4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2021-N-0973]

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 Life Technologies Corporation (a part of Thermo Fisher Scientific, Inc.) (Thermo Fisher) for the TaqPath COVID-19 MS2 Combo Kit 2.0. FDA revoked this Authorization on September 27, 2021, under the Federal Food, Drug, and Cosmetic Act (FD&C Act). The revocation, which includes an explanation of the reasons for revocation, is reprinted in this document.

DATES: The Authorization for the TaqPath COVID-19 MS2 Combo Kit 2.0 is revoked as of September 27, 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) as amended by the Project BioShield Act of 2004 (Pub. L. 108-276) and the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (Pub. L. 113-5) 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 August 2, 2021, FDA issued an EUA to Thermo Fisher for the TaqPath COVID-19 MS2 Combo Kit 2.0, subject to the terms of the Authorization. Notice of the issuance of the Authorization is published elsewhere in this issue of the *Federal Register*, 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) of the FD&C Act, be revoked when the criteria under section 564(c) of the FD&C Act for issuance of such authorization are no longer met (section 564(g)(2)(B) of the FD&C Act), or other circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the FD&C Act).

II. EUA Revocation Request

On September 22, 2021, Thermo Fisher requested the revocation of, and on September 27, 2021, FDA revoked the Authorization for, the TaqPath COVID-19 MS2 Combo Kit 2.0. Because Thermo Fisher has notified FDA that it is longer commercially supporting the TaqPath COVID-19 MS2 Combo Kit 2.0 and requested FDA revoke the Authorization, 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 revocation are available on the internet at https://www.regulations.gov/.

IV. The Revocation

Having concluded that the criteria for revocation of the Authorization under section 564(g) of the FD&C Act are met, FDA has revoked the EUA for the TaqPath COVID-19 MS2 Combo Kit 2.0. 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.

U.S. FOOD & DRUG ADMINISTRATION

September 27, 2021

Ashley Vu
Regulatory Affairs Manager
Thermo Fisher Scientific, Inc.
5781 Van Allen Way
Carlsbad, CA 92008
Re: Revocation of EUA210447

Dear Ms. Vu:

This letter is in response to Thermo Fisher Scientific, Inc.'s request on behalf of Life Technologies Corporation (a part of Thermo Fisher Scientific, Inc.) dated September 22, 2021, that the U.S. Food and Drug Administration (FDA) revoke the Emergency Use Authorization (EUA210447) for the TaqPath COVID-19 MS2 Combo Kit 2.0 issued on August 2, 2021. Thermo Fisher Scientific, Inc. indicated that it has decided to not commercially support the TaqPath COVID-19 MS2 Combo Kit 2.0 at this time "due to the current public clinical needs being met by our other EUA assays that are available and on market."

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 Thermo Fisher Scientific, Inc. has notified FDA that it is longer commercially supporting the TaqPath COVID-19 MS2 Combo Kit 2.0 and requests FDA revoke the authorization, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA210447 for the TaqPath COVID-19 MS2 Combo Kit 2.0, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the TaqPath COVID-19 MS2 Combo Kit 2.0 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,

/s/

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RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

Dated: October 22, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021-23500 Filed: 10/27/2021 8:45 am; Publication Date: 10/28/2021]