

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-2022-D-2315 for “Early Lyme Disease as Manifested by Erythema Migrans: Developing Drugs for Treatment.” Received comments 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.” The Agency 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 this 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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT:

Shabnam Naseer, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6239, Silver Spring, MD 20993, 301-796-8539.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a final guidance for industry entitled “Early Lyme Disease as Manifested by Erythema Migrans: Developing Drugs for Treatment.”

The purpose of this guidance is to assist sponsors in the clinical development of drugs for the treatment of early Lyme disease as manifested by EM.

This guidance finalizes the draft guidance of the same name issued on February 1, 2023 (88 FR 6759). FDA made clarifying edits in response to pertinent public comments that were received on the background section, as well as regarding endpoints (e.g., patient-reported outcome development), missing data, and safety database size.

This guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on “Early Lyme Disease as Manifested by Erythema Migrans: Developing Drugs for Treatment.” It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to

previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3521). The collections of information in 21 CFR part 312 pertaining to investigational new drug applications have been approved under OMB control number 0910-0014. The collections of information in 21 CFR part 314 pertaining to new drug applications have been approved under OMB control number 0910-0001. The collections of information in 21 CFR part 601 pertaining to biologics license applications have been approved under OMB control number 0910-0338. The collections of information in 21 CFR part 201 pertaining to prescription product labeling requirements have been approved under OMB control number 0910-0572.

III. Electronic Access

Persons with access to the internet may obtain the guidance at <https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs>, <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>, or <https://www.regulations.gov>.

Dated: June 20, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025-11809 Filed 6-25-25; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2022-N-0150]

Revocation of Authorization of Emergency Use of In Vitro Diagnostic Device for Detection and/or Diagnosis of COVID-19; 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 Cepheid for the Xpert Xpress SARS-CoV-2 test. FDA revoked the Authorization under the Federal Food, Drug, and Cosmetic Act (FD&C Act) as requested by the Authorization holder. The revocation, which includes an explanation of the reason for revocation, is reprinted at the end of this document.

DATES: The revocation of the Authorization for the Cepheid's Xpert Xpress SARS-CoV-2 test was effective as of May 28, 2025.

ADDRESSES: Submit written requests for a single copy of the revocation to the Office of Policy, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, 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 revocation may be sent. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the revocation.

FOR FURTHER INFORMATION CONTACT: Kim Sapsford-Medintz, Office of Product Evaluation and Quality, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3216, Silver Spring, MD 20993-0002, 301-796-0311 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION:

I. Background

Section 564 of the FD&C Act (21 U.S.C. 360bbb-3) as amended by the Project BioShield Act of 2004 (Pub. L. 108-276) and the Pandemic and All-

Hazards Preparedness Reauthorization Act of 2013 (Pub. L. 113-5) allows FDA to strengthen the public health protections against biological, chemical, radiological, or nuclear agent or 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 March 20, 2020, FDA issued the Authorization to Cepheid for the Xpert Xpress SARS-CoV-2 test, subject to the terms of the Authorization. Notice of the issuance of this Authorization was published in the **Federal Register** on June 5, 2020 (85 FR 34638), as required by section 564(h)(1) of the FD&C Act.

Subsequent updates to the Authorization were made available on FDA's website. The authorization of a device 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. Authorization Revocation Request

In a request received by FDA on May 21, 2025, Cepheid requested the revocation of, and on May 28, 2025, FDA revoked, the Authorization for the Cepheid's Xpert Xpress SARS-CoV-2 test. Cepheid notified FDA that all its U.S. customers transitioned to the Xpert Xpress SARS-CoV-2 *plus* product that was authorized under EUA220187, and requested FDA revoke the Cepheid's Xpert Xpress SARS-CoV-2 test. FDA has determined that it is appropriate to protect the public health or safety to revoke this Authorization.

III. Electronic Access

An electronic version of this document and the full text of the revocation is available on the internet at <https://www.regulations.gov/>.

IV. The Revocation

Having concluded that the criteria for revocation of the Authorization under section 564(g)(2)(C) of the FD&C Act are met, FDA has revoked the EUA for Cepheid's Xpert Xpress SARS-CoV-2 test. The revocation in its entirety follows and provides an explanation of the reason for revocation, as required by section 564(h)(1) of the FD&C Act.

BILLING CODE 4164-01-P



May 28, 2025

Sharmin Bhathena
Senior Manager, Regulatory Affairs
Cepheid
904 Caribbean Drive
Sunnyvale, CA 94089
Re: Revocation of EUA200035

Dear Sharmin Bhathena:

This letter is in response to the request from Cepheid, in a letter dated May 21, 2025, that the U.S. Food and Drug Administration (FDA) revoke the EUA for the Xpert Xpress SARS-CoV-2 test issued on March 20, 2020, revised and reissued on January 7, 2021, and amended on April 10, 2020, April 28, 2020, August 8, 2020, September 16, 2020, September 23, 2021, and April 26, 2022. Cepheid indicated that all their U.S. customers have transitioned to the Xpert Xpress SARS-CoV-2 *plus* product that was authorized under EUA220187.

The authorization of a device 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). Because Cepheid has requested that FDA revoke the EUA for the Xpert Xpress SARS-CoV-2 test, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA200035 for the Xpert Xpress SARS-CoV-2, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the Xpert Xpress SARS-CoV-2 test 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.

Sincerely,

/s/

Ellen J. Flannery, J.D.
Deputy Center Director for Policy
Director, Office of Policy
Center for Devices and Radiological Health
Food and Drug Administration

Dated: June 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-1623]

Generic Drug User Fees; Consultation Meetings on Reauthorization of Generic Drug User Fee Amendments for Fiscal Years 2028-2032; Request for Notification of Intention to Participate

AGENCY: Food and Drug Administration,
HHS.

ACTION: Notice; request for notification
of participation.

SUMMARY: The Food and Drug Administration (FDA or Agency) is issuing this notice to request that interested parties, including patient and consumer advocacy groups, health care professionals, and scientific and academic experts notify FDA of their intent to participate in periodic consultation meetings on the reauthorization of the Generic Drug User Fee Amendments (GDUFA) for Fiscal Years (FYs) 2028-2032. At the end of September 2027, new legislation will be required for FDA to continue collecting