October 9, 2024

Chanda Owens
Cue Health Inc.
4890 Carroll Canyon Road, Suite 100
San Diego, CA 92121
Re: Revocation of EUA200248

Dear Chanda Owens:

This letter is in response to the request from Cue Health Inc., in a letter dated September 9, 2024, that the U.S. Food and Drug Administration (FDA) revoke the EUA for the Cue COVID-19 Test issued on June 10, 2020, amended on August 20, 2020, reissued on March 26, 2021, and then amended on March 1, 2022, March 9, 2022, and March 8, 2023. Cue Health Inc. indicated that they have ceased manufacture, shipping and distribution of the authorized product and requested that the EUA be revoked. FDA understands that as of the date of this letter any remaining viable Cue COVID-19 Test cartridges in distribution in the United States cannot be used due to the disabling of the Cue Health Mobile Application (Cue Health App) required to run the test.

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 Cue Health Inc. has requested that FDA revoke the EUA for the Cue COVID-19 Test, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA200248 for the Cue COVID-19 Test, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the Cue COVID-19 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,

_____
Ellen J. Flannery, J.D.
Deputy Center Director for Policy
Director, Office of Policy
Center for Devices and Radiological Health
Food and Drug Administration