4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

Revocation of Two Authorizations of Emergency Use of In Vitro Diagnostic Devices 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 Authorizations (EUAs) (the Authorizations) issued to Pfizer Inc. for the Lucira by Pfizer COVID-19 & Flu Test and Lucira by Pfizer COVID-19 & Flu Home Test. FDA revoked the Authorizations under the Federal Food, Drug, and Cosmetic Act (FD&C Act) as requested by the Authorization holder. The revocations, which include an explanation of the reasons for each revocation, are reprinted at the end of this document.

DATES: The revocation of the Authorizations for the Pfizer Inc.'s Lucira by Pfizer COVID-19 & Flu Test and Lucira by Pfizer COVID-19 & Flu Home Test were effective as of October 22, 2025.

ADDRESSES: Submit written requests for a single copy of the revocations to the Office of Policy, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5441, 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: 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 November 22, 2022, FDA issued the Authorization to Lucira Health, Inc. for the Lucira COVID-19 & Flu Test, subject to the terms of the Authorization[1]. Notice of the issuance of this Authorization was published in the *Federal Register* on January 23, 2023 (88 FR 3995), as required by section 564(h)(1) of the FD&C Act.

On February 24, 2023, FDA issued the Authorization to Lucira Health, Inc. for the Lucira COVID-19 & Flu Home Test, subject to the terms of the Authorization[2]. Notice of the issuance of this Authorization was published in the *Federal Register* on March 10, 2023 (88 FR 15051), as required by section 564(h)(1) of the FD&C Act.

Subsequent updates to the Authorizations 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

---

[1] Ownership of the EUA for the Lucira COVID-19 & Flu Test was transferred from Lucira Health Inc. to Pfizer Inc., on June 15, 2023, and the name was changed to Lucira by Pfizer COVID-19 & Flu Test.

[2] Ownership of the EUA for the Lucira COVID-19 & Flu Home Test was transferred from Lucira Health Inc. to Pfizer Inc., on June 15, 2023, and the name was changed to Lucira by Pfizer COVID-19 & Flu Home Test.

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. Authorizations Revocation Requests

In a request received by FDA on October 10, 2025, Pfizer Inc. requested the revocation of, and on October 22, 2025, FDA revoked, the Authorization for the Pfizer Inc.'s Lucira by Pfizer COVID-19 & Flu Test. Pfizer Inc. notified FDA as the date of the letter there is no viable Lucira by Pfizer COVID-19 & Flu Test reagents remaining in the United States, and requested FDA revoke the Pfizer Inc.'s Lucira by Pfizer COVID-19 & Flu Test. 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 October 10, 2025, Pfizer Inc., requested the revocation of, and on October 22, 2025, FDA revoked, the Authorization for the Pfizer Inc.'s Lucira by Pfizer COVID-19 & Flu Home Test. Pfizer Inc. notified FDA that as the date of the letter there is no viable Lucira by Pfizer COVID-19 & Flu Home Test reagents remaining in the United States, and requested FDA revoke the Pfizer Inc.'s Lucira by Pfizer COVID-19 & Flu Home 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 revocations are available on the internet at https://www.regulations.gov/.

IV. 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 EUA for Pfizer Inc.'s Lucira by Pfizer COVID-19 & Flu Test and Lucira by Pfizer COVID-19 & Flu Home Test. The revocations in their entirety follow and provide an explanation of the reasons for revocation, as required by section 564(h)(1) of the FD&C Act.

U.S. FOOD & DRUG ADMINISTRATION

October 22, 2025

William Vogt
Director, Global Regulatory Sciences
Pfizer Inc.
66 Hudson Boulevard East
New York, NY 10001

Re: Revocation of EUA220333

Dear William Vogt:

This letter is in response to the request from Pfizer Inc., in a letter dated October 10, 2025, that the U.S. Food and Drug Administration (FDA) revoke the EUA for the Lucira by Pfizer COVID-19 & Flu Test issued on November 22, 2022, revised and reissued on June 15, 2023, and amended on March 22, 2023, August 3, 2023, and September 6, 2023. FDA understands that as of the date of this letter there is no viable Lucira by Pfizer COVID-19 & Flu Test reagent remaining in distribution in the United States.

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 Pfizer Inc. has requested that FDA revoke the EUA for the Lucira by Pfizer COVID-19 & Flu Test, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA220333 for the Lucira by Pfizer COVID-19 & Flu Test, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the Lucira by Pfizer COVID-19 & Flu 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,

Ellen J. Flannery -S

Digitally signed by Ellen J. Flannery -S
Date: 2025.10.22 08:07:18 -04'00'

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

U.S. FOOD & DRUG ADMINISTRATION

October 22, 2025

William Vogt
Director, Global Regulatory Sciences
Pfizer Inc.
66 Hudson Boulevard East
New York, NY 10001

Re: Revocation of EUA220490

Dear William Vogt:

This letter is in response to the request from Pfizer Inc., in a letter dated October 10, 2025, that the U.S. Food and Drug Administration (FDA) revoke the EUA for the Lucira by Pfizer COVID-19 & Flu Home Test issued on February 24, 2023, revised and reissued on June 15, 2023, and amended on March 22, 2023, August 3, 2023, and September 6, 2023. FDA understands that as of the date of this letter there is no viable Lucira by Pfizer COVID-19 & Flu Home Test reagents remaining in distribution in the United States.

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 Pfizer Inc. has requested that FDA revoke the EUA for the Lucira by Pfizer COVID-19 & Flu Home Test, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA220490 for the Lucira by Pfizer COVID-19 & Flu Home Test, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the Lucira by Pfizer COVID-19 & Flu Home 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,

Ellen J. Flannery -S

Digitally signed by Ellen J. Flannery -S
Date: 2025.10.22 14:19:05 -04'00'

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

Lowell M. Zeta,

Acting Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025-24155 Filed: 12/31/2025 8:45 am; Publication Date: 1/2/2026]