

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 fdoma@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 (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]

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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]

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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