January 29, 2025

Lisa Baumhardt, MS, MJ, MT(ASCP), RAC, FRAPS
Senior Medical Device Regulatory Expert
Hyman, Phelps & McNamara, P.C.
Representing:
OSANG LLC
215 N. Marengo Ave., 3rd Floor
Pasadena, CA 91101

Re: Revocation of EUA240007

Dear Lisa Baumhardt:

This letter is in response to your request on behalf of OSANG LLC, in a letter dated January 14, 2025, that the U.S. Food and Drug Administration (FDA) revoke the EUA for the QuickFinder COVID-19/Flu Antigen Self Test, issued on April 3, 2024, and revised on May 21, 2024, and October 18, 2024. OSANG LLC indicated that they discontinued distribution of the QuickFinder COVID-19/Flu Antigen Self Test for the EUA labeled product as of January 14, 2025, and requested that the EUA be revoked. As of the date of this letter OSANG LLC, has fully transitioned to the QuickFinder COVID-19/Flu Antigen Self Test product that was cleared under K243262. FDA understands that as of the date of this letter OSANG LLC has discontinued distribution of the QuickFinder COVID-19/Flu Antigen Self Test for the EUA labeled product, and there is no viable EUA labeled product in distribution in the United States or undistributed in OSANG LLC's inventory.

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 OSANG LLC has requested that FDA revoke the EUA for the QuickFinder COVID-19/Flu Antigen Self Test, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA240007 for the QuickFinder COVID-19/Flu Antigen Self Test, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the QuickFinder COVID-19/Flu Antigen Self 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