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,

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