U.S. FOOD & DRUG ADMINISTRATION

April 2, 2025

Elizabeth Mauro
Director, Global Regulatory Science
Pfizer Inc.
66 Hudson Boulevard East
New York, NY 10001
Re: Revocation of EUA210196

Dear Elizabeth Mauro:
This letter is in response to the request from Pfizer Inc., in letter dated March 14, 2025, that the U.S. Food and Drug Administration (FDA) revoke the EUA for the Lucira CHECK-IT COVID-19 Test Kit issued on April 9, 2021, amended on September 23, 2021, July 28, 2022, and December 12, 2022, and revised and reissued on June 29, 2023. Pfizer Inc. indicated that they did not distribute the authorized product and requested that the EUA be revoked. FDA understands that as of the date of this letter there are no viable Lucira CHECK-IT COVID-19 Test Kit reagents 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 CHECK-IT COVID-19 Test Kit, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA210196 for the Lucira CHECK-IT COVID-19 Test Kit, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the Lucira CHECK-IT COVID-19 Test Kit 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