FEE SCHEDULE FOR EACH VESSEL SIZE—Continued

Vessel size (GT [1])	Operational inspection [2] fee (US$)	Construction and renovation inspection [3] fee (US$)
Tier 3 (110,001–180,000 GT)	32,292	64,584
Tier 4 (180,001 GT)	64,584	129,168

[1] Gross tonnage in cubic feet, as shown in *Lloyd's Register of Shipping* (*https://www.lr.org/en/*).
[2] Operations inspections and reinspections involve the same procedures and require the same amount of time, so they are charged at the same rates.
[3] Construction and renovation inspections require at least twice the amount of time as operations inspections, so they are charged double the rates.

[FR Doc. 2025–15595 Filed 8–14–25; 8:45 am]
BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–0150]

Revocation of Authorization 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 Authorization (EUA) (the Authorization) issued to LumiraDx UK Ltd. for the LumiraDx SARS CoV–2 RNA STAR Complete. FDA revoked the Authorization under the Federal Food, Drug, and Cosmetic Act (FD&C Act) as requested by the Authorization holder. The revocation, which includes an explanation of the reason for revocation, is reprinted at the end of this document.

DATES: The revocation of the Authorization for the LumiraDx UK Ltd.'s LumiraDx SARS CoV–2 RNA STAR Complete was effective as of April 15, 2025.

ADDRESSES: Submit written requests for a single copy of the revocation to the Office of Policy, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5441, 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: 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 14, 2020, FDA issued the Authorization to LumiraDx UK Ltd. for the LumiraDx SARS CoV–2 RNA STAR Complete, 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.

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. Authorization Revocation Request

In a request received by FDA on November 8, 2024, LumiraDx UK Ltd. requested the revocation of, and on April 15, 2025, FDA revoked, the Authorization for the LumiraDx UK Ltd.'s LumiraDx SARS CoV–2 RNA STAR Complete. LumiraDx UK Ltd. notified FDA that they have ceased manufacture of the authorized product, and requested FDA revoke the LumiraDx UK Ltd.'s LumiraDx SARS CoV–2 RNA STAR Complete. 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 for LumiraDx UK Ltd.'s LumiraDx SARS CoV–2 RNA STAR Complete. The revocation in its entirety follows and provide an explanation of the reason for revocation, as required by section 564(h)(1) of the FD&C Act.

BILLING CODE 4164–01–P

U.S. FOOD & DRUG ADMINISTRATION

April 15, 2025

Justin Davis
Regulatory Affairs, U.S. Representative
LumiraDx UK Ltd.
Roche House Charles Avenue
Burgess Hill, England, RH15 9RY
Re: Revocation of EUA202584

Dear Justin Davis:
This letter is in response to the request from LumiraDx UK Ltd., in an email dated November 8, 2024, that the U.S. Food and Drug Administration (FDA) revoke the EUA for the LumiraDx SARS CoV-2 RNA STAR Complete issued on October 14, 2020, revised and reissued on February 9, 2021, March 29, 2021, November 30, 2021, and February 18, 2022, and amended on March 22, 2021, April 13, 2021, September 23, 2021, April 25, 2022, August 17, 2022, September 15, 2022, February 22, 2023, and July 10, 2023. LumiraDx UK Ltd. indicated that they have ceased manufacture 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 LumiraDx SARS CoV-2 RNA STAR Complete 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 LumiraDx UK Ltd. has requested that FDA revoke the EUA for the LumiraDx SARS CoV-2 RNA STAR Complete, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA202584 for the LumiraDx SARS CoV-2 RNA STAR Complete, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the LumiraDx SARS CoV-2 RNA STAR Complete 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//

Ellen J. Flannery, J.D.
Deputy Center Director for Policy
Director, Office of Policy
Center for Devices and Radiological Health
Food and Drug Administration

Technical Correction June 26, 2025: Edit to correct the date the EUA for the LumiraDx SARS CoV-2 RNA STAR Complete was originally issued.

Dated: August 11, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–15556 Filed 8–14–25; 8:45 am]

BILLING CODE 4164–01–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–N–2787]

Advancing the Development of Interchangeable Products: Identifying Future Needs; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the following public workshop entitled ''Advancing the Development of Interchangeable Products: Identifying Future Needs.'' The purpose of the public workshop is to address a commitment FDA made in the Biosimilar User Fee Act (BsUFA) reauthorization commitment letter for