DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–N–0418]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Tropical Disease Priority Review Vouchers

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.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 0910–0822. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Tropical Disease Priority Review Vouchers

OMB Control Number 0910–0822—Extension

This information collection supports implementation of statutory requirements as discussed in Agency guidance. Section 524 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360n) is designed to encourage development of new drug or biological products for prevention and treatment of certain tropical diseases affecting millions of people throughout the world and makes provisions for awarding priority review vouchers for future applications to sponsors of tropical disease products. Section 524 of the FD&C Act serves to stimulate new drug development for drugs to treat a ''tropical disease'' (as defined in section 524(a)(3)) by offering additional incentives for obtaining FDA approval for pharmaceutical treatments for these diseases. As defined in section 524(a)(4) of the FD&C Act, a sponsor of a ''tropical disease product application'' may be eligible for a voucher that can be used to obtain a priority review for any other application submitted under section 505(b)(1) of the FD&C Act (21 U.S.C. 355(b)(1)) or section 351 of the Public Health Service Act (PHS Act) (42 U.S.C. 262).

Accordingly, we developed the procedural guidance document entitled, ''Tropical Disease Priority Review Vouchers'' (October 2016), (available at *https://www.fda.gov/media/72569/download*). The guidance document explains how FDA implements provisions of section 524 of the FD&C Act and how sponsors may qualify for a priority review voucher based on eligibility criteria set forth in the statute, how to use priority review vouchers, and how priority review vouchers may be transferred to other sponsors. The guidance also communicates that section 524 of the FD&C Act requires attestation by the sponsor of eligibility for a priority review voucher upon submission of the marketing application.

Description of Respondents: Sponsors submitting applications under section 505(b)(1) of the FD&C Act or section 351 of the PHS Act.

In the **Federal Register** of May 1, 2025 (90 FR 18680) we published a 60-day notice soliciting comment on the proposed collection of information. Comments received supported that the collection of information provided utility to FDA and encouraged its continued use. The comments also suggested FDA consider a broader scope of information collection and greater use of technological submission mechanisms. We appreciate all comments and are committed to making enhancements to our collection systems as our limited resources allow. At the same time, the comments suggested no adjustment in FDA's estimate of burden for the information collection.

We estimate the burden of the information collection as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Reporting under section 524 of the FD&C Act	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Priority Review Voucher Request	1	1	1	8	8
Notifications of Intent To Use a Voucher	2	1	2	8	16
Letters Indicating the Transfer of a Voucher Letter	1	1	1	8	8
Acknowledging the Receipt of a Transferred Voucher	1	1	1	8	8
Attestation of Eligibility	1	1	1	2	2
Total					42

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

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.

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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