July 30, 2024

Se Hyeong An
Regulatory Affairs Specialist, Global Regulatory Affairs 2 Team
Celltrion USA, Inc.
One Evertrust Plaza, Suite 1207
Jersey City, NJ 07302

Re: Revocation of EUA202357

Dear Se Hyeong An:

This letter is in response to the request from Celltrion USA, Inc., in an email dated July 5, 2024, that the U.S. Food and Drug Administration (FDA) revoke the EUA for the Sampinute COVID-19 Antigen MIA issued on October 23, 2020, and amended on September 23, 2021, November 1, 2022, and March 27, 2023. Celltrion USA, Inc. indicated that the authorized product was never manufactured or distributed after its authorization and requested that the EUA be revoked. FDA understands that as of the date of this letter there are no viable Sampinute COVID-19 Antigen MIA 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 Celltrion USA, Inc. has requested that FDA revoke the EUA for the Sampinute COVID-19 Antigen MIA, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA202357 for the Sampinute COVID-19 Antigen MIA, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the Sampinute COVID-19 Antigen MIA 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