DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–0412]

Revocation of Authorization of Emergency Use of an 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 Authorization (EUA) (the Authorization) issued to Laboratorio Clinico Toledo for the Laboratorio Clinico Toledo SARS–CoV–2 Assay. FDA revoked this Authorization under the Federal Food, Drug, and Cosmetic Act (FD&C Act). The revocation, which includes an explanation of the reasons for revocation, is reprinted in this document.

DATES: The Authorization for the Laboratorio Clinico Toledo SARS–CoV–2 Assay is revoked as of September 21, 2022.

ADDRESSES: Submit a written request for a single copy of the revocation 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 revocation may be sent. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the revocation.

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 July 6, 2020, FDA issued an EUA to Laboratorio Clinico Toledo for the Laboratorio Clinico Toledo SARS–CoV–2 Assay, subject to the terms of the Authorization. Notice of the issuance of this Authorization was published in the **Federal Register** on November 20, 2020 (85 FR 74346), as required by section 564(h)(1) of the FD&C Act. Subsequent updates to the Authorization 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 Request

In a request received by FDA on September 8, 2022, Laboratorio Clinico Toledo requested withdrawal of, and on September 21, 2022, FDA revoked, the Authorization for the Laboratorio Clinico Toledo SARS–CoV–2 Assay. Because Laboratorio Clinico Toledo notified FDA that Laboratorio Clinico Toledo has decided to no longer test using the Laboratorio Clinico Toledo SARS–CoV–2 Assay and requested FDA withdraw the EUA for the Laboratorio Clinico Toledo SARS–CoV–2 Assay, 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 revocation is available on the internet at *https://www.regulations.gov/.*

IV. The Revocation

Having concluded that the criteria for revocation of the Authorization under section 564(g)(2)(C) of the FD&C Act are met, FDA has revoked the EUA of Laboratorio Clinico Toledo for the Laboratorio Clinico Toledo SARS–CoV–2 Assay. The revocation in its entirety follows and provides 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

September 21, 2022

Ilia M. Toledo Garcia
President & Director
Laboratorio Clinico Toledo
51 Palma St.
Arecibo PR 00612
Re: Revocation of EUA200207

Dear Ilia M. Toledo Garcia:

This letter is in response to the request from Laboratorio Clinico Toledo, received via email on September 8, 2022, that the U.S. Food and Drug Administration (FDA) withdraw the EUA for the Laboratorio Clinico Toledo SARS-CoV-2 Assay issued on July 6, 2020, and amended on December 28, 2020, and September 23, 2021. Laboratorio Clinico Toledo indicated in their email and cover letter that they are no longer testing with the Laboratorio Clinico Toledo SARS-CoV-2 Assay and have none of the reagents in stock in their laboratory.

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 Laboratorio Clinico Toledo has notified FDA that it has decided to no longer test using the Laboratorio Clinico Toledo SARS-CoV-2 Assay and requested FDA withdraw the EUA for the Laboratorio Clinico Toledo SARS-CoV-2 Assay, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA200207 for the Laboratorio Clinico Toledo SARS-CoV-2 Assay, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the Laboratorio Clinico Toledo SARS-CoV-2 Assay 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: October 4, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–21998 Filed 10–7–22; 8:45 am]

BILLING CODE 4164–01–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–D–1253]

Laser-Assisted In Situ Keratomileusis Lasers—Patient Labeling Recommendations; Draft Guidance for Industry and Food and Drug Administration Staff; Availability; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is extending the comment period for the notice of availability that appeared in the **Federal Register** of July 28, 2022. In the notice of availability, FDA requested comments on draft guidance for industry and FDA staff entitled ''Laser-Assisted In Situ Keratomileusis (LASIK) Lasers—Patient Labeling Recommendations.'' The Agency is taking this action in response to requests for an extension to allow