cruise operators' practices and procedures, including through simulated voyages, CDC may require the following:

(1) Post-day of disembarkation laboratory testing of passengers and crew.

(2) Additional laboratory testing of passengers and crew and reporting of results during a voyage.

(c) CDC may issue additional technical instructions or orders regarding health and safety standards for restricted passenger voyages.

Minimum Standards for Management of Passengers and Crew From COVID–19-Affected Cruise Ships for Restricted Passenger Voyages

(a) Based on COVID–19 being detected in passengers or crew, as determined through CDC technical instructions or orders, a cruise ship operator must immediately take the following actions:

(1) Conduct such notifications of passengers, crew members, and other government entities as CDC may require.

(2) Immediately isolate any sick or infected passengers and crew in single occupancy cabins with private bathrooms and quarantine all remaining passengers and non-essential crew.

(3) Disembark and evacuate passengers and crew only in such a manner as prescribed in the cruise ship operator's preexisting port and local health authority agreements.

(4) Arrange to disembark and transport passengers and crew using noncommercial transportation or other transportation in accordance with CDC's technical instructions and orders.

(5) Instruct disembarking passengers and crew to stay home and continue to practice physical distancing after reaching their final destination as per CDC technical instructions or orders.

(6) Inform ship pilots, ground transportation, aircraft operators, and other agencies with relevant jurisdiction that COVID–19 has been detected in passengers or crew and confirm that the operators have plans in place to notify and protect the health and safety of their staff (*e.g.,* drivers, air crews).

(7) If the ship meets the red ship criteria,[56] immediately end the restricted passenger voyage, cancel future restricted passenger voyages until directed by CDC that such voyages may resume, and return the ship to the U.S. port of embarkation.

(b) CDC may issue additional technical instructions or orders regarding what measures cruise ship operators must take in the event that a threshold of COVID–19 cases is detected in passengers or crew.

Denials, Suspension, Revocation, and Reinstatement of a Cruise Ship Operator's COVID–19 Conditional Sailing Certificate

(a) CDC may deny an application for a COVID–19 Conditional Sailing Certificate, or revoke, or suspend a COVID–19 Conditional Sailing Certificate if:

(1) The cruise ship operator is not in compliance with CDC's standards for mitigating the risk of COVID–19 on board cruise ships; or

(2) the cruise ship operator is not in compliance with the terms of its COVID–19 Conditional Sailing Certificate; or

(3) necessary to protect human health or safety based on public health considerations specific to the particular cruise ship operator, cruise ship, or affecting cruise travel as a whole.

(b) CDC may reinstate a suspended or revoked COVID–19 Conditional Sailing Certificate after:

(1) Inspecting the cruise ship operator's properties and records, including, but are not limited to, its vessels, facilities, vehicles, equipment, communications, manifests, list of passengers, and employee and passenger health records;

(2) conferring with the cruise ship operator, responsible officials, or other persons under the cruise ship operator's employ; and

(3) receiving information and written assurances from the cruise ship operator and/or its responsible officials that any deficiencies have been rectified and actions taken to ensure future compliance.

Administrative Review

(a) A cruise ship operator may appeal a denial of its application for a COVID–19 Conditional Sailing Certificate or a revocation or suspension of its COVID–19 Conditional Sailing Certificate based on specific factors particular to that operator.

(b) The cruise ship operator's appeal must be in writing, state the factual basis for the appeal, and be submitted to the CDC Director within 30 calendar days of the decision.

(c) The CDC Director's decision will be issued in writing and will constitute final agency action. Prior to deciding upon an appeal, the Director may further investigate the reasons for the denial, revocation, or suspension, including by conferring with the cruise ship operator, responsible officials, or other persons under the cruise ship operator's employ.

This Order enters into effect on November 1, 2021 at 12:01 a.m. (EDT) upon the expiration of the current Order. While this temporary extension retains current requirements in place and does not impose any new obligations or burdens, CDC is committed to working with cruise ship operators who have requested a minimum of 14 days' advance notice to inform their passenger clientele, adjust itineraries as needed, and extend existing contractual arrangements and memorandums of understanding with port, housing, and medical providers.

This Order shall remain in effect until the earliest of (1) the expiration of the Secretary of Health and Human Services' declaration that COVID–19 constitutes a public health emergency; (2) the CDC Director rescinds or modifies the order based on specific public health or other considerations; or (3) January 15, 2022 at 12:01 a.m. (EST).

Authority

The authority for these orders is Sections 361 and 365 of the Public Health Service Act (42 U.S.C. 264, 268) and 42 CFR 70.2, 71.31(b), 71.32(b).

Dated: October 25, 2021.

Sherri Berger,

Chief of Staff, Centers for Disease Control and Prevention.

[FR Doc. 2021–23573 Filed 10–26–21; 11:15 am]

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[56] A ship will be considered as meeting red ship criteria if the ship has sustained transmission of COVID–19 or CLI, or potential for COVID–19 cases to overwhelm on board medical center resources. CDC may adjust these criteria based on lessons learned from simulated voyages or restricted passenger voyages, the evolution of the pandemic, or other factors.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2010–N–0190; FDA–2012–N–0197; FDA–2014–N–1414; and FDA–2014–N–0913]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approvals

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of information collections that have been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Operations, Food

and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–7726, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The following is a list of FDA information collections recently approved by OMB under section 3507 of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507). The OMB control number and expiration date of OMB approval for each information collection are shown in table 1. Copies of the supporting statements for the information collections are available on the internet at *http://www.reginfo.gov/public/do/PRAMain.* An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

TABLE 1—LIST OF INFORMATION COLLECTIONS APPROVED BY OMB

Title of collection	OMB control No.	Date approval expires
Infant Formula Requirements	0910–0256	5/31/2024
Shortages Data Collection	0910–0491	6/30/2024
Guidance on Labeling for Natural Rubber Latex Condoms	0910–0633	6/30/2024
Section 513(g) Requests for Information	0910–0705	6/30/2024

Dated: October 22, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021–23504 Filed 10–27–21; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–0973]

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 Life Technologies Corporation (a part of Thermo Fisher Scientific, Inc.) (Thermo Fisher) for the TaqPath COVID–19 MS2 Combo Kit 2.0. FDA revoked this Authorization on September 27, 2021, 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 TaqPath COVID–19 MS2 Combo Kit 2.0 is revoked as of September 27, 2021.

ADDRESSES: Submit written requests 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, 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 August 2, 2021, FDA issued an EUA to Thermo Fisher for the TaqPath COVID–19 MS2 Combo Kit 2.0, subject to the terms of the Authorization. Notice of the issuance of the Authorization is published elsewhere in this issue of the **Federal Register**, as required by section 564(h)(1) of the FD&C Act. 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

On September 22, 2021, Thermo Fisher requested the revocation of, and on September 27, 2021, FDA revoked the Authorization for, the TaqPath COVID–19 MS2 Combo Kit 2.0. Because Thermo Fisher has notified FDA that it is longer commercially supporting the TaqPath COVID–19 MS2 Combo Kit 2.0 and requested FDA revoke the Authorization, 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 are 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) of the FD&C Act are met, FDA has revoked the EUA for the TaqPath COVID–19 MS2 Combo Kit 2.0. 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.

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