information. Comments should not include any information such as confidential information that would not be appropriate for public disclosure.

Comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors, Ann E. Misback, Secretary of the Board, 20th Street and Constitution Avenue NW, Washington, DC 20551–0001, not later than September 2, 2025.

A. Federal Reserve Bank of Richmond (Brent B. Hassell, Assistant Vice President) P.O. Box 27622, Richmond, Virginia 23261. Comments can also be sent electronically to *Comments.applications@rich.frb.org:*

1. *Shermen Holdings, Inc., Washington, DC;* to establish Shermen Bank International, Washington, DC, as an Edge Corporation.

Board of Governors of the Federal Reserve System.

Michele Taylor Fennell,

Associate Secretary of the Board.

[FR Doc. 2025–15594 Filed 8–14–25; 8:45 am]

BILLING CODE 6210–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Fees for Cruise Ship Operational Sanitation, Construction, and Renovation Inspections

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: General notice.

SUMMARY: The Centers for Disease Control and Prevention (CDC), within the Department of Health and Human Services (HHS) announces the vessel sanitation inspection fees instituted in fiscal year (FY) 2025 will continue in FY 2026 and remain in place until further notice or a modification is published. These inspections are conducted by HHS/CDC's Vessel Sanitation Program (VSP). VSP helps the cruise line industry fulfill its responsibility for developing and implementing comprehensive sanitation programs to minimize the risk for environmentally associated illnesses and hazards. Every vessel that has a foreign itinerary and carries 13 or more passengers is subject to twice-yearly unannounced operations inspections and, when necessary, reinspection.

DATES: Fiscal year (FY) 2025 fees for vessel sanitation inspections will continue in FY 2026 and remain in place until further notice.

FOR FURTHER INFORMATION CONTACT: CAPT Luis Rodriguez, Chief, Vessel Sanitation Program, National Center for Environmental Health, Centers for Disease Control and Prevention, 4770 Buford Highway NE, MS 106–6, Atlanta, Georgia 30341–3717; phone: 800–323–2132; email: *vsp@cdc.gov*.

SUPPLEMENTARY INFORMATION:

Purpose and Background

HHS/CDC established the Vessel Sanitation Program (VSP) in the 1970s as a cooperative activity with the cruise ship industry. VSP helps the cruise ship industry prevent and control the introduction and spread of environmentally associated illnesses and hazards on cruise ships. VSP operates under the authority of the Public Health Service Act (Section 361 of the Public Health Service Act; 42 U.S.C. 264, ''Control of Communicable Diseases''). Regulations found at 42 CFR 71.41 (Foreign Quarantine—Requirements Upon Arrival at U.S. Ports: Sanitary Inspection; General Provisions) state that carriers arriving at U.S. ports from foreign areas are subject to sanitary inspections to determine potential rodent, insect, or other vermin infestations; contaminated food or water; or other sanitary conditions requiring measures to prevent introduction or spread of communicable diseases.

The fee schedule for sanitation inspections of passenger cruise ships by VSP was first published in the **Federal Register** on November 24, 1987 (52 FR 45019). HHS/CDC began collecting fees on March 1, 1988. The fee schedule was most recently published in the **Federal Register** on September 23, 2024 (89 FR 77513). This notice announces FY 2025 fees for inspections will continue in FY26 and remain in place until further notice or a modification is published. The fee schedule is presented in Appendix A.

The following formula will be used to determine the fees:

$$Average\ cost\ per\ inspection = \frac{Total\ cost\ of\ VSP}{Weighted\ number\ of\ annual\ inspections}$$

Total cost of VSP = Total cost of operating the program, such as administration, travel, staffing, sanitation inspections, and outbreak response.

Weighted number of annual inspections = Total number of ships and inspections per year accounting for vessel size, number of inspectors needed for vessel size, travel logistics to conduct inspections, and vessel location and arrivals in U.S. jurisdiction per year.

Fee

The fee schedule (Appendix A) will remain in place until further notice.

Applicability

The fees will apply to all passenger cruise vessels for which inspections are conducted as part of HHS/CDC's VSP.

Noah Aleshire,

Chief Regulatory Officer, Centers for Disease Control and Prevention.

Appendix A

FEE SCHEDULE FOR EACH VESSEL SIZE

Vessel size (GT [1])	Operational inspection [2] fee (US$)	Construction and renovation inspection [3] fee (US$)
Tier 1 (<30,000 GT)	8,073	16,146
Tier 2 (30,001–110,000 GT)	16,146	32,292

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.

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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