August 7, 2024

Barbara-Ann Conway-Myers, Ph.D.
Principal, Regulatory Affairs, North America
LumiraDx UK Ltd.
Building 115, Bedford Technology Park,
Thurleigh
Bedford MK44 2YA, United Kingdom
Re: Revocation of EUA220457

Dear Dr. Conway-Myers:
This letter is in response to the request from LumiraDx UK Ltd., in an email dated February 22, 2024, that the U.S. Food and Drug Administration (FDA) revoke the EUA for the LumiraDx SARS CoV-2 & Flu A/B RNA STAR Complete Assay issued on February 3, 2023, and amended on June 30, 2023. LumiraDx UK Ltd. indicated that they have ceased manufacture of the authorized product and requested that the EUA be revoked. FDA understands that as of the date of this letter there are no viable LumiraDx SARS CoV-2 & Flu A/B RNA STAR Complete Assay 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 LumiraDx UK Ltd. has requested that FDA revoke the EUA for the LumiraDx SARS CoV-2 & Flu A/B RNA STAR Complete Assay, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA220457 for the LumiraDx SARS CoV-2 & Flu A/B RNA STAR Complete Assay, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the LumiraDx SARS CoV-2 & Flu A/B RNA STAR Complete Assay 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, J.D.
Deputy Center Director for Policy
Director, Office of Policy
Center for Devices and Radiological Health
Food and Drug Administration