4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2022-N-0150]

Revocation of Two Authorizations of Emergency Use of In Vitro Diagnostic Devices 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 Authorizations (EUAs) (the Authorizations) issued to Becton, Dickinson and Company (BD) for the BD SARS-CoV-2/Flu for BD MAX System, and Talis Biomedical Corporation (Talis) for the Talis One COVID-19 Test System. FDA revoked these Authorizations under the Federal Food, Drug, and Cosmetic Act (FD&C Act). The revocations, which include an explanation of the reasons for each revocation, are reprinted in this document.

DATES: The Authorization for the BD SARS-CoV-2/Flu for BD MAX System is revoked as of August 1, 2022. The Authorization for the Talis One COVID-19 Test System is revoked as of August 23, 2022.

ADDRESSES: Submit written requests for a single copy of the revocations 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 revocations may be sent. See the SUPPLEMENTARY INFORMATION section for electronic access to the revocations.

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, 301-796-8510 (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 February 10, 2021, FDA issued an EUA to BD for the BD SARS-CoV-2/Flu for BD MAX System, subject to the terms of the Authorization. Notice of the issuance of this Authorization was published in the *Federal Register* on April 23, 2021 (86 FR 21749), as required by section 564(h)(1) of the FD&C Act. On November 5, 2021, FDA issued an EUA to Talis for the Talis One COVID-19 Test System, subject to the terms of the Authorization. Notice of the issuance of this Authorization was published in the *Federal Register* on March 22, 2022 (87 FR 16196), as required by section 564(h)(1) of the FD&C Act. Subsequent updates to the Authorizations were made available on FDA's website. 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 Requests

In a request received by FDA on July 26, 2022, BD requested withdrawal of, and effective August 1, 2022, FDA revoked, the Authorization for the BD SARS-CoV-2/Flu for BD MAX System. Because BD notified FDA that BD has discontinued the sale of the BD SARS-CoV-2/Flu for BD MAX System and requested FDA to withdraw the authorization of the BD

SARS-CoV-2/Flu for BD MAX System, FDA has determined that it is appropriate to protect the public health or safety to revoke this Authorization.

In a request received by FDA on August 12, 2022, Talis requested revocation of, and on August 23, 2022, FDA revoked, the Authorization for the Talis One COVID-19 Test System. Because Talis notified FDA that Talis has not commercially distributed the authorized product in the United States and requested FDA revoke the authorization of the Talis One COVID-19 Test System, 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/.

IV. The Revocations

Having concluded that the criteria for revocation of the Authorizations under section 564(g)(2)(C) of the FD&C Act are met, FDA has revoked the EUA of BD for the BD SARS-CoV-2/Flu for BD MAX System and of Talis for the Talis One COVID-19 Test System. The revocations in their entirety follow and provide an explanation of the reasons for each revocation, as required by section 564(h)(1) of the FD&C Act.

July 29, 2022

Melissa Barhoover
Senior Regulatory Affairs Manager
7 Loveton Circle
Sparks, Maryland 21152
Re: Revocation of EUA202975

Dear Melissa Barhoover:

This letter is in response to a request from Becton, Dickinson and Company (BD), received July 26, 2022, that the U.S. Food and Drug Administration (FDA) withdraw the EUA for the BD SARS-CoV-2/Flu for BD MAX System issued on February 10, 2021, and updated on April 09, 2021, and September 23, 2021. BD discontinued the sale of BD SARS-CoV-2/Flu for BD MAX System in the United States on July 01, 2022. The revocation is effective August 01, 2022.

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. Because BD notified FDA that BD has discontinued the sale of the BD SARS-CoV-2/Flu for BD MAX System, and requested FDA to withdraw the authorization of the BD SARS-CoV-2/Flu for BD MAX System, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, pursuant to section 564(g)(2)(C) of the Act, FDA revokes EUA202975.

Effective on August 01, 2022, the BD SARS-CoV-2/Flu for BD MAX System is no longer authorized for emergency use by FDA. FDA encourages BD to instruct laboratories to discontinue use of and discard any remaining inventory.

Notice of this revocation will be published in the *Federal Register*, pursuant to section 564(h)(1) of the Act.

Sincerely,

/s/

Jacqueline A. O'Shaughnessy, Ph.D.
Acting Chief Scientist
Food and Drug Administration

August 23, 2022

Brooke McCutchan, MT(ASCP)
Talis Biomedical Corporation
3400 Bridge Pkwy
Redwood City, CA 94065

Re: Revocation of EUA210502

Dear Brooke McCutchan:

This letter is in response to a request from Talis Biomedical Corporation, received August 12, 2022, that the U.S. Food and Drug Administration (FDA) revoke the Talis One COVID-19 Test System – EUA210502 issued on November 5, 2021. The Talis One COVID-19 Test System has not been commercially distributed by Talis Biomedical Corporation in the U.S.

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. Because Talis Biomedical Corporation notified FDA that Talis Biomedical Corporation has not commercially distributed the authorized product in the U.S. and requested FDA revoke the authorization of the Talis One COVID-19 Test System, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, pursuant to section 564(g)(2)(C) of the Act, FDA revokes EUA210502. As of the date of this letter, the Talis One COVID-19 Test System 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/

Namandjé N. Bumpus, Ph.D.
Chief Scientist
Food and Drug Administration

Dated: September 2, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

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