transmitted malaria by testing blood donations from donors at risk of malaria exposure. The meeting will be open to the public. FDA is establishing a docket for public comment on this topic.

**DATES:** The meeting will be held on May 9, 2024, from 9:30 a.m. to 3:10 p.m. eastern time.

**ADDRESSES:** All meeting participants will be heard, viewed, captioned, and recorded for this advisory committee meeting via an online teleconferencing and/or video conferencing platform.

Answers to commonly asked questions about FDA advisory committee meetings, may be accessed at: <https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm>.

The online web conference meeting will be available at the following link on the day of the meeting: <https://youtube.com/live/eYsJqANkdmQ>.

FDA is establishing a docket for public comment on this meeting topic. The docket number is FDA-2024-N-0948. The docket will close on May 8, 2024. Please note that late, untimely filed comments will not be considered. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. eastern time on May 8, 2024. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date. Written comments filed after this deadline will not be considered by FDA.

Comments received on or before May 2, 2024, will be provided to the Committee. Comments received after May 2, 2024, and before the May 8, 2024, deadline will be taken into consideration by FDA. In the event that the meeting is cancelled, FDA will continue to evaluate any relevant information, and consider any comments submitted to the docket, as appropriate.

You may submit comments as follows:

#### *Electronic Submissions*

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

#### *Written/Paper Submissions*

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

*Instructions:* All submissions received must include the Docket No. FDA-2024-N-0948 for "Blood Products Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments." Comments filed in a timely manner (see **ADDRESSES**) will be placed in the docket

and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- **Confidential Submissions**—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." FDA will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify the information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

#### **FOR FURTHER INFORMATION CONTACT:**

Christina Vert, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Silver Spring, MD 20993-0002, 240-731-3544, [CBERBPAC@fda.hhs.gov](mailto:CBERBPAC@fda.hhs.gov); or FDA Advisory Committee Information Line, 1-800-741-8138 (301)-443-0572 in the Washington, DC area. A notice in the **Federal Register** about last-minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice.

Therefore, you should always check FDA's website at <https://www.fda.gov/AdvisoryCommittees/default.htm> and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before the meeting.

#### **SUPPLEMENTARY INFORMATION:**

*Agenda:* The meeting presentations will be heard, viewed, captioned, and recorded through an online teleconferencing and/or video conferencing platform. On May 9, 2024, the Committee will meet in open session to discuss strategies to reduce the risk of transfusion-transmitted malaria by testing blood donations from donors at risk of malaria exposure.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available on FDA's website at the time of the advisory committee meeting. Background material and the link to the online video conference meeting will be available at <https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee meeting link.

The meeting will include slide presentations with audio and video components to allow the presentation of materials in a manner that most closely resembles an in-person advisory committee meeting.

*Procedure:* On May 9, 2024, from 9:30 a.m. to 3:10 p.m. eastern time, the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the Committee. All electronic and written submissions to the Docket (see **ADDRESSES**) on or before May 2, 2024, will be provided to the Committee. Oral presentations from the public will be scheduled between approximately 1 p.m. to 2 p.m. eastern time on May 9, 2024. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, along with their names, email addresses, and direct contact phone numbers of proposed participants, and an indication of the approximate time requested to make their presentation on or before 12 noon eastern time on April 24, 2024. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably

accommodated during the scheduled open public hearing session, FDA 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 April 25, 2024.

For press inquiries, please contact the Office of Media Affairs at [fdadoma@fda.hhs.gov](mailto:fdadoma@fda.hhs.gov) or 301-796-4540.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Christina Vert at [CBERBPAC@fda.hhs.gov](mailto:CBERBPAC@fda.hhs.gov) (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at <https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. 1001 *et seq.*). This meeting notice also serves as notice that, pursuant to 21 CFR 10.19, the requirements in 21 CFR 14.22(b), (f), and (g) relating to the location of advisory committee meetings are hereby waived to allow for this meeting to take place using an online meeting platform. This waiver is in the interest of allowing greater transparency and opportunities for public participation, in addition to convenience for advisory committee members, speakers, and guest speakers. The conditions for issuance of a waiver under 21 CFR 10.19 are met.

Dated: March 5, 2024.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2024-05074 Filed 3-8-24; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2020-D-1824]

#### Assessing COVID-19-Related Symptoms in Outpatient Adult and Adolescent Subjects in Clinical Trials of Drugs and Biological Products for COVID-19 Prevention or Treatment; Guidance for Industry; Correction

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Correction.

**SUMMARY:** The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** on February 22, 2024. The document announced the availability of a final guidance for industry entitled “Assessing COVID-19-Related Symptoms in Outpatient Adult and Adolescent Subjects in Clinical Trials of Drugs and Biological Products for COVID-19 Prevention or Treatment.” The document was published with an incorrect docket number. This document corrects that error.

**FOR FURTHER INFORMATION CONTACT:** David Reasner, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6373, Silver Spring, MD 20993, 301-837-7667; or James Myers, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of February 22, 2024 (89 FR 13351), in FR Doc. 2024-03622, the following correction is made:

On page 13351, in the first column in the header of the document and in the third column in the second line of the first paragraph, “Docket No. FDA-2024-D-0584” is corrected to read “Docket No. FDA-2020-D-1824.”

Dated: March 5, 2024.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2024-05081 Filed 3-8-24; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2023-N-2057]

#### Revocation of Emergency Use of a Drug Product During the COVID-19 Pandemic; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the revocation of the Emergency Use Authorization (EUA) (the Authorization) issued to Eli Lilly and Co. (Lilly), for bamlanivimab and etesevimab administered together. FDA revoked the Authorization on December 14, 2023, under the Federal Food, Drug, and Cosmetic Act (FD&C Act). The revocation, which includes an

explanation of the reasons for the revocation, is reprinted in this document.

**DATES:** The Authorization is revoked as of December 14, 2023.

**ADDRESSES:** Submit written requests for a single copy of the revocation to the Office of Executive Programs, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, 6th Floor, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request or include a Fax number to which the Authorization may be sent. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the Authorization.

**FOR FURTHER INFORMATION CONTACT:** Johanna McLatchy, Office of Executive Programs, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, 6th Floor, Silver Spring, MD 20993-0002, 301-796-3200 (this is not a toll-free number).

**SUPPLEMENTARY INFORMATION:**

### I. Background

Section 564 of the FD&C Act (21 U.S.C. 360bbb-3) allows FDA to strengthen the public health protections against biological, chemical, nuclear, and radiological agents. Among other things, section 564 of the FD&C Act allows FDA to authorize the use of an unapproved medical product or an unapproved use of an approved medical product in certain situations. On February 9, 2021, FDA issued an Authorization (EUA 094) to Lilly for bamlanivimab and etesevimab administered together, subject to the terms of the Authorization. Notice of the issuance of the Authorization was published in the **Federal Register** on May 27, 2021 (86 FR 28608), as required by section 564(h)(1) of the FD&C Act. The authorization of a drug for emergency use under section 564 of the FD&C Act may, pursuant to section 564(g)(2) of the FD&C Act, be revoked when the criteria under section 564(c) of the FD&C Act for issuance of such authorization are no longer met (section 564(g)(2)(B) of the FD&C Act), or other circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the FD&C Act).

### II. EUA Revocation Request

In a request received by FDA on October 23, 2023, Lilly requested revocation of, and on December 14, 2023, FDA revoked, the Authorization for bamlanivimab and etesevimab