U.S. FOOD & DRUG ADMINISTRATION

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.

[FR Doc. 2025–11822 Filed 6–25–25; 8:45 am]

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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

generic drug user fees for subsequent fiscal years for the generic drug program. The Federal Food, Drug, and Cosmetic Act (FD&C Act) requires that FDA consult with a range of interested parties in developing recommendations for the next GDUFA program. The FD&C Act also requires that FDA hold continued discussions with patient and consumer advocacy groups at least monthly during FDA's negotiations with the regulated industry. The purpose of this request for notification is to ensure continuity and progress in these monthly discussions by establishing consistent representation by interested parties.

DATES: Submit notification of intention to participate in these series of meetings by September 4, 2025. Meetings will be held monthly throughout the duration of negotiations with regulated industry, and it is anticipated that they will commence in the Fall of 2025. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: Submit notification of intention to participate in monthly consultation meetings by email to *GDUFAReauthorization@fda.hhs.gov.* The meetings will be held in person at the FDA campus in White Oak, MD: 10903 New Hampshire Ave., Silver Spring, MD 20993 and virtually using the Microsoft Teams platform.

FOR FURTHER INFORMATION CONTACT: Dat Doan, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 3334, Silver Spring, MD 20993–0002, 240–402–8926, *GDUFAReauthorization@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is requesting that interested parties, including patient and consumer advocacy groups, healthcare professionals, and scientific and academic experts, notify the Agency of their intent to participate in periodic consultation meetings on the reauthorization of GDUFA. GDUFA authorizes FDA to collect user fees from the regulated industry for the current program (GDUFA III). At the end of September 2027, new legislation will be required for FDA to continue collecting user fees for subsequent fiscal years for the generic drug program. Without new legislation, FDA will no longer be able to collect user fees for future fiscal years to fund human generic drug activities. Section 744C(f)(1) (21 U.S.C. 379j–43(f)(1)) of the FD&C Act requires that FDA consult with a range of interested parties in developing recommendations for the next GDUFA program, including representatives from patient and consumer groups, health care professionals, and scientific and academic experts. FDA will initiate this process by holding a public meeting on July 11, 2025, at which interested parties and other members of the public will be given an opportunity to present their views on reauthorization (90 FR 21313, May 19, 2025). Section 744C(f)(3) (21 U.S.C. 379j–43(f)(3)) of the FD&C Act further requires that FDA continue meeting with these interested parties at least once every month during negotiations with the regulated industry to continue discussions of views from interested parties on the reauthorization. It is anticipated that these monthly consultation meetings will commence in the Fall of 2025.

FDA is issuing this **Federal Register** notice to request that interested representatives from patient and consumer advocacy groups, health care professional associations, as well as scientific and academic experts notify FDA of their intent to participate in periodic consultation meetings on GDUFA reauthorization. FDA believes that consistent representation by interested parties at these meetings will be important to ensure progress in these discussions. If you wish to participate in the consultation meetings, please designate one or more representatives from your organization who will commit to attending these meetings and preparing for the discussions, as needed. Interested parties who identify themselves through this notice will be included in all discussions with interested parties during the period that FDA negotiates with the regulated industry. Interested parties who decide to participate in these monthly meetings at a later time may still participate in remaining monthly meetings by notifying FDA (see **ADDRESSES**). These discussions with interested parties will satisfy the periodic consultation requirement in section 744C(f)(3) (21 U.S.C. 379j–43(f)(3)) of the FD&C Act.

II. Notification of Intent To Participate in Periodic Consultation Meetings

If you intend to participate in continued periodic consultation meetings regarding GDUFA reauthorization, please provide notification by email to *GDUFAReauthorization@fda.hhs.gov* by September 4, 2025. Your email should contain complete contact information, including name, title, affiliation, address, email address, phone number, and notice of any special accommodations required because of disability. Interested parties will receive confirmation and additional information about the first periodic consultation meeting after FDA receives this notification. Information concerning GDUFA, including the GDUFA III Commitment Letter, key **Federal Register** documents, GDUFA-related guidances, performance reports, and financial reports may be found on the FDA website at *https://www.fda.gov/gdufa.*

Dated: June 23, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–11769 Filed 6–25–25; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: COVID–19 Provider Relief Fund (PRF) and American Rescue Plan (ARP) Rural Payment Reporting Activities, OMB No. 0906–0068—Revision

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this ICR should be received no later than August 25, 2025.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 14NWH04, 5600 Fishers Lane, Rockville, Maryland 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call Samantha Miller, the HRSA Information Collection Clearance Officer, at (301) 443–3983.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the ICR title for reference.