April 18, 2023

Stacey Moltchanoff
Regulatory Affairs Manager
Life Technologies Corporation (a part of Thermo Fisher Scientific Inc.)
5781 Van Allen Way
Carlsbad, CA 92008

Re: Revocation of EUA220461

Dear Stacey Moltchanoff:

This letter is in response to the request from Life Technologies Corporation (a part of Thermo Fisher Scientific Inc.), in a letter received April 13, 2023, that the U.S. Food and Drug Administration (FDA) revoke the EUA for TaqPath Monkeypox/Orthopox Virus DNA Kit issued on December 13, 2022. Thermo Fisher Scientific Inc. has decided not to commercially support the EUA product and requested that the EUA be revoked. FDA understands that, as of the date of this letter, no TaqPath Monkeypox/Orthopox Virus DNA Kit reagents were distributed 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 Thermo Fisher Scientific Inc. has requested that FDA revoke the EUA for the TaqPath Monkeypox/Orthopox Virus DNA Kit, FDA has determined that it is appropriate, to protect the public health or safety, to revoke this authorization. Accordingly, FDA hereby revokes EUA220461 for the TaqPath Monkeypox/Orthopox Virus DNA Kit, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the TaqPath Monkeypox/Orthopox Virus DNA 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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Jeffrey E. Shuren, M.D., J.D.
Director
Center for Devices and Radiological Health
Food and Drug Administration