record is inaccurate, incomplete, untimely, or irrelevant.

NOTIFICATION PROCEDURES:

To find out if the system of records contains a record about you, submit a written notification request to the System Manager identified in the ''System Manager'' section of this SORN. The request must identify this system of records, contain the same information required for an access request, and include verification of your identity in the same manner required for an access request.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

None.

HISTORY:

87 FR 69026 (Nov. 17, 2022).

[FR Doc. 2024–10838 Filed 5–16–24; 8:45 am]

BILLING CODE 4184–42–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 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 Authorizations (EUAs) (the Authorizations) issued to Bio-Rad Laboratories Inc., for the Bio-Rad SARS–CoV–2 ddPCR Kit, and Fast Track Diagnostics Luxembourg S.á.r.l. (A Siemens Healthineers Company), for the FTD SARS–CoV–2. FDA revoked the Authorizations under the Federal Food, Drug, and Cosmetic Act (FD&C Act) as requested by the Authorization holders. The revocations, which include an explanation of the reasons for each revocation, are reprinted at the end of this document.

DATES: The revocation of the Authorization for the Bio-Rad Laboratories Inc.'s Bio-Rad SARS–CoV–2 ddPCR Kit is effective as of March 27, 2024. The revocation of the Authorization for the Fast Track Diagnostics Luxembourg S.á.r.l.'s (A Siemens Healthineers Company), FTD SARS–CoV–2 is effective as of April 18, 2024.

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 May 1, 2020, FDA issued the Authorization to Bio-Rad Laboratories Inc., for the Bio-Rad SARS–CoV–2 ddPCR Kit, subject to the terms of the Authorization. Notice of the issuance of this Authorization was published in the **Federal Register** on July 14, 2020 (85 FR 42409), as required by section 564(h)(1) of the FD&C Act.

On May 5, 2020, FDA issued the Authorization to Fast Track Diagnostics Luxembourg S.á.r.l. (a Siemens Healthineers Company) for the FTD SARS–CoV–2, subject to the terms of the Authorization. Notice of the issuance of this Authorization was published in the **Federal Register** on July 14, 2020 (85 FR 42409), 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. Authorizations Revocation Requests

In a request received by FDA on March 16, 2024, Bio-Rad Laboratories Inc., requested the revocation of, and on March 27, 2024, FDA revoked, the Authorization for the Bio-Rad Laboratories Inc.'s Bio-Rad SARS–CoV–2 ddPCR Kit. Because Bio-Rad Laboratories Inc., notified FDA that they ceased United States distribution of the Bio-Rad SARS–CoV–2 ddPCR Kit and requested FDA revoke Bio-Rad Laboratories Inc.'s Bio-Rad SARS–CoV–2 ddPCR Kit, 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 April 11, 2024, Fast Track Diagnostics Luxembourg S.á.r.l. (a Siemens Healthineers Company), requested the deregister of, and on April 18, 2024, FDA revoked, the Authorization for Fast Track Diagnostics Luxembourg S.á.r.l.'s FTD SARS–CoV–2. Because Fast Track Diagnostics Luxembourg S.á.r.l. notified FDA that they have ceased United States distribution of the FTD SARS–CoV–2 and requested FDA deregister the Fast Track Diagnostics Luxembourg S.á.r.l.'s FTD SARS–CoV–2, 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 Bio-Rad Laboratories Inc.'s Bio-Rad SARS–CoV–2 ddPCR Kit, and Fast Track Diagnostics Luxembourg S.á.r.l.'s (a Siemens Healthineers Company) FTD SARS–CoV–2. The revocations in their entirety follow and provide an explanation of the reasons for revocation, as required by section 564(h)(1) of the FD&C Act.

BILLING CODE 4164–01–P

U.S. FOOD & DRUG ADMINISTRATION

March 27, 2024

Elizabeth Platt, MLS(ASCP)^{CM}, CLS, ACRP-CP, CMDA, CQA, CSSGB, CMQ/OE, RAC
(Devices, Global, US)
VP, Regulatory & Clinical Affairs
Bio-Rad Laboratories Inc.
4000 Alfred Nobel Drive
Hercules, CA 94547
Re: Revocation of EUA200440

Dear Dr. Platt:

This letter is in response to the request from Bio-Rad Laboratories Inc., in a letter dated March 16, 2024, that the U.S. Food and Drug Administration (FDA revoke the EUA for the Bio-Rad SARS-CoV-2 ddPCR Kit issued on May 1, 2020, reissued on September 18, 2020, and amended on December 9, 2020, September 23, 2021, and March 15, 2022. Bio-Rad Laboratories Inc. indicated that they have ceased United States distribution of the authorized product and requested that the EUA be revoked. FDA understands that as of the date of this letter there are no viable Bio-Rad SARS-CoV-2 ddPCR Kit 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 Bio-Rad Laboratories Inc. has requested that FDA revoke the EUA for the Bio-Rad SARS-CoV-2 ddPCR Kit, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA200440 for the Bio-Rad SARS-CoV-2 ddPCR Kit, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the Bio-Rad SARS-CoV-2 ddPCR Kit 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

U.S. FOOD & DRUG ADMINISTRATION

April 18, 2024

Oliver Jahnel
Regulatory Affairs Scientist, Molecular Diagnostics
Fast Track Diagnostics Luxembourg S.a.r.l.
A Siemens Healthineers Company
29, Rue Henri Koch
L-4354 Esch-sur-Alzette, Luxembourg
Re: Revocation of EUA200571

Dear Oliver Jahnel:

This letter is in response to the request from Fast Track Diagnostics Luxembourg S.á.r.l. (a Siemens Healthineers Company), in an email dated April 11, 2024, that the U.S. Food and Drug Administration (FDA) deregister the EUA for the FTD SARS-CoV-2 issued on May 5, 2020, amended on July 9, 2020, reissued on January 26, 2021, and amended on April 7, 2021, September 23, 2021, and January 19, 2022. Fast Track Diagnostics Luxembourg S.á.r.l. indicated that they have ceased United States distribution of the authorized product and requested that the EUA be deregistered. Communication with the company made clear that, based on their request, FDA would revoke the EUA. FDA understands that as of the date of this letter there are no viable FTD SARS-CoV-2 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 Fast Track Diagnostics Luxembourg S.á.r.l. has requested that FDA deregister the EUA for the FTD SARS-CoV-2, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA200571 for the FTD SARS-CoV-2, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the FTD SARS-CoV-2 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 14, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–10910 Filed 5–16–24; 8:45 am]

BILLING CODE 4164–01–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–D–0369]

Product-Specific Guidances; Draft and Revised Draft Guidances 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 additional draft and revised draft product-specific guidances. The draft guidances provide product-specific recommendations on, among other things, the design of bioequivalence (BE) studies to support abbreviated new drug applications (ANDAs). In the **Federal Register** of June 11, 2010, FDA announced the availability of a guidance for industry entitled ''Bioequivalence Recommendations for Specific Products'' that explained the process that would be used to make product-specific guidances available to the public on FDA's website. The draft