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:* December 21, 2017. The applicant claims November 28, 2017, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was December 21, 2017, which was the first date after receipt of the IND that the investigational studies were allowed to proceed.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the FD&C Act:* January 3, 2020. FDA has verified the applicant's claim that the new drug application (NDA) for Detectnet (NDA 213227) was initially submitted on January 3, 2020.

3. *The date the application was approved:* September 3, 2020. FDA has verified the applicant's claim that NDA 213227 was approved on September 3, 2020.

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 application for patent extension, this applicant seeks 312 days 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: May 4, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–09891 Filed 5–9–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–0973]

Revocation of Three 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 Thermo Fisher Scientific Inc., for the OmniPATH COVID–19 Total Antibody ELISA Test; Detect, Inc., for the Detect Covid–19 Test; and Cepheid, for the Xpert Xpress SARS–CoV–2/Flu/RSV. FDA revoked these Authorizations under the Federal Food, Drug, and Cosmetic Act (FD&C Act) as requested by each Authorization holder. The revocations, which include an explanation of the reasons for each revocation, are reprinted at the end of this document.

DATES: The Authorization for the Thermo Fisher Scientific Inc.'s OmniPATH COVID–19 Total Antibody ELISA Test is revoked as of April 13, 2023. The Authorization for the Detect, Inc.'s Detect Covid–19 Test is revoked as of April 14, 2023. The Authorization for the Cepheid's Xpert Xpress SARS–CoV–2/Flu/RSV is revoked as of April 17, 2023.

ADDRESSES: Submit written requests for a single copy of the revocations to the Office of Policy, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, 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: Kim Sapsford-Medintz, Office of Product Evaluation and Quality, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3216, Silver Spring, MD 20993–0002, 301–796–0311 (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, radiological, or nuclear agent or 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 October 2, 2020, FDA issued the Authorization to Thermo Fisher Scientific Inc., for the OmniPATH COVID–19 Total Antibody ELISA Test, 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 October 28, 2021, FDA issued the Authorization to Detect, Inc., for the Detect Covid–19 Test, 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 16198), as required by section 564(h)(1) of the FD&C Act. On September 24, 2020, FDA issued the Authorization to Cepheid, for the Xpert Xpress SARS–CoV–2/Flu/RSV, 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 21751), 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. Authorization Revocation Requests

In a request received by FDA on April 10, 2023, Thermo Fisher Scientific Inc., requested the withdrawal of, and on April 13, 2023, FDA revoked, the Authorization for the Thermo Fisher Scientific Inc.'s OmniPATH COVID–19

Total Antibody ELISA Test. Because Thermo Fisher Scientific Inc., notified FDA that it is no longer manufacturing or producing the OmniPATH COVID–19 Total Antibody ELISA Test and requested FDA withdraw the Thermo Fisher Scientific Inc.'s, OmniPATH COVID–19 Total Antibody ELISA Test, 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 March 16, 2023, Detect, Inc., requested revocation of, and on April 14, 2023, FDA revoked, the Authorization for the Detect, Inc.'s Detect Covid–19 Test. Because Detect, Inc., indicated to FDA that as of February 1, 2023, there are no viable/nonexpired Detect Covid–19 Tests in distribution in the United States and requested FDA revoke the Authorization for the Detect Covid–19 Test, 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 March 7, 2023, Cepheid, requested revocation of, and on April 17, 2023, FDA revoked, the Authorization for the Cepheid's Xpert Xpress SARS–CoV–2/Flu/RSV. Because Cepheid, indicated to FDA that they have stopped sales of the authorized product and requested FDA revoke the Authorization for the Cepheid's Xpert Xpress SARS–CoV–2/Flu/RSV, 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 Thermo Fisher Scientific Inc.'s OmniPATH COVID–19 Total Antibody ELISA Test; Detect, Inc's Detect Covid–19 Test; and of Cepheid's Xpert Xpress SARS–CoV–2/Flu/RSV. 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.

BILLING CODE 4161–01–P

U.S. FOOD & DRUG ADMINISTRATION

April 13, 2023

Colleen Watson
Senior Director Regulatory Affairs
Fisher Diagnostics
Part of Thermo Fisher Scientific Inc.
8365 Valley Pike
Middletown, VA 22645

Re: Revocation of EUA202212

Dear Colleen Watson:

This letter is in response to the request from Thermo Fisher Scientific Inc., in a letter received April 10, 2023, that the U.S. Food and Drug Administration (FDA) withdraw the EUA for the OmniPATH COVID-19 Total Antibody ELISA Test issued on October 2, 2020 and revised on September 23, 2021. Thermo Fisher Scientific Inc. indicated that they are no longer manufacturing or producing the authorized product and requested that the EUA be withdrawn. FDA understands that, as of the date of this letter, there are no viable OmniPATH COVID-19 Total Antibody ELISA Test reagents remaining in distribution in the United States.

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 requested that FDA withdraw the EUA for OmniPATH COVID-19 Total Antibody ELISA Test, FDA has determined that it is appropriate, to protect the public health or safety, to revoke this authorization. Accordingly, FDA hereby revokes EUA202212 for the OmniPATH COVID-19 Total Antibody ELISA Test, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the OmniPATH COVID-19 Total Antibody ELISA Test 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//

Jeffrey E. Shuren, M.D., J.D.
Director
Center for Devices and Radiological Health
Food and Drug Administration

April 14, 2023

Sarai Meyer
Principal Regulatory Affairs Specialist
Detect, Inc.
530 Old Whitfield St.
Guilford, CT 06437

Re: Revocation of EUA210534

Dear Sarai Meyer:

This letter is in response to the request from Detect, Inc., in a letter received March 16, 2023, that the U.S. Food and Drug Administration (FDA) revoke the EUA for the Detect Covid-19 Test issued on October 28, 2021, reissued April 11, 2022, and revised on January 12, 2022, and August 17, 2022. FDA understands that as of the date of this letter there are no viable Detect Covid-19 Test reagents remaining in distribution in the United States.

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 Detect, Inc. has requested FDA revoke the EUA for Detect Covid-19 Test, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA210534 for the Detect Covid-19 Test, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the Detect Covid-19 Test 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//

Jeffrey E. Shuren, M.D., J.D.
Director
Center for Devices and Radiological Health
Food and Drug Administration

April 17, 2023

Julie Purcell
Director, US Regulatory Affairs
Cepheid
904 Caribbean Drive
Sunnyvale, CA 94089

Re: Revocation of EUA200453

Dear Julie Purcell:

This letter is in response to the request from Cepheid, in a letter received March 7, 2023, that the U.S. Food and Drug Administration (FDA) revoke the EUA for the Xpert Xpress SARS-CoV-2/Flu/RSV issued on September 24, 2020, reissued October 1, 2020, and revised on January 27, 2021, and September 23, 2021. Cepheid indicated that they have stopped sales of the authorized product and requested that the EUA be revoked. FDA understands that as of the date of this letter there will no longer be any viable Xpert Xpress SARS/CoV-2/Flu/RSV reagents remaining in distribution in the United States.

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 Cepheid has requested FDA revoke the EUA for the Xpert Xpress SARS-CoV-2/Flu/RSV, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA200453 for the Xpert Xpress SARS-CoV-2/Flu/RSV, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the Xpert Xpress SARS-CoV-2/Flu/RSV 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//

Jeffrey E. Shuren, M.D., J.D.
Director
Center for Devices and Radiological Health
Food and Drug Administration

Dated: May 4, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–09879 Filed 5–9–23; 8:45 am]

BILLING CODE 4161–01–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–D–1573]

Testing of Glycerin, Propylene Glycol, Maltitol Solution, Hydrogenated Starch Hydrolysate, Sorbitol Solution, and Other High-Risk Drug Components for Diethylene Glycol and Ethylene Glycol; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing the availability of a final guidance for industry entitled ''Testing of Glycerin, Propylene Glycol, Maltitol Solution, Hydrogenated Starch Hydrolysate, Sorbitol Solution, and Other High-Risk Drug Components for Diethylene Glycol and Ethylene Glycol.'' This guidance provides updated recommendations on testing and other activities that will help pharmaceutical manufacturers, repackers, other suppliers, and compounders prevent the use of high-risk drug components, including