BILLING CODE 4164–01–C

Dated: August 26, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–18777 Filed 8–30–21; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–0412]

Revocation of Authorization of Emergency Use of an In Vitro Diagnostic Device for Detection and/or Diagnosis of COVID–19; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the revocation of the Emergency Use Authorization (EUA) (the Authorization) issued to Curative Inc. for the Curative SARS–Cov–2 Assay. FDA revoked the Authorization on July 15, 2021, under the Federal Food, Drug, and Cosmetic Act (FD&C Act), as requested by Curative Inc. on June 16, 2021. The revocation, which includes an explanation of the reasons for the revocation, is reprinted in this document.

DATES: The Authorization for the Curative SARS–Cov–2 Assay is revoked as of July 15, 2021.

ADDRESSES: Submit written requests for a single copy of the revocation to the Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4338, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the revocation may be sent. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the revocation.

FOR FURTHER INFORMATION CONTACT: Jennifer J. Ross, Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4332, Silver Spring, MD 20993–0002, 240–402–8155 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION:

I. Background

Section 564 of the FD&C Act (21 U.S.C. 360bbb-3) allows FDA to strengthen the public health protections against biological, chemical, nuclear, and radiological agents. Among other things, section 564 of the FD&C Act allows FDA to authorize the use of an unapproved medical product or an unapproved use of an approved medical product in certain situations. On April 16, 2020, FDA issued the Authorization to Curative Inc. (original issuance to KorvaLabs, Inc. under the name Curative-Korva SARS–Cov–2 Assay). Notice of the issuance of the Authorization was published in the **Federal Register** on July 14, 2020 (85 FR 42407), as required by section 564(h)(1) of the FD&C Act. The authorization of a device for emergency use under section 564 of the FD&C Act may, pursuant to section 564(g)(2)(C) of the FD&C Act, be revoked when circumstances make such revocation appropriate to protect the public health or safety.

II. EUA Revocation Request of an In Vitro Diagnostic Device

On June 16, 2021, Curative Inc. requested the revocation of, and on July 15, 2021, FDA revoked, the Authorization for the Curative SARS–Cov–2 Assay. Because Curative Inc. notified FDA that it will no longer be using the Curative SARS–Cov–2 Assay as of July 15, 2021, and requested 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.

III. Electronic Access

An electronic version of this document and the full text of the revocations are available on the internet at *https://www.regulations.gov/* and *https://www.fda.gov/media/150773/download.*

IV. The Revocation

Having concluded that the criteria for revocation of the Authorization under section 564(g)(2)(C) of the FD&C Act are met, FDA has revoked the EUA for the Curative SARS–Cov–2 Assay. The revocation in its entirety follows and provides an explanation of the reasons for revocation, as required by section 564(h)(1) of the FD&C Act.

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U.S. FOOD & DRUG ADMINISTRATION

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,

Denise M. Hinton -S
Digitally signed by Denise M. Hinton -S
Date: 2021.07.15 07:51:38 -04'00'

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

Dated: August 26, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Statement of Organization, Functions, and Delegations of Authority

Part R (Health Resources and Services Administration) of the Statement of Organization, Functions and Delegations of Authority of the Department of Health and Human Services (60 FR 56605, as amended November 6, 1995; as last amended at 86 FR 6344–6349 dated January 21, 2021) is amended to reorganize sections of the Office of the Administrator, the Healthcare Systems Bureau, and the Bureau of Primary Health Care.

Key functional changes include re-establishing, retaining and renaming the Healthcare Systems Bureau to the Health Systems Bureau; changing the name of the Office of Provider Support to the Provider Relief Bureau; changing the name of the Office of Regional