



July 15, 2021

Fred Turner
Chief Executive Officer
Curative Inc.
1600 Adams Drive, Suite 105
Menlo Park, CA 94025
Re: Revocation of EUA200132

Dear Mr. Turner:

This letter is in response to Curative Inc.'s (Curative) request dated June 16, 2021, that the U.S. Food and Drug Administration (FDA) revoke the Emergency Use Authorization (EUA200132) for the Curative SARS-Cov-2 Assay issued on April 16, 2020, under the original name Curative-Korva SARS-Cov-2 Assay, and amended on June 11, 2020. As was also announced in its June 16, 2021 press release,¹ Curative has indicated that it is transitioning to the use of different EUA-authorized SARS-CoV-2 tests for the testing offered at its laboratories. In its June 16 letter, Curative requested that the revocation of the Curative SARS-Cov-2 Assay be effective July 15, 2021, noting that it will no longer be in use as of July 15, 2021.

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 Curative has notified FDA that it will no longer be using the Curative SARS-Cov-2 Assay as of July 15, 2021 and requests FDA revoke the authorization effective that day, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA200132 for the Curative SARS-Cov-2 Assay, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the Curative SARS-Cov-2 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,

RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

¹ <https://www.prnewswire.com/news-releases/curative-expands-testing-options-for-covid-19-flu-and-rsv-across-nationwide-healthcare-delivery-network-301314095.html>