Dated: June 21, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–13606 Filed 6–24–22; 8:45 am]

BILLING CODE 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 Quanterix Corp. for the Simoa Semi-Quantitative SARS–CoV–2 IgG Antibody Test and for the Simoa SARS–CoV–2 N Protein Antigen Test. 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 Authorizations for the Simoa Semi-Quantitative SARS–CoV–2 IgG Antibody Test and for the Simoa SARS–CoV–2 N Protein Antigen Test are revoked as of May 10, 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, 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 December 23, 2020, FDA issued an EUA to Quanterix Corp. for the Simoa Semi-Quantitative SARS–CoV–2 IgG Antibody 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 January 5, 2021, FDA issued an EUA to Quanterix Corp. for the Simoa SARS–CoV–2 N Protein Antigen 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, 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 requests received by FDA on May 5, 2022, and May 9, 2022, Quanterix Corp. requested withdrawal of, and on May 10, 2022, FDA revoked, the Authorization for the Simoa Semi-Quantitative SARS–CoV–2 IgG Antibody Test. Because Quanterix Corp. notified FDA that Quanterix Corp. did not distribute the authorized product in the United States and requested FDA to withdraw the authorization of the Simoa Semi-Quantitative SARS–CoV–2 IgG Antibody Test, FDA determined that it is appropriate to protect the public health or safety to revoke this Authorization.

In requests received by FDA on May 5, 2022, and May 9, 2022, Quanterix Corp. requested withdrawal of, and on May 10, 2022, FDA revoked, the Authorization for the Simoa SARS–CoV–2 N Protein Antigen Test. Because Quanterix Corp. notified FDA that Quanterix Corp. has discontinued distribution of the authorized product and requested FDA withdraw the authorization of the Simoa SARS–CoV–2 N Protein Antigen Test, FDA 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 EUAs of Quanterix Corp. for the Simoa Semi-Quantitative SARS–CoV–2 IgG Antibody Test and for the Simoa SARS–CoV–2 N Protein Antigen Test. 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.

U.S. FOOD & DRUG ADMINISTRATION

May 10, 2022

Brian Ciccariello
Quanterix Corporation
900 Middlesex Turnpike, Building One
Billerica, MA 01821

Re: Revocation of EUA201648

Dear Brian Ciccariello:

This letter is in response to a request from Quanterix Corporation, received May 5, 2022, and May 9, 2022, that the U.S. Food and Drug Administration (FDA) withdraw the Simoa Semi-Quantitative SARS-CoV-2 IgG Antibody Test issued on December 23, 2020, and updated April 15, 2021, and September 23, 2021. FDA understands that Quanterix Corporation did not distribute their Simoa Semi-Quantitative SARS-CoV-2 IgG Antibody Test in the US and there are no viable (non-expired) tests remaining.

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 Quanterix Corporation has notified FDA that Quanterix Corporation did not distribute the authorized product in the US and requested FDA to withdraw the authorization of the Simoa Semi-Quantitative SARS-CoV-2 IgG Antibody Test, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA201648 for the Simoa Semi-Quantitative SARS-CoV-2 IgG Antibody Test, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the Simoa Semi-Quantitative SARS-CoV-2 IgG Antibody 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/

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

CC: Sarah O. Kalil, SK Consulting

U.S. FOOD & DRUG ADMINISTRATION

May 10, 2022

Brian Ciccariello
Quanterix Corporation
900 Middlesex Turnpike, Building One
Billerica, MA 01821

Re: Revocation of EUA202912

Dear Brian Ciccariello:

This letter is in response to a request from Quanterix Corporation, received May 5, 2022, and May 9, 2022, that the U.S. Food and Drug Administration (FDA) withdraw the Simoa SARS-CoV-2 N Protein Antigen Test issued on January 5, 2021, and reissued on September 10, 2021, and December 21, 2021. FDA understands that Quanterix Corporation discontinued distribution of their Simoa SARS-CoV-2 N Protein Antigen Test and there are no viable (non-expired) tests remaining.

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 Quanterix Corporation has notified FDA that Quanterix Corporation has discontinued distribution of the authorized product and requested FDA withdraw the authorization of the Simoa SARS-CoV-2 N Protein Antigen Test, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA202912 for the Simoa SARS-CoV-2 N Protein Antigen Test, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the Simoa SARS-CoV-2 N Protein Antigen 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/

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

Dated: June 21, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–13639 Filed 6–24–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–0584]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Pilot Survey To Develop Standardized Reporting Forms for Federally Funded Public Health Projects

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by July 27, 2022.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information