

product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: a testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA has approved for marketing the human drug product, ORLISSA (elagolix sodium) indicated for the management of moderate to severe pain associated with endometriosis. Subsequent to this approval, the USPTO received patent term restoration applications for ORLISSA (U.S. Patent Nos. 7,056,927 and 7,419,983) from Neurocrine Biosciences, Inc. and the USPTO requested FDA's assistance in determining the patents' eligibility for patent term restoration. In a letter dated October 29, 2019, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of ORLISSA represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for ORLISSA is 5,452 days. Of this time, 5,117 days occurred during the testing phase of the regulatory review period, while 335 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(i)) became effective:* August 21,

2003. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on August 21, 2003.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the FD&C Act:* August 23, 2017. FDA has verified the applicant's claim that the new drug application (NDA) for ORLISSA (NDA 210450) was initially submitted on August 23, 2017.

3. *The date the application was approved:* July 23, 2018. FDA has verified the applicant's claim that NDA 210450 was approved on July 23, 2018.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its applications for patent extension, this applicant seeks 5 years of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21 CFR 60.30), any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must comply with all the requirements of § 60.30, including but not limited to: must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to <https://www.regulations.gov> at Docket No. FDA-2013-S-0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: August 30, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022-19506 Filed 9-8-22; 8:45 am]

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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.

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July 29, 2022

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

Dear Melissa Bar Hoover:

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.

[FR Doc. 2022-19491 Filed 9-8-22; 8:45 am]

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**DEPARTMENT OF HEALTH AND
HUMAN SERVICES**

Food and Drug Administration

[Docket No. FDA-2022-D-1837]

**Statement of Identity and Strength—
Content and Format of Labeling for
Human Nonprescription Drug
Products; Draft Guidance for Industry;
Availability**

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled

“Statement of Identity and Strength—Content and Format of Labeling for Human Nonprescription Drug Products.” This draft guidance provides recommendations for the content and format of the required statement of identity on the labeling of human nonprescription drug products. This draft guidance also provides recommendations on the inclusion of the drug product’s strength on the labeling. The recommendations in this draft guidance are intended to help manufacturers, packers, distributors, applicants, relabelers, and sponsors ensure consistent content and format of the statement of identity and strength for all human nonprescription drug products. Consistent content and format