DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–0412]

Authorization and Revocations of Emergency Use of Certain 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 issuance of one, and revocation of three, Emergency Use Authorizations (EUAs) (the Authorizations) issued to STS Lab Holdco (a subsidiary of *Amazon.com* Services LLC) (''STS''). FDA issued one Authorization under the Federal Food, Drug, and Cosmetic Act (FD&C Act), as requested by STS, for the Amazon Real-Time RT–PCR DTC Test for Detecting SARS–CoV–2. The Authorization contains, among other things, conditions on the emergency use of the authorized product. The Authorization follows the February 4, 2020, determination by the Secretary of Health and Human Services (HHS) that there is a public health emergency that has a significant potential to affect national security or the health and security of U.S. citizens living abroad, and that involves the virus that causes COVID–19, and the subsequent declaration on February 4, 2020, that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of the virus that causes COVID–19, subject to the terms of any authorization issued under the FD&C Act. The Authorization, which includes an explanation of the reasons for issuance, is listed in this document, and further information can be accessed on FDA's website from the links indicated. FDA is also announcing the subsequent revocation of the Authorization issued to STS for the Amazon Real-Time RT–PCR DTC Test for Detecting SARS–CoV–2. In addition, FDA is announcing the revocation of the Authorizations issued to STS for the Amazon Multi-Target SARS–CoV–2 Real-Time RT–PCR DTC Test and Amazon Multi-Target SARS–CoV–2 Real-Time RT–PCR Test. FDA issued and revoked the Authorizations under the 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 Amazon Real-Time RT–PCR DTC Test for Detecting SARS–CoV–2 was effective May 28, 2021. The revocations for the Amazon Real-Time RT–PCR DTC Test for Detecting SARS–CoV–2, Amazon Multi-Target SARS–CoV–2 Real-Time RT–PCR DTC Test, and Amazon Multi-Target SARS–CoV–2 Real-Time RT–PCR Test are effective as of July 19, 2022.

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

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. With this EUA authority, FDA can help ensure that medical countermeasures may be used in emergencies to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by biological, chemical, nuclear, or radiological agents when there are no adequate, approved, and available alternatives.

II. Criteria for EUA Authorization

Section 564(b)(1) of the FD&C Act provides that, before an EUA may be issued, the Secretary of HHS must declare that circumstances exist justifying the authorization based on one of the following grounds: (1) a determination by the Secretary of Homeland Security that there is a domestic emergency, or a significant potential for a domestic emergency, involving a heightened risk of attack with a biological, chemical, radiological, or nuclear agent or agents; (2) a determination by the Secretary of Defense that there is a military emergency, or a significant potential for a military emergency, involving a heightened risk to U.S. military forces, including personnel operating under the authority of title 10 or title 50 of the U.S. Code, of attack with (A) a biological, chemical, radiological, or nuclear agent or agents; or (B) an agent or agents that may cause, or are otherwise associated with, an imminently life-threatening and specific risk to U.S. military forces;[1] (3) a determination by the Secretary of HHS that there is a public health emergency, or a significant potential for a public health emergency, that affects, or has a significant potential to affect, national security or the health and security of U.S. citizens living abroad, and that involves a biological, chemical, radiological, or nuclear agent or agents, or a disease or condition that may be attributable to such agent or agents; or (4) the identification of a material threat by the Secretary of Homeland Security pursuant to section 319F–2 of the Public Health Service (PHS) Act (42 U.S.C. 247d–6b) sufficient to affect national security or the health and security of U.S. citizens living abroad.

Once the Secretary of HHS has declared that circumstances exist justifying an authorization under section 564 of the FD&C Act, FDA may authorize the emergency use of a drug, device, or biological product if the Agency concludes that the statutory criteria are satisfied. Under section 564(h)(1) of the FD&C Act, FDA is required to publish in the **Federal Register** a notice of each authorization, and each termination or revocation of an authorization, and an explanation of the reasons for the action. Under section 564(h)(1) of the FD&C Act, revisions to an authorization shall be made available on the FDA website. Section 564 of the FD&C Act permits FDA to authorize the introduction into interstate commerce of a drug, device, or biological product intended for use when the Secretary of HHS has declared that circumstances exist justifying the authorization of emergency use. Products appropriate for emergency use may include products and uses that are not approved, cleared, or licensed under section 505, 510(k), 512, or 515 of the FD&C Act (21 U.S.C. 355, 360(k), 360b, or 360e) or section 351 of the PHS Act (42 U.S.C. 262), or

[1] In the case of a determination by the Secretary of Defense, the Secretary of HHS shall determine within 45 calendar days of such determination, whether to make a declaration under section 564(b)(1) of the FD&C Act, and, if appropriate, shall promptly make such a declaration.

conditionally approved under section 571 of the FD&C Act (21 U.S.C. 360ccc). FDA may issue an EUA only if, after consultation with the HHS Assistant Secretary for Preparedness and Response, the Director of the National Institutes of Health, and the Director of the Centers for Disease Control and Prevention (to the extent feasible and appropriate given the applicable circumstances), FDA [2] concludes: (1) that an agent referred to in a declaration of emergency or threat can cause a serious or life-threatening disease or condition; (2) that, based on the totality of scientific evidence available to FDA, including data from adequate and well-controlled clinical trials, if available, it is reasonable to believe that (A) the product may be effective in diagnosing, treating, or preventing (i) such disease or condition; or (ii) a serious or life-threatening disease or condition caused by a product authorized under section 564, approved or cleared under the FD&C Act, or licensed under section 351 of the PHS Act, for diagnosing, treating, or preventing such a disease or condition caused by such an agent; and (B) the known and potential benefits of the product, when used to diagnose, prevent, or treat such disease or condition, outweigh the known and potential risks of the product, taking into consideration the material threat posed by the agent or agents identified in a declaration under section 564(b)(1)(D) of the FD&C Act, if applicable; (3) that there is no adequate, approved, and available alternative to the product for diagnosing, preventing, or treating such disease or condition; (4) in the case of a determination described in section 564(b)(1)(B)(ii), that the request for emergency use is made by the Secretary of Defense; and (5) that such other criteria as may be prescribed by regulation are satisfied. No other criteria for issuance have been prescribed by regulation under section 564(c)(4) of the FD&C Act

[2] The Secretary of HHS has delegated the authority to issue an EUA under section 564 of the FD&C Act to the Commissioner of Food and Drugs.

III. Authorizations

Having concluded that the criteria for the issuance of the Authorization under section 564(c) of the FD&C Act are met, on May 28, 2021, FDA issued an EUA to STS for the Amazon Real-Time RT–PCR DTC Test for Detecting SARS–CoV–2, subject to the terms of the Authorization. Notice of the issuance of this Authorization is provided, as required by section 564(h)(1) of the FD&C Act.[3]

On August 11, 2021, FDA issued EUAs to STS Lab Holdco for the Amazon Multi-Target SARS–CoV–2 Real-Time RT–PCR DTC Test and Amazon Multi-Target SARS–CoV–2 Real-Time RT–PCR Test, subject to the terms of the respective Authorizations. Notice of the issuance of these Authorizations was published in the **Federal Register** on October 28, 2021 (86 FR 59738), 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).

[3] An explanation of the reasons for issuance of the Authorization is provided, as required by section 564(h)(1) of the FD&C Act. As set forth in the EUA for the Amazon Real-Time RT–PCR DTC Test for Detecting SARS–CoV–2, FDA has concluded that (1) SARS–CoV–2 can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus; (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that the Amazon Real-Time RT–PCR DTC Test for Detecting SARS–CoV–2 may be effective in diagnosing COVID–19, and that the known and potential benefits of the Amazon Real-Time RT–PCR DTC Test for Detecting SARS–CoV–2 when used for diagnosing COVID–19, outweigh the known and potential risks of the Amazon Real-Time RT–PCR DTC Test for Detecting SARS–CoV–2; and (3) there is no adequate, approved, and available alternative to the emergency use of Amazon Real-Time RT–PCR DTC Test for Detecting SARS–CoV–2.

IV. EUA Revocation Requests

On July 11, 2022, STS Lab Holdco requested revocation of, and on July 19, 2022, FDA revoked, the Authorizations for the Amazon Real-Time RT–PCR DTC Test for Detecting SARS–CoV–2, Amazon Multi-Target SARS-CoV–2 Real-Time RT–PCR DTC Test, and Amazon Multi-Target SARS–CoV–2 Real-Time RT–PCR Test. Because STS Lab Holdco has notified FDA that there is no viable (non-expired) Amazon Real-Time RT–PCR DTC Test for Detecting SARS–CoV–2, Amazon Multi-Target SARS–CoV–2 Real-Time RT–PCR DTC Test, or Amazon Multi-Target SARS–CoV–2 Real-Time RT–PCR Test remaining in distribution in the United States and requested FDA revoke the Authorizations for these devices, FDA has determined that it is appropriate to protect the public health or safety to revoke these Authorizations.

V. 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/*. The full text of the Authorization, including any revisions, and of the revocations and can be accessed from the FDA web page available at: *https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization-archived-information.*

VI. 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 for STS Lab Holdco's Amazon Real-Time RT–PCR DTC Test for Detecting SARS–CoV–2, Amazon Multi-Target SARS–CoV–2 Real-Time RT–PCR DTC Test, and Amazon Multi-Target SARS–CoV–2 Real-Time RT–PCR 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.

BILLING CODE 4164–01–P

July 19, 2022

Jon Nakamoto
Amazon.com Services LLC
c/o Amazon Legal Dept
410 Terry Ave. N.
Seattle, WA 98109
Re: Revocation of EUA210308

Dear Jon Nakamoto:

This letter is in response to a request from STS Lab Holdco (a subsidiary of Amazon.com Services LLC), received July 11, 2022, that the U.S. Food and Drug Administration (FDA) revoke the EUA for the Amazon Real-Time RT-PCR DTC Test for Detecting SARS-CoV-2 issued on May 28, 2021, re-issued on January 26, 2022, and amended on December 17, 2021. FDA understands there is no viable (non-expired) Amazon Real-Time RT-PCR DTC Test for Detecting SARS-CoV-2 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. Because STS Lab Holdco (a subsidiary of Amazon.com Services LLC) has notified FDA that there is no viable (non-expired) Amazon Real-Time RT-PCR DTC Test for Detecting SARS-CoV-2 remaining in distribution in the United States and requested FDA revoke the authorization of the Amazon Real-Time RT-PCR DTC Test for Detecting 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 EUA210308 for the Amazon Real-Time RT-PCR DTC Test for Detecting SARS-CoV-2, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the Amazon Real-Time RT-PCR DTC Test for Detecting 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/

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

cc: Kenneth Bedsted, Director, Amazon Labs

U.S. FOOD & DRUG ADMINISTRATION

July 19, 2022

Jon Nakamoto
Amazon.com Services LLC
c/o Amazon Legal Dept
410 Terry Ave. N.
Seattle, WA 98109
Re: Revocation of EUA210480

Dear Jon Nakamoto:

This letter is in response to a request from STS Lab Holdco (a subsidiary of Amazon.com Services LLC), received July 11, 2022, that the U.S. Food and Drug Administration (FDA) revoke the EUA for the Amazon Multi-Target SARS-CoV-2 Real-Time RT-PCR DTC Test issued on August 11, 2021, re-issued on January 26, 2022, and updated on December 17, 2021. FDA understands there is no viable (non-expired) Amazon Multi-Target SARS-CoV-2 Real-Time RT-PCR DTC Test 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. Because STS Lab Holdco (a subsidiary of Amazon.com Services LLC) has notified FDA that there is no viable (non-expired) Amazon Multi-Target SARS-CoV-2 Real-Time RT-PCR DTC Test remaining in distribution in the United States and requested FDA revoke the authorization of the Amazon Multi-Target SARS-CoV-2 Real-Time RT-PCR DTC Test, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA210480 for the Amazon Multi-Target SARS-CoV-2 Real-Time RT-PCR DTC Test, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the Amazon Multi-Target SARS-CoV-2 Real-Time RT-PCR DTC 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: Kenneth Bedsted, Director, Amazon Labs

U.S. FOOD & DRUG ADMINISTRATION

July 19, 2022

Jon Nakamoto
Amazon.com Services LLC
c/o Amazon Legal Dept
410 Terry Ave. N.
Seattle, WA 98109
Re: Revocation of EUA210481

Dear Jon Nakamoto:

This letter is in response to a request from STS Lab Holdco (a subsidiary of Amazon.com Services LLC), received July 11, 2022, that the U.S. Food and Drug Administration (FDA) revoke the EUA for the Amazon Multi-Target SARS-CoV-2 Real-Time RT-PCR Test issued on August 11, 2021, and amended on December 17, 2021, and January 26, 2022. FDA understands there is no viable (non-expired) Amazon Multi-Target SARS-CoV-2 Real-Time RT-PCR Test 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. Because STS Lab Holdco (a subsidiary of Amazon.com Services LLC) has notified FDA that there is no viable (non-expired) Amazon Multi-Target SARS-CoV-2 Real-Time RT-PCR Test remaining in distribution in the United States and requested FDA revoke the authorization of the Amazon Multi-Target SARS-CoV-2 Real-Time RT-PCR Test, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA210481 for the Amazon Multi-Target SARS-CoV-2 Real-Time RT-PCR Test, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the Amazon Multi-Target SARS-CoV-2 Real-Time RT-PCR 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: Kenneth Bedsted, Director, Amazon Labs

Dated: August 22, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–18529 Filed 8–25–22; 8:45 am]

BILLING CODE 4164–01–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS–0990–0407–30D]

Agency Information Collection Request. 30-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

DATES: Comments on the ICR must be received on or before September 26, 2022.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain*. Find this particular