Based on our evaluation of the information collection since the last OMB review and approval, the burden estimate decreased based on receipt of fewer vouchers and other information collection activities. Our estimated burden for the information collection reflects an overall decrease of 46 hours and a decrease of 8 responses.

Dated: July 23, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–14223 Filed 7–28–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–N–1892]

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 Authorizations (EUAs) (the Authorizations) issued to Regeneron Pharmaceuticals, Inc. (Regeneron) for REGEN–COV (casirivimab and imdevimab administered together), to GlaxoSmithKline LLC (GSK) for sotrovimab, to Eli Lilly and Company (Lilly) for bebtelovimab, and to AstraZeneca Pharmaceuticals LP (AstraZeneca) for EVUSHELD (tixagevimab co-packaged with cilgavimab). FDA revoked these Authorizations on December 13, 2024, under the Federal Food, Drug, and Cosmetic Act (FD&C Act). The revocations, including an explanation of the reasons for the revocations, are reprinted in this document.

DATES: The Authorizations are revoked as of December 13, 2024.

ADDRESSES: Submit written requests for a single copy of the revocations 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 revocations may be sent. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the revocations.

FOR FURTHER INFORMATION CONTACT: Andrea Gormley, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., 2nd Floor, Silver Spring, MD 20993–0002, 301–796–2210 (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 November 21, 2020, FDA issued an Authorization to Regeneron for REGEN–COV (EUA 091), subject to the terms of the Authorization. Notice of the issuance of the Authorization was published in the **Federal Register** on February 19, 2021 (86 FR 10290), as required by section 564(h)(1) of the FD&C Act.

On May 26, 2021, FDA issued an Authorization to GSK for sotrovimab (EUA 100), subject to the terms of the Authorization. Notice of the issuance of the Authorization was published in the **Federal Register** on August 5, 2021 (86 FR 42850), as required by section 564(h)(1) of the FD&C Act.

On December 8, 2021, FDA issued an Authorization to AstraZeneca for EVUSHELD (EUA 104), subject to the terms of the Authorization. Notice of the issuance of the Authorization was published in the **Federal Register** on February 4, 2022 (87 FR 6578), as required by section 564(h)(1) of the FD&C Act.

On February 11, 2022, FDA issued an Authorization to Lilly for bebtelovimab (EUA 111), subject to the terms of the Authorization. Notice of the issuance of the Authorization was published in the **Federal Register** on March 22, 2022 (87 FR 16201), 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 Requests

In a request received by FDA on November 25, 2024, Regeneron requested revocation of, and on December 13, 2024, FDA revoked, the Authorization for REGEN–COV. Because Regeneron has informed FDA that all lots of REGEN–COV manufactured, labeled, and distributed for use under EUA 091 have expired, and that Regeneron does not intend to offer this product in the United States anymore, Regeneron requested FDA revoke the EUA for REGEN–COV. FDA has determined that it is appropriate to protect the public health or safety to revoke this Authorization.

In a request received by FDA on November 22, 2024, GSK requested revocation of, and on December 13, 2024, FDA revoked, the Authorization for sotrovimab. Because GSK has informed FDA that all lots of sotrovimab manufactured, labeled, and distributed for use under EUA 100 have expired, and that GSK does not intend to offer this product in the United States anymore, GSK requested FDA revoke the EUA for sotrovimab. FDA has determined that it is appropriate to protect the public health or safety to revoke this Authorization.

In a request received by FDA on November 21, 2024, AstraZeneca requested revocation of, and on December 13, 2024, FDA revoked, the Authorization for EVUSHELD. Because AstraZeneca has informed FDA that all lots of EVUSHELD manufactured, labeled, and distributed for use under EUA 104 have expired, and that AstraZeneca does not intend to offer this product in the United States anymore, AstraZeneca requested FDA revoke the EUA for EVUSHELD. FDA has determined that it is appropriate to protect the public health or safety to revoke this Authorization.

In a request received by FDA on December 5, 2024, Lilly requested revocation of, and on December 13, 2024, FDA revoked, the Authorization for bebtelovimab. Because Lilly has informed FDA that all lots of bebtelovimab manufactured, labeled, and distributed for use under EUA 111 have expired, and that Lilly does not intend to offer this product in the United States anymore, Lilly requested FDA revoke the EUA for bebtelovimab. FDA has determined that it is appropriate to protect the public health or safety to revoke this Authorization.

III. The Revocations

Having concluded that the criteria for revocation of the Authorizations under section 564(g)(2)(C) of the FD&C Act are

met, FDA has revoked the EUAs for REGEN–COV, sotrovimab, bebtelovimab, and EVUSHELD. These revocations in their entirety follow and provide explanations of the reasons for revocation, as required by section 564(h)(1) of the FD&C Act.

IV. Electronic Access

An electronic version of this document and the full text of the Authorizations are available on the internet at: *https://www.regulations.gov/*.

BILLING CODE 4164–01–P

U.S. FOOD & DRUG ADMINISTRATION

December 13, 2024

Regeneron Pharmaceuticals, Inc.
Attention: Danise Subramanian, PhD
Senior Director, Regulatory Affairs
777 Old Saw Mill River Road
Tarrytown, NY 15091-6707

Re: Revocation of EUA 091

Dear Dr. Subramanian:

This letter is in response to the request from Regeneron Pharmaceuticals, Inc. (Regeneron), received on November 25, 2024[1], that the U.S. Food and Drug Administration (FDA) revoke the EUA for REGEN-COV (casirivimab and imdevimab administered together). The EUA for REGEN-COV was issued initially on November 21, 2020. Regeneron has informed the FDA that all lots of REGEN-COV manufactured, labeled and distributed for use under EUA 091 have expired and that Regeneron does not intend to offer this product in the United States anymore. FDA understands that Regeneron will issue a communication to notify healthcare providers that have received REGEN-COV under the EUA of this revocation with instructions for product destruction for any product that remains in distribution.

The authorization of a drug for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360bbb-3) may, pursuant to section 564(g)(2) of the Act, be revoked when circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the Act). While there is no new safety concern with REGEN-COV, because FDA understands that Regeneron no longer intends to offer REGEN-COV in the United States under the EUA; because all product manufactured, labeled and distributed pursuant to the EUA has expired; and because Regeneron has requested that FDA revoke the EUA for REGEN-COV, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization.

Accordingly, FDA hereby revokes EUA 091 for REGEN-COV pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, REGEN-COV is no longer authorized for emergency use by FDA.

Notice of this revocation will be published in the *Federal Register*, pursuant to section 564(h)(1) of the Act.

[1] At the time of Regeneron's request, REGEN-COV was not authorized for use in any region of the United States due to the high frequency of circulating SARS-CoV-2 variants that are non-susceptible to REGEN-COV.

U.S. FOOD & DRUG ADMINISTRATION

December 13, 2024

GlaxoSmithKline LLC
Attention: Danielle Lumbatis, MBA, RAC
Associate Director, Global Regulatory Affairs
Specialty Therapeutic Group
1250 S. Collegeville Rd.
Collegeville, PA 19426

Re: Revocation of EUA 100

Dear Ms. Lumbatis:

This letter is in response to the request from GlaxoSmithKline LLC (GSK), received on November 22, 2024[1], that the U.S. Food and Drug Administration (FDA) revoke the EUA for sotrovimab. The EUA for sotrovimab was issued initially on May 26, 2021. GSK has informed the FDA that all lots of sotrovimab manufactured, labeled and distributed for use under EUA 100 have expired and that GSK does not intend to offer this product in the United States anymore. FDA understands that GSK will issue a communication to notify healthcare providers that have received sotrovimab under the EUA of this revocation with instructions for product destruction or return for any product that remains in distribution.

The authorization of a drug for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360bbb-3) may, pursuant to section 564(g)(2) of the Act, be revoked when circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the Act). While there is no new safety concern with sotrovimab, because FDA understands that GSK no longer intends to offer sotrovimab in the United States under the EUA; because all product manufactured, labeled and distributed pursuant to the EUA has expired; and because GSK has requested that FDA revoke the EUA for sotrovimab, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization.

Accordingly, FDA hereby revokes EUA 100 for sotrovimab pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, sotrovimab is no longer authorized for emergency use by FDA.

Notice of this revocation will be published in the *Federal Register*, pursuant to section 564(h)(1) of the Act.

[1] At the time of GSK's request, sotrovimab was not authorized for use in any region of the United States due to the high frequency of circulating SARS-CoV-2 variants that are non-susceptible to sotrovimab.

U.S. FOOD & DRUG ADMINISTRATION

December 13, 2024

Eli Lilly and Company
Attention: Jennifer Riddle Camp
Senior Director, GRA-NA
Lilly Corporate Center
Drop Code 2543
Indianapolis, IN 46285

Re: Revocation of EUA 111

Dear Ms. Riddle Camp:

This letter is in response to the request from Eli Lilly and Company (Lilly), received on December 5, 2024[1], that the U.S. Food and Drug Administration (FDA) revoke the EUA for bebtelovimab. The EUA for bebtelovimab was issued initially on February 11, 2022. Lilly has informed the FDA that all lots of bebtelovimab manufactured, labeled and distributed for use under EUA 111 have expired and that Lilly does not intend to offer this product in the United States anymore. FDA understands that Lilly will issue a communication to notify healthcare providers that have received bebtelovimab under the EUA of this revocation with instructions for product destruction or return for any product that remains in distribution.

The authorization of a drug for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360bbb-3) may, pursuant to section 564(g)(2) of the Act, be revoked when circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the Act). While there is no new safety concern with bebtelovimab, because FDA understands that Lilly no longer intends to offer bebtelovimab in the United States under the EUA; because all product manufactured, labeled and distributed pursuant to the EUA has expired; and because Lilly has requested that FDA revoke the EUA for bebtelovimab, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization.

Accordingly, FDA hereby revokes EUA 111 for bebtelovimab pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, bebtelovimab is no longer authorized for emergency use by FDA.

Notice of this revocation will be published in the *Federal Register*, pursuant to section 564(h)(1) of the Act.

[1] At the time of Lilly's request, bebtelovimab was not authorized for use in any region of the United States due to the high frequency of circulating SARS-CoV-2 variants that are non-susceptible to bebtelovimab.

U.S. FOOD & DRUG ADMINISTRATION

December 13, 2024

AstraZeneca Pharmaceuticals LP
Attention: Lei Hua, PhD, PMP, RAC
Associate Regulatory Affairs Director
One MedImmune Way
Gaithersburg, MD 20878

Re: Revocation of EUA 104

Dear Dr. Hua:

This letter is in response to the request from AstraZeneca Pharmaceuticals LP (AstraZeneca), received on November 21, 2024[1], that the U.S. Food and Drug Administration (FDA) revoke the EUA for EVUSHELD (tixagevimab co-packaged with cilgavimab). The EUA for EVUSHELD was issued initially on December 8, 2021. AstraZeneca has informed the FDA that all lots of EVUSHELD manufactured, labeled and distributed for use under EUA 104 have expired and that AstraZeneca does not intend to offer this product in the United States anymore. FDA understands that AstraZeneca will issue a communication to notify customers and providers that have received EVUSHELD under the EUA of this revocation with instructions for product destruction or return for any product that remains in distribution.

The authorization of a drug for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360bbb-3) may, pursuant to section 564(g)(2) of the Act, be revoked when circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the Act). While there is no new safety concern with EVUSHELD, because FDA understands that AstraZeneca no longer intends to offer EVUSHELD in the United States under the EUA; because all product manufactured, labeled, and distributed pursuant to the EUA has expired; and because AstraZeneca has requested that FDA revoke the EUA for EVUSHELD, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization.

Accordingly, FDA hereby revokes EUA 104 for EVUSHELD pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, EVUSHELD is no longer authorized for emergency use by FDA.

Notice of this revocation will be published in the *Federal Register*, pursuant to section 564(h)(1) of the Act.

[1] At the time of AstraZeneca's request, EVUSHELD was not authorized for emergency use in the United States due to the high frequency of circulating SARS-CoV-2 variants that are non-susceptible to EVUSHELD.

Dated: July 23, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–14233 Filed 7–28–25; 8:45 am]

BILLING CODE 4164–01–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–0383]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Public Health Service Guideline on Infectious Disease Issues in Xenotransplantation

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by August 28, 2025.