

estimate of the public burden of this collection of information is accurate, and based on valid assumptions and methodology; ways to enhance the quality, utility, and clarity of the information to be collected; and ways in which we can minimize the burden of the collection of information on those who are to respond, through the use of appropriate technological collection techniques or other forms of information technology.

*Obtaining Copies of Proposals:* Requesters may obtain a copy of the information collection documents from the General Services Administration, Regulatory Secretariat Division (MVCB), 1800 F Street, Washington, DC 20405, telephone 202-501-4755. Please cite OMB Control No. 3090-0163, Information Specific to a Contract or Contracting Action (Not Required by Regulation), in all correspondence.

**Jeffrey A. Koses,**

*Senior Procurement Executive, Office of Acquisition Policy, Office of Government-wide Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

#### No Sail Order and Suspension of Further Embarkation; Third Modification and Extension of No Sail Order and Other Measures Related to Operations

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

**ACTION:** Notice.

**SUMMARY:** The Centers for Disease Control and Prevention (CDC), a component of the U.S. Department of Health and Human Services (HHS), announces a third modification and extension of the No Sail Order and Other Measures Related to Operations that was issued on July 16, 2020. This Order applies to cruise ships defined as commercial, non-cargo, passenger-carrying vessels with the capacity to carry 250 or more individuals (passengers and crew) and with an itinerary anticipating an overnight stay onboard or a 24-hour stay onboard for either passengers or crew, that are operating in international, interstate, or intrastate waterways, subject to the jurisdiction of the United States. This Order shall additionally apply to cruise ships operating outside of U.S. waters if

the cruise ship operator intends for the ship to return to operating in international, interstate, or intrastate waterways, subject to the jurisdiction of the United States during the period that this Order is in effect.

**DATES:** This action was effective September 30, 2020.

**FOR FURTHER INFORMATION CONTACT:** Jennifer Buigut, Division of Global Migration and Quarantine, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS V18-2, Atlanta, GA 30329. Phone: 404-498-1600. Email: [dgmqpolicyoffice@cdc.gov](mailto:dgmqpolicyoffice@cdc.gov).

**SUPPLEMENTARY INFORMATION:** This Order renews the No Sail Order and Other Measures Related to Operations signed by the CDC Director on March 14, 2020, as further modified and extended effective April 15, 2020, and July 16, 2020 subject to the modifications and additional stipulated conditions as set forth in this Order.

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) October 31, 2020.

A copy of the order is provided below and a copy of the signed order can be found at <https://www.cdc.gov/quarantine/cruise/index.html>.

**U.S. Department of Health and Human Services (HHS)**

**Centers for Disease Control and Prevention (CDC)**

**Order Under Sections 361 & 365 of the Public Health Service Act (42 U.S.C. 264, 268) and 42 Code of Federal Regulations Part 70 (Interstate) and Part 71 (Foreign):**

**Third Modification and Extension of No Sail Order and Other Measures Related to Operations**

#### *Executive Summary*

The coronavirus disease 2019 (COVID-19) pandemic continues to spread rapidly around the world with no approved treatment or vaccine. By July 16, 2020, the date of the second modification and extension of the No Sail Order, there were over 13 million confirmed cases and over 580,000 confirmed deaths worldwide. As of September 28, 2020, a cumulative total of over 33 million cases and almost 1 million confirmed deaths have now been reported worldwide. Even in countries that have managed to slow the rate of transmission, the risks for

COVID-19 resurgence remains. In the United States, as of September 28, 2020, there have been over 7 million cases and more than 200,000 confirmed deaths with over 300,000 new cases reported in the last 7 days.

Since HHS/CDC's original No Sail Order, signed on March 14, 2020, which suspended the embarkation of passengers, CDC has worked to control the spread of the virus associated with COVID-19 on cruise ships that remained in U.S. jurisdiction, while protecting against further introduction and spread of the virus associated with COVID-19 into U.S. communities. Cruise ships continue to be an unsafe environment with close quarters where the disease spreads easily and is not readily detected.

Cumulative CDC data from March 1 through September 28, 2020, show a total of 3,689 confirmed cases of COVID-19<sup>1</sup> or COVID-like illness<sup>2</sup> cases on cruise ships and 41 deaths. These data have also revealed a total of 102 outbreaks on 124 different cruise ships, meaning more than 82% of ships within U.S. jurisdiction were affected by COVID-19 during this time frame. In addition, four cruise ships still have ongoing or resolving COVID-19 outbreaks on board. Recent outbreaks on cruise ships overseas continue to demonstrate that reduced capacity alone has not diminished transmission.

The challenges described in this document highlight the need for further action prior to cruise ships safely resuming passenger operations in the United States. CDC supports the decision by the Cruise Line International Association (CLIA) and its members to voluntarily extend the suspension of operations for passenger cruise ship travel through October 31, 2020.<sup>3</sup> CDC further supports the decisions of numerous cruise ship operators that have voluntarily canceled scheduled voyages involving U.S. ports beyond the date specified by CLIA, including Cunard,<sup>4</sup> Crystal Cruises,<sup>5</sup>

<sup>1</sup> Confirmed COVID-19 means laboratory confirmation for presence of SARS-CoV-2, the virus that causes COVID-19, by polymerase chain reaction (PCR) testing.

<sup>2</sup> COVID-like illness means acute respiratory illness (ARI), influenza-like illness (ILI), or diagnosis of pneumonia.

<sup>3</sup> Press Release, *CLIA and Its Ocean-Going Cruise Line Members Announce Third Voluntary Suspension of U.S. Operations*, <https://cruising.org/en/news-and-research/press-room/2020/august/clia-announces-third-voluntary-suspension-of-us-cruise-operations> Last accessed September 30, 2020.

<sup>4</sup> Cunard Extends Pause in Operations, <https://www.cunard.com/en-us/contact-us/press-releases> Last accessed September 30, 2020.

<sup>5</sup> <https://www.crystalcruises.com/advisory-alerts/voyage-cancellations>. Last accessed September 30, 2020.

Holland America,<sup>6</sup> Oceania Cruises,<sup>7</sup> Princess Cruise Lines,<sup>8</sup> Viking Ocean Cruises,<sup>9</sup> and Windstar Cruises.<sup>10</sup>

However, because not all cruise ship operators subject to the No Sail Order are members of CLIA or have made similar commitments, CDC is extending its No Sail Order to continue to protect the public's health by ensuring that passenger operations do not resume prematurely.

#### *Previous Orders and Incorporation by Reference*

This Order renews the No Sail Order and Other Measures Related to Operations signed by the CDC Director on March 14, 2020,<sup>11</sup> as further modified and extended effective April 15, 2020,<sup>12</sup> and July 16, 2020<sup>13</sup>—subject to the modifications and additional stipulated conditions as set forth in this Order.

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) October 31, 2020.

The findings and other evidence relied upon in issuing the March 14 Order, and April 15 and July 16, 2020, modifications and extensions, are

<sup>6</sup> Press Release, Holland America Line Extends Its Pause Of Cruise Operations To All Departures Through Dec. 15, 2020, [https://www.hollandamerica.com/en\\_US/news/2020-press-releases/news-08112020-FurtherPauseAug11\\_Dec1520.html](https://www.hollandamerica.com/en_US/news/2020-press-releases/news-08112020-FurtherPauseAug11_Dec1520.html) Last accessed September 30, 2020.

<sup>7</sup> <https://www.oceaniacruises.com/coronavirus-statement>. Last accessed September 30, 2020.

<sup>8</sup> Princess Cruises Extends Pause of Select Global Ship Operations Until December 15, [https://www.princess.com/news/notices\\_and\\_advisories/notices/global-ship-operations-pause-december-2020.html](https://www.princess.com/news/notices_and_advisories/notices/global-ship-operations-pause-december-2020.html). Last accessed September 30, 2020.

<sup>9</sup> A letter from Chairman Torstein Hagen—August 12, 2020, <https://www.vikingcruises.com/oceans/my-trip/current-sailings/index.html> Last accessed September 30, 2020.

<sup>10</sup> Windstar Cruises Travel Advisory—August 27, 2020, <https://www.windstarcruises.com/travel-health-advisory/> Last accessed September 30, 2020.

<sup>11</sup> No Sail Order and Suspension of Further Embarkation. <https://www.federalregister.gov/documents/2020/03/24/2020-06166/no-sail-order-and-suspension-of-further-embarkation>. Last accessed September 29, 2020.

<sup>12</sup> No Sail Order and Suspension of Further Embarkation; Notice of Modification and Extension and Other Measures Related to Operations. <https://www.federalregister.gov/documents/2020/04/15/2020-07930/no-sail-order-and-suspension-of-further-embarkation-notice-of-modification-and-extension-and-other>. Last accessed September 29, 2020.

<sup>13</sup> No Sail Order and Suspension of Further Embarkation. <https://www.federalregister.gov/documents/2020/07/21/2020-15810/no-sail-order-and-suspension-of-further-embarkation-second-modification-and-extension-of-no-sail>. Last accessed September 29, 2020.

incorporated herein by reference. Any ambiguity or conflict between the March 14 Order, and April 15 and July 16 modifications and extensions, as further modified and extended by the current Order, shall be resolved in favor of the current Order.

#### *Statement of Intent*

This Order shall be interpreted and implemented in a manner as to achieve the following paramount objectives:

- Preserving human life;
- Preserving the health and safety of cruise ship crew members, port personnel, and communities;
- Preventing the further introduction, transmission, and spread of COVID-19 into and throughout the United States;
- Preserving the public health and other critical resources of Federal, State, and local governments;
- Preserving hospital, healthcare, and emergency response resources within the United States; and
- Maintaining the safety of shipping and harbor conditions.

#### *Definitions*

The following definitions shall apply for the purposes of this Order:

“COVID-19” means coronavirus disease 2019, the disease caused by the coronavirus SARS-CoV-2.

“Itinerary” means a plan to engage in operations.

“Layup” means reducing cruise ship operations to those levels needed to maintain essential machinery and equipment so that the ship may be returned to service at some future date.

“Operations,” “Operate,” and “Operating” in U.S. waters mean any action by a cruise ship operator (e.g., shifting berths, moving to anchor, discharging waste, making port, or embarking or disembarking passengers or crew) to bring or cause a cruise ship to be brought into or transit in or between any international, interstate, or intrastate waterways, that are subject to the jurisdiction of the United States, or maintaining a ship in layup status in waters that are subject to the jurisdiction of the United States.

“Operator” means the Master of the vessel (cruise ship) and any other crew member responsible for cruise ship operations and navigation, as well as any person or entity (including a corporate entity) that authorizes or directs the use of a cruise ship (e.g., as owner, lessee, or otherwise). A cruise ship operator may be either the cruise ship captain or the cruise line to which the cruise ship belongs, or both. The term “Operator” as used in this Order further incorporates the terms “company,” “designated person,” and

“responsible person” as defined in 33 CFR 96.120.

#### *Applicability*

This Modification and Extension of No Sail Order and Other Measures Related to Operations shall apply only to the subset of carriers<sup>14</sup> described below and hereinafter referred to as “cruise ships”:

All commercial, non-cargo,<sup>15</sup> passenger-carrying vessels with the capacity<sup>16</sup> to carry 250<sup>17</sup> or more individuals (passengers and crew) and with an itinerary anticipating an overnight stay onboard or a twenty-four (24) hour stay onboard for either passengers or crew that are operating<sup>18</sup> in international, interstate, or intrastate waterways that are subject to the jurisdiction of the United States.<sup>19</sup>

This Order shall apply to cruise ships operating outside of U.S. waters if the cruise ship operator intends for the ship to return to operating in international, interstate, or intrastate waterways that are subject to the jurisdiction of the United States during the period that this Order is in effect. The Order shall additionally apply regardless of whether the cruise ship operator has voluntarily agreed to suspend operations.

<sup>14</sup> Carrier is defined by 42 CFR 71.1 to mean, “a ship, aircraft, train, road vehicle, or other means of transport, including military.”

<sup>15</sup> Given the substantial risk of person-to-person transmission of COVID-19, as opposed to transmission via indirect contact, this Order is currently limited to passenger, non-cargo vessels.

<sup>16</sup> A ship's capacity shall be determined based on the number of persons listed in the U.S. Coast Guard Certificate of Inspection issued in accordance with 46 CFR 2.01-5 and that was in effect on July 16, 2020.

<sup>17</sup> Based on substantial epidemiologic evidence related to congregate settings and mass gatherings, this Order suspends operation of vessels with the capacity to carry 250 individuals or more. Evidence shows that settings as small as nursing homes or movie theaters can proliferate the spread of a communicable disease. As the numbers of passengers and crew on board a ship increase, certain recommended mitigation efforts such as social distancing become more difficult to implement. In light of the demonstrated rapid spread of COVID-19 in cruise ship settings, application of this Order to vessels carrying 250 or more individuals is a prudent and warranted public health measure.

<sup>18</sup> This Order does not apply to cruise ships that were in layup prior to March 14, 2020 and have continuously remained in lay-up status since that date.

<sup>19</sup> This Order shall not apply to vessels operated by a U.S. Federal or State government agency. Nor shall it apply to vessels being operated solely for purposes of the provision of essential services, such as the provision of medical care, emergency response, activities related to public health and welfare, or government services, such as food, water, and electricity.

*Background on CDC Actions To Control the Spread of COVID-19 on Cruise Ships*

Under the No Sail Order, as modified and extended on April 15 and July 16, 2020, cruise ship operations were limited, and cruise ship operators required to submit plans to prevent, mitigate, and respond to the spread of COVID-19 as a condition of obtaining or retaining controlled free pratique to engage in cruise ship operations in any international, interstate, or intrastate waterways that are subject to the jurisdiction of the United States. Cruise ship operators were also required to submit No Sail Order (NSO) response plans that ensured a safe environment for crew to work and disembark, and that minimized the impact on U.S. government operations or the operations of any state or local government, or the U.S. healthcare system.

As of April 29, 2020, seven<sup>20</sup> cruise ship operators submitted NSO response plans representing 108 cruise ships or about 95% of cruise ships subject to the April 15, 2020, modification and extension. As of September 6, all five<sup>21</sup> cruise ship operators with ships remaining in U.S. waters have NSO response plans that are complete, accurate, and acknowledged. Only 31 out of the 108 ships (29%) that were in U.S. waters at the start of the NSO modification and extension on April 15 remain in U.S. waters as of September 28, 2020. Pending approval of a cruise ship operator's NSO response plan, CDC allowed cruise ship operators to disembark and repatriate crew members from cruise ships in U.S. waters if the operator attested to complying with requirements to disembark crew members through noncommercial means so as to minimize the risk to other travelers and communities. Through this non-commercial travel attestation process, CDC worked with cruise ship operators to assist in the disembarkation and safe return home of approximately 8,990 crew members, including 329 U.S. citizens and residents.

CDC published its *Interim Guidance for Mitigation of COVID-19 Among Cruise Ship Crew During the Period of the No Sail Order* to assist cruise ship

operators in preventing, detecting, and medically managing confirmed and suspected cases of COVID-19 and exposures among crew members.<sup>22</sup> CDC also established an enhanced surveillance process to provide a more complete picture of COVID-19 activity on cruise ships. Under the *Interim Guidance*, CDC requires weekly submission of the "Enhanced Data Collection (EDC) During COVID-19 Pandemic Form."<sup>23</sup>

COVID-19 often presents as mild illness and many cases are asymptomatic among people of all ages. When symptoms are present, they are nonspecific and similar to those of many other respiratory infections and noninfectious conditions such as seasonal allergies. CDC *Interim Guidance* recommended that cruise ships' surveillance include routine viral testing for COVID-19, including intermittent testing of a random sample of symptomatic and asymptomatic crew members. Viral tests diagnose acute infection; the U.S. Food and Drug Administration-authorized viral tests include those that detect SARS-CoV-2 nucleic acid (*i.e.*, polymerase chain reaction [PCR]) or antigen (a rapid test).

However, availability of such routine viral testing on cruise ships remains limited. For these reasons, CDC does not limit its data collection to just confirmed cases of COVID-19 but collects data on both confirmed cases and COVID-like illness. These data create a more accurate picture of the spread of COVID-19 and its effects in the United States and provide additional data to inform the national public health response. As of September 28, EDC reports have shown a total of 6,088 PCR tests performed, 294 (5%) of which were positive for COVID-19; 24 hospitalizations; two instances of mechanical ventilation; and 15 medical evacuations for crew on ships within U.S. jurisdiction since April 13, 2020.

CDC established a "COVID-19 Color Coding System" for ships applicable to cruise ship operators with an appropriate NSO response plan for crew management. Classification of ships under this system requires cruise company officials to sign an acknowledgment of the completeness and accuracy of their NSO response

plans upon completion of CDC review of the plan. CDC additionally provides a provisional color status for ships belonging to cruise ship operators that do not yet have a complete and accurate plan. CDC assesses the status of a ship by reviewing surveillance data from the weekly EDC form as well as recent embarkations or crew transfers. Additional details regarding the color-coding system and color coding status for individual ships (which is updated weekly) may be found at <https://www.cdc.gov/coronavirus/2019-ncov/travelers/crew-disembarkations-commercial-travel.html>.

Since July 16, 2020, CDC has conducted implementation checks on 11 cruise ships operating in U.S. jurisdiction to review compliance with the NSO. These implementation checks showed that cruise ship operators were adhering to the requirements of the NSO and their NSO response plans.

*Challenges and Limitations in Testing Crew on Cruise Ships During the NSO*

While cruise ship operators have adhered to their NSO response plans during this time of suspended passenger operations, challenges remain. These challenges include the limitations of viral test results, including the possibility of false negative test results, the importance of crew quarantine in preventing disease spread, and concerns relating to reporting of symptoms by crew.

Two specific cases help illustrate these challenges. In the first case, following a cruise ship operator's policy to test all newly embarking crew prior to joining a ship, a crew member was tested in his home country and found to be PCR-negative for COVID-19 prior to flying to the United States to board the ship. Pursuant to CDC recommendations, the crew member immediately began a 14-day quarantine in a private cabin, and other crew members sanitized his boarding pathway after embarkation. Approximately 9 hours later during a routine temperature check, the crew member was found dead in bed.<sup>24</sup> The cruise line contacted the decedent's family who reported that the crew member had a dry cough and itchy throat prior to traveling despite reporting no symptoms during the pre-boarding process. A postmortem nasopharyngeal swab was collected for PCR testing, and the result was positive for COVID-19.

<sup>24</sup> This case is included in CDC's count of deaths from COVID-19 based on the positive PCR test result and lack of any other apparent explanation for the cause of death.

<sup>20</sup> These operators included Bahamas Paradise Cruise Lines, Carnival Corporation, Disney Cruise Lines, Norwegian Cruise Line Holdings, Royal Caribbean Group, Virgin Voyages, and Windstar Cruises. MSC Cruises submitted an NSO response plan on May 7, 2020, covering three of its ships.

<sup>21</sup> Carnival Corporation, Virgin Voyages, and Windstar Cruises initially submitted NSO response plans but later withdrew their ships from U.S. waters. Accordingly, CDC has held its review of these NSO response plans in abeyance.

<sup>22</sup> CDC, *Interim Guidance for Mitigation of COVID-19 Among Cruise Ship Crew During the Period of the No Sail Order* at: <https://www.cdc.gov/quarantine/cruise/management/interim-guidance-no-sail-order.html>.

<sup>23</sup> This EDC Form is used to conduct surveillance for COVID-19 among crew who remain on board cruise ships using cumulative reports of acute respiratory illness (ARI), influenza-like illness (ILI), and pneumonia, and other clinical indicators.

In the second case, another crew member onboard the same ship was tested in his home country and was also PCR-negative for COVID-19 prior to flying to the United States to board the ship. Again, pursuant to CDC recommendations, the crew member immediately began a 14-day quarantine in a private cabin, and other crew members sanitized his boarding pathway after embarkation. During this quarantine period, the crew member developed symptoms of nasal congestion and upon examination was found to have a rapid heart rate without a fever. When the cruise ship performed PCR testing of all 174 crew, this crew member was the only one who tested positive for COVID-19, indicating that the crew member became infected in the crew member's home country before travel.

These cases illustrate the importance of the 14-day quarantine period for embarking crew and how test results cannot eliminate the need for or reduce the length of quarantine. Testing represents a snapshot in time. A negative test result means that the virus that causes COVID-19 was not found in the sample collected. However, it is possible for any test to give a negative result that is incorrect ("false negative") in some people with COVID-19; testing may also be negative while a person is in the 2-14-day incubation period for COVID-19. The accuracy of any diagnostic test depends on many factors, including whether the sample was collected properly, whether the sample was maintained in appropriate conditions while it was shipped to the laboratory, and when during the course of the infection the testing was conducted.

When viral testing is negative, the possibility of a false negative result should be considered in the context of the individual's recent exposures and the presence of clinical signs and symptoms consistent with COVID-19. The possibility of a false negative result should be considered especially if recent exposures or clinical presentation indicate that COVID-19 is likely, and diagnostic tests for other causes of illness (e.g., other respiratory illness) are negative. If COVID-19 is still suspected based on exposure history together with other clinical findings, re-testing should be considered by healthcare providers in consultation with public health authorities.

As these cases illustrate, a single negative test result cannot be used to rule out the possibility of COVID-19, especially if the individual may have been recently exposed to the virus or is displaying symptoms. Relying on crew

testing alone without quarantine would not have been enough to prevent these two infected crew members from exposing others onboard. Despite preboarding screening efforts, one of these crew members was also reluctant to report symptoms. These factors should be considered carefully by cruise ship operators in planning for an eventual return to passenger operations.

#### *Dangers of Prematurely Resuming Passenger Operations on Cruise Ships*

There have been several recent instances of outbreaks of COVID-19 onboard cruise ships in those countries that have allowed passenger operations to resume, despite cruise ship operators implementing measures to control the disease. On the Hurtigruten cruise ship *MS Roald Amundsen*, 41 crew members and 21 passengers were confirmed to have COVID-19 after two voyages occurring between July 17-24 and July 25-31 in Norway.<sup>25</sup> The ship had 209 passengers on the first voyage and 178 on the second.<sup>26</sup> The cruise ship operator permitted passengers to disembark on July 31, before the announcement of the outbreak, potentially spreading the virus to dozens of towns and villages along Norway's western coast and setting off an effort by public health authorities to trace and locate the nearly 400 potentially exposed passengers.<sup>27</sup> While the outbreak onboard the *MS Roald Amundsen* is still under investigation, Hurtigruten has revealed that its internal review "uncovered several deviations from procedures, for example when it comes to quarantining foreign crews and the internal flow of important information."<sup>28</sup>

Cases of COVID-19 have also been documented on other cruise ships that have attempted to resume passenger operations. The SeaDream Yacht Club temporarily halted cruising onboard the *SeaDream I* in July after a passenger who had previously shown no symptoms disembarked from the ship

<sup>25</sup> Hurtigruten crew members and guests test positive for COVID-19, <https://www.hurtigruten.com/practical-information/coronavirus-update/ra31072020/>. Last accessed September 30, 2020.

<sup>26</sup> AP News, *Outbreak hits Norway cruise ship, could spread along coast*, <https://apnews.com/781a3faabde06d44749bfe57139da>. Last accessed September 30, 2020.

<sup>27</sup> Maritime Executive, *Hurtigruten's COVID-19 Fallout Continues*, <https://www.maritime-executive.com/index.php/article/fallout-continues-from-hurtigruten-s-covid-19-incident>. Last accessed September 30, 2020.

<sup>28</sup> *The COVID-19 situation: Update from Hurtigruten*, <https://presse.hurtigruten.no/pressreleases/the-covid-19-situation-update-from-hurtigruten-3024635>. Last accessed September 30, 2020.

and tested positive for COVID-19 upon returning to his home country of Denmark.<sup>29</sup> The Tahiti-based Paul Gauguin cruises had a passenger test positive for COVID-19 just three days into its first voyage with international passengers.<sup>30</sup> The incident required the French Polynesia High Commission to initiate a contact-tracing investigation to determine who may have been exposed to the passenger in question.<sup>31</sup> About 148 passengers and 192 crew members were on board the cruise ship at the time.<sup>32</sup> In late July, ten crew members on board AIDA Cruises' *AIDAbly* and *AIDamar* tested positive for COVID-19 after boarding in Rostok, Germany.<sup>33</sup> In the United States, Uncruise Adventures canceled its remaining voyages in Alaska after a passenger on board the 60-person<sup>34</sup> passenger vessel *Wilderness Adventurer* tested positive for COVID-19.<sup>35</sup> The incident necessitated a contact tracing investigation by Alaska public health authorities and the quarantine of passengers at a hotel in Juneau and of crew on board the ship.<sup>36</sup>

In the above examples, cruise ship operators had health and safety protocols to prevent the transmission and spread of COVID-19. The protocols adopted by the Hurtigruten included new sanitation measures, elimination of self-serve buffet dining, implementation of onboard social distancing procedures, operating at 50% capacity, a preboarding health questionnaire, and restricted shore excursions.<sup>37</sup> While investigations are still ongoing, the statement by Hurtigruten's CEO that the company failed to abide by its own

<sup>29</sup> Travel Weekly, *Another small-ship line reports a passenger with a positive Covid test*, <https://www.travelweekly.com/Cruise-Travel/SeaDream-reports-passenger-with-a-positive-Covid-test>. Last accessed September 30, 2020.

<sup>30</sup> The Maritime Executive, *One Suspected COVID-19 Case On Cruise Ship Paul Gauguin*, <https://www.maritime-executive.com/article/one-suspected-covid-19-case-on-cruise-ship-paul-gauguin>. Last accessed September 30, 2020.

<sup>31</sup> *Id.*

<sup>32</sup> *Id.*

<sup>33</sup> USA Today, *Ten AIDA cruise crew members test positive for COVID-19; ships will still sail in August*, <https://www.usatoday.com/story/travel/cruises/2020/07/28/aida-cruises-crew-members-test-positive-covid-19/5525310002/>. Last accessed September 30, 2020.

<sup>34</sup> This is below the capacity established by the NSO for passenger-carrying vessels.

<sup>35</sup> Uncruise Adventures, Press Release, <https://www.uncruise.com/about-us/media/press-releases/covid-cruise-not-uncruise-adventures>. Last accessed September 30, 2020.

<sup>36</sup> *Id.*

<sup>37</sup> <https://www.hurtigruten.com/practical-information/health-and-safety-on-board/>. Last accessed September 30, 2020.

protocols<sup>38</sup> suggests a need for further education, training, and experience in implementing new health and safety protocols prior to resuming passenger operations in any significant capacity.

In these examples, even when health and safety protocols were apparently observed, resuming passenger operations significantly burdened public health authorities by creating the need for additional testing, contact tracing, and quarantine. While the SeaDream Yacht Club has claimed that the passenger on board the *SeaDream I* was a “false positive,” a statistically rare event,<sup>39</sup> the incident still necessitated the quarantine of passengers and non-essential crew as directed by the Norwegian Directorate of Health as a public health precaution.<sup>40</sup> Paul Gauguin cruises required passengers to present proof of a negative COVID-19 test (PCR) at embarkation, excluding residents and visitors who had been in French Polynesia for more than 14 days,<sup>41</sup> yet the French Polynesia High Commission still conducted a lengthy contact investigation after a passenger later tested positive. The ship was carrying approximately 148 passengers (less than half of its 332-guest capacity) and 192 crew members at the time of the outbreak.<sup>42</sup> In the case of the *AIDA* cruise ships, all ten crew members initially tested negative in their home countries of Indonesia and the Philippines, yet when retested upon arrival in Germany were determined to be positive and required isolation on board the cruise ships.<sup>43</sup> A quarantine under the supervision of the local public health authority was similarly required when a passenger who had tested negative upon boarding the *Uncruise Adventures’ Wilderness*

*Adventurer* subsequently tested positive. In these examples, voyages were cancelled, passengers and crew quarantined or isolated, and contact tracing investigations conducted for those on the ship and for passengers who had returned to their home communities.

#### *More Time Needed To Assess Effectiveness of Proposed Public Health Interventions Prior to Resuming Passenger Operations*

Cruise ship operators have taken steps to advance their public health response to COVID-19, improve safety, and achieve readiness to safely resume passenger operations. Under the co-chairmanship of former Health and Human Services Secretary Michael O. Leavitt, two cruise lines, Royal Caribbean Group and Norwegian Cruise Line Holdings, assembled a “Healthy Sail Panel” of subject-matter experts from a variety of disciplines.<sup>44</sup> The World Travel & Tourism Council (WTTC) and Carnival Corporation also recently hosted a global science summit on COVID-19 designed, “to inform practical, adaptable and science-based solutions for mitigating and living with COVID-19.”<sup>45</sup> MSC Cruises further established its own industry-led panel with “competency to review policy initiatives, technical innovations, or operational measures related to COVID-19,”<sup>46</sup> and will presumably implement these recommendations as its passenger operations continue to resume in the Mediterranean with residents of Schengen countries.<sup>47</sup> At the moment, however, it is too early to assess whether these initiatives will produce a viable set of policies and practices that will mitigate the transmission and spread of COVID-19 onboard cruise ships while minimizing the potential burden and need for public health response activities.

To gather more information regarding these industry-led efforts and solicit public input, on July 20, 2020, CDC

published a Request for Information (RFI) in the **Federal Register** related to cruise ship planning and infrastructure, resumption of passenger operations, and additional summary questions.<sup>48</sup> The document had a comment period that ended on September 21, 2020 and almost 13,000 comments were received. In light of the number of submissions and high level of public interest, additional time is needed for CDC to review these comments, which may be used to inform future public health guidance and preventive measures relating to travel on cruise ships.

#### *Findings and Immediate Action*

The continued spread of the COVID-19 pandemic worldwide, risk of resurgence in countries that have suppressed transmission, ongoing concerns related to the restart of cruising internationally, and need for additional time to assess industry measures to control potential COVID-19 onboard cruise ships with passengers without burdening public health, support continuing to defer resumption of passenger operations at this time.

Accordingly, and consistent with 42 CFR 70.2, 71.31(b), and 71.32(b), the Director of CDC (“Director”) continues to find that cruise ship travel exacerbates the global spread of COVID-19, that the scope of this pandemic is inherently and necessarily a problem that is international and interstate in nature, and such transmission has not been controlled sufficiently by the cruise ship industry or individual State or local health authorities. As described in the March 14, 2020, Order, cruise ship travel markedly increases the risk and impact of the COVID-19 disease epidemic within the United States. If unrestricted cruise ship passenger operations were permitted to resume, infected and exposed persons disembarking cruise ships would place federal partners (e.g., Customs and Border Protection and the U.S. Coast Guard), healthcare workers, port personnel, and communities at substantial unnecessary risk.

The Director also continues to find evidence to support a reasonable belief that cruise ships are or may be infected or contaminated with a quarantinable communicable disease.<sup>49</sup> This

<sup>38</sup> Seatrade Cruise News, ‘Mistakes were made . . . We failed’ to follow own coronavirus protocols: Hurtigruten CEO, <https://www.seatrade-cruise.com/news/mistakes-were-made-we-failed-follow-own-coronavirus-protocols-hurtigruten-ceo>. Last accessed September 30, 2020.

<sup>39</sup> Watson J, Whiting PF, Brush JE. Interpreting a covid-19 test result. *BMJ* 2020; 369: m1808. doi: <https://www.bmj.com/content/369/bmj.m1808>. Last accessed September 30, 2020.

<sup>40</sup> The Maritime Executive, *Third Cruise Ship in a Week Reports COVID-19 Situation in Norway*, <https://www.maritime-executive.com/article/third-cruise-ship-in-a-week-reports-covid-19-situation-in-norway>. Last accessed September 30, 2020.

<sup>41</sup> <https://www.pgcruiises.com/travel-advisory>. Last accessed September 30, 2020.

<sup>42</sup> Paul Gauguin Ship Returns to Port After Suspected COVID-19 Case, <https://www.msn.com/en-us/travel/news/paul-gauguin-ship-returns-to-port-after-suspected-covid-19-case/ar-BB17wniX>. Last accessed September 30, 2020.

<sup>43</sup> Crew Center, *10 Crew Members of AIDA Cruises Test Positive for COVID-19*, <https://crew-center.com/10-crew-members-aida-cruises-test-positive-covid-19>. Last accessed September 30, 2020.

<sup>44</sup> <https://www.rclcorporate.com/royal-caribbean-group-and-norwegian-cruise-line-holdings-form-healthy-sail-panel/>. Last accessed September 30, 2020.

<sup>45</sup> Press Release, <https://www.carnivalcorp.com/news-releases/news-release-details/world-leading-experts-headline-covid-19-summit-hosted-wttc>. Last accessed September 30, 2020.

<sup>46</sup> MSC Cruise Announces Blue-Ribbon COVID Expert Group, Engages Specialized Maritime Classification Society to Provide Third-Party Verification That Its Protocol Meets Established Guidance, <https://www.msccruisesusa.com/news/blue-ribbon-covid-expert-group>. Last accessed September 30, 2020.

<sup>47</sup> Cruise Critic News, *MSC Cruises Restarts Cruising in the Mediterranean*, <https://www.cruise critic.com/news/5533/>. Last accessed September 30, 2020.

<sup>48</sup> Request for Information Related to Cruise Ship Planning and Infrastructure, Resumption of Passenger Operations, and Summary Questions, <https://www.federalregister.gov/documents/2020/07/21/2020-15812/request-for-information-related-to-cruise-ship-planning-and-infrastructure-resumption-of-passenger>. Last accessed September 30, 2020.

<sup>49</sup> COVID-19 is a communicable disease for which quarantine is authorized under Section 361 of the Public Health Service Act (42 U.S.C. 264) and

reasonable belief is based on information from epidemiologic and other data included in this document and the information described in the March 14, 2020, Order and the April 15 and July 16, 2020, modifications and extensions. As a result, persons on board or seeking to board cruise ships may likely be or would likely become infected with or exposed to COVID-19 by virtue of being on board at a time when cases of COVID-19 continue to be reported in increasingly significant numbers globally.<sup>50</sup> Additionally, persons infected on cruise ships would be likely to transmit COVID-19 to U.S. communities by traveling interstate after cruising.

Accordingly, under 42 CFR 70.2, the Director determines that measures taken by State and local health authorities regarding COVID-19 onboard cruise ships are inadequate to prevent the further interstate spread of the disease.

This Order is not a rule within the meaning of the Administrative Procedure Act (“APA”), but rather an emergency action taken under the existing authority of 42 CFR 70.2, 71.31(b), and 71.32(b). In the event that this Order qualifies as a rule under the APA, notice and comment and a delay in effective date are not required because there is good cause to dispense with prior public notice and the opportunity to comment on this Order.<sup>51</sup> Considering the public health emergency caused by COVID-19 based on, among other things, its potential for spread on board cruise ships, it would be impracticable and contrary to the public’s health, and by extension the public’s interest, to delay the issuance and effective date of this Order. Similarly, if this Order qualifies as a rule per the definition in the APA, the Office of Information and Regulatory Affairs has determined that it would be a major rule, but there would not be a delay in its effective date as the agency has invoked the good cause provision of the APA.

If any provision in this Order, or the application of any provision to any carriers, persons, or circumstances, shall be held invalid, the remainder of the provisions, or the application of such provisions to any carriers, persons, or circumstances other than those to which

it is held invalid, shall remain valid and in effect.

In accordance with 42 U.S.C. 264(e), this Order shall supersede any provision under State law (including regulations and provisions established by political subdivisions of States), that conflict with an exercise of Federal authority, including instructions by U.S. Coast Guard or HHS/CDC personnel permitting ships to make port or disembark persons under stipulated conditions, under this Order.

This Order shall be enforceable through the provisions of 18 U.S.C. 3559, 3571; 42 U.S.C. 243, 268, 271; and 42 CFR 70.18, 71.2.

Therefore, in accordance with 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), for all cruise ships described above for the period described below, it is ordered:

Measures Related To Protecting Public Health of Communities Signed on March 14, 2020

These measures were implemented to provide public health authorities, in concert with the cruise ship industry, the necessary pause in operations to develop and implement an appropriate and robust plan (1) to prevent and mitigate the further spread of COVID-19 in communities, and (2) to prevent the spread of the disease onboard and ensure the health of cruise ship passenger and crew.

Accordingly, the following terms and conditions of the *No Sail Order and Other Measures Related to Operations* signed on March 14, 2020, as modified and extended by this order, shall remain in effect. Consequently, it remains ordered:

1. Cruise ship operators shall not disembark or reembark crew members except as directed by the USCG, in consultation with HHS/CDC personnel and, as appropriate, as coordinated with Federal, State, and local authorities.

2. Cruise ship operators shall not embark any new passengers or crew, except as approved by USCG, or other Federal authorities as appropriate, in consultation with HHS/CDC personnel.

3. While in port, the cruise ship operator shall observe health precautions as directed by HHS/CDC personnel.

4. The cruise ship operator shall comply with all HHS/CDC, USCG, and other Federal agency instructions to follow CDC recommendations and guidance for any public health actions relating to passengers, crew, ship, or any article or thing on board the ship, as needed, including by making ships’ manifests and logs available and

collecting any specimens for COVID-19 testing.

Measures Related to Protecting Public Health and Crew Safety Signed on April 9, 2020, and Made Effective on April 15, 2020

These measures were implemented to, among other things, ensure a safe environment for crew members to work and disembark by requiring the submission of appropriate NSO response plans by cruise ship operators as a condition of obtaining controlled free pratique<sup>52</sup> to continue to engage in any cruise ship operations in any international, interstate, or intrastate waterways that are subject to the jurisdiction of the United States.

Accordingly, the terms and conditions of the *Modification and Extension of No Sail Order and Other Measures Related to Operations*, intended to protect public health and crew safety, signed on April 9, 2020, and made effective on April 15, 2020, as modified and extended by this order, shall remain in effect. Consequently, it remains ordered:

1. As a condition of obtaining controlled free pratique to continue to engage in any cruise ship operations in any international, interstate, or intrastate waterways that are subject to the jurisdiction of the United States, cruise ship operators shall develop, implement, and operationalize, an appropriate, actionable, and robust plan to prevent, mitigate, and respond to the spread of COVID-19 among crew onboard cruise ships.

2. As a condition of obtaining controlled free pratique to continue to engage in any cruise ship operations in any international, interstate, or intrastate waterways that are subject to the jurisdiction of the United States, the cruise ship operator shall make the plan described in paragraph 1, above, available to HHS/CDC and USCG personnel.

3. An appropriate plan is one that adequately prevents, mitigates, and responds to the spread of COVID-19 among crew onboard cruise ships and that, at a minimum, addresses the following elements:

a. Onboard surveillance of crew with acute respiratory illnesses, influenza-like illnesses, pneumonia, and COVID-19, including reporting to HHS/CDC on a weekly basis on overall case counts, methods of testing, and number of crew requiring hospitalization or medical evacuation;

<sup>52</sup> Under 42 CFR 71.1, controlled free pratique means permission for a carrier to enter a U.S. port, disembark, and begin operation under certain stipulated conditions.

42 CFR 70.1, 71.1, as listed in Executive Order 13295, as amended by Executive Orders 13375 and 13674.

<sup>50</sup> Since the March 14, 2020, Order, the number of global cases of COVID-19 reported by the World Health Organization (WHO) has risen from 142,534 to more than 33 million as of September 28, 2020, with more than 1 million deaths. See Situation Reports, WHO, <https://www.who.int/emergencies/diseases/novel-coronavirus-2019/situation-reports>.

<sup>51</sup> See 5 U.S.C. 553(b)(B), (d)(3).

b. Reports on the number of crew onboard the cruise ship and any increase in the numbers of crew with COVID-19 made to HHS/CDC and USCG on a daily basis for as long as the cruise ship is within waters subject to the jurisdiction of the United States.

c. Onboard monitoring of crew through temperature checks and medical screening, including addressing frequency of monitoring and screening;

d. Training of all crew on COVID-19 prevention, mitigation, and response activities;

e. Protocols for any COVID-19 testing, including details relating to the shore-side transport, administration, and operationalization of laboratory work if onboard laboratory work is not feasible;

f. Onboard isolation, quarantine, and social distancing protocols to minimize the risk of transmission and spread of COVID-19;

g. Onboard medical staffing, including number and type of staff, and equipment in sufficient quantity to provide a hospital level of care (e.g., ventilators, facemasks, personal protective equipment) for the infected so as to minimize the need for hospitalization onshore;

h. An outbreak management and response plan to provision and assist an affected cruise ship that relies on industry resources, e.g., mobilization of additional cruise ships or other vessels to act as “hospital” ship for the infected, “quarantine” ship for the exposed, and “residential” ship for those providing care and treatment, including the ability to transport individuals between ships as needed;

i. Categorization of affected crew into risk categories with clear stepwise approaches for care and management of each category;

j. A medical care plan addressing onboard care versus evacuation to on-shore hospitals for critically ill crew, specifying how availability of beds for critically ill at local hospitals will be determined in advance and how the cruise ship operator will ensure acceptance at local medical facilities to treat the critically ill in a manner that limits the burden on Federal, State, and local resources and avoids, to the greatest extent possible, medivac situations. If medical evacuation is necessary arrangements for evacuation must be made with commercial resources (e.g., ship tender, chartered standby vessel, chartered airlift) and arrangements made with a designated medical facility that has agreed to accept such evacuees. All medical evacuation plans must be coordinated with the U.S. Coast Guard;

k. Detailed logistical planning for evacuating and repatriating both U.S. citizens and foreign nationals to their respective communities and home countries via foreign government or industry-chartered private transport and flights, including the steps the cruise ship operator will take to ensure those involved in the transport are not exposed (i.e., without the use of commercial flights to evacuate or repatriate individuals, whether within or from the United States);

l. The projected logistical and resource impact on State and local government and public health authorities and steps taken to minimize the impact and engage with these authorities; all plans must provide for industry/cruise line management of suspected or confirmed cases of COVID-19 without resource burden on Federal, State, or local governments;

m. Plan execution in all U.S. geographical areas—all plans must be capable of being executed anywhere in international, interstate, or intrastate waterways that are subject to the jurisdiction of the United States; and

n. Cleaning and disinfection protocols for affected cruise ships.

4. An appropriate plan shall be designed to minimize, to the greatest extent possible, any impact on U.S. government operations or the operations of any State or local government, or the U.S. healthcare system.

5. The cruise ship operator shall further ensure that the plan is consistent with the most current CDC recommendations and guidance for any public health actions related to COVID-19. Where appropriate, a cruise ship operator may coordinate the development, implementation, and operationalization of a plan with other cruise ship operators, including an industry trade group.

Measures Related to Continued Protection of Public Health and Crew Safety Signed on July 16, 2020, as Modified and Extended by This Order

These measures were intended to continue to protect U.S. communities, ensure a safe environment for crew to work and disembark, and defer the embarkation of passengers until there is a clear pathway for a safe return to passenger operations.

Accordingly, the terms and conditions of the *Second Modification and Extension of No Sail Order and Other Measures Related to Operations*, signed on July 16, 2020, as modified and extended by this order, shall remain in effect.

Consequently, it remains ordered:

1. Cruise ship operators shall continue to suspend passenger operations and not embark passengers, except as approved by HHS/CDC personnel and USCG, in consultation with other federal authorities as appropriate.

2. As a condition of obtaining or retaining controlled free pratique to operate in any international, interstate, or intrastate waterways that are subject to the jurisdiction of the United States, cruise ship operators shall continue to follow CDC's *Interim Guidance for Mitigation of COVID-19 Among Cruise Ship Crew During the Period of the No Sail Order*, including reporting to HHS/CDC through weekly submission of the Enhanced Data Collection (EDC) form, as may be updated. Additionally, cruise ship operators shall report to USCG via Advance Notice of Vessel Arrival (ANOA), whenever in U.S. waters.

3. For cruise ship operators with ships that have not been in U.S. waters during the period of the No Sail Order or voluntarily withdrew their ships, the following conditions must be met prior to a ship returning to U.S. waters: (1) submission of the EDC form for 28-days preceding expected arrival in U.S. waters; and (2) having a complete and accurate NSO response plan, including having submitted to CDC a signed *Acknowledgment of No Sail Order Response Plan Completeness and Accuracy*.

4. As a condition of obtaining or retaining controlled free pratique to operate in any international, interstate, or intrastate waterways that are subject to the jurisdiction of the United States, cruise ship operators with appropriate NSO response plans shall continue to follow the *COVID-19 Color Coding System for Cruise Ships During the Period of the No Sail Order* requiring preventive measures for crew onboard based on the ship's status, as determined by HHS/CDC.

5. As a condition of obtaining or retaining controlled free pratique to operate in any international, interstate, or intrastate waterways that are subject to the jurisdiction of the United States, cruise ship operators with appropriate NSO response plans shall conduct viral testing for COVID-19 for crew in such a manner as described in the relevant CDC guidance with reporting of results on the EDC form.

6. As a condition of obtaining or retaining controlled free pratique to operate in any international, interstate, or intrastate waterways that are subject to the jurisdiction of the United States, cruise ship operators must observe the requirements of this Order, the previous Orders, and the most current CDC

recommendations and guidance for any public health actions related to COVID-19, even when outside of U.S. waters for any ships that intend to return to U.S. waters during the period that this Order remains in effect.

This Order is effective upon signature and 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) October 31, 2020.

**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 1, 2020.

**Nina B. Witkofsky,**

*Acting Chief of Staff, Centers for Disease Control and Prevention.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2020-N-1602]

#### Revocation of Authorizations of Emergency Use of In Vitro Diagnostic Devices for Detection of Antibodies Against SARS-CoV-2, the Virus That Causes Coronavirus Disease 2019 (COVID-19)

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the revocations of the Emergency Use Authorizations (EUAs) (the Authorizations) issued to Autobio Diagnostics Co. Ltd. ("Autobio") for the Anti-SARS-CoV-2 Rapid Test ("Autobio's Test") and to Manufacturers and Other Stakeholders ("Stakeholders") for certain in vitro diagnostic SARS-CoV-2 Antibody Tests. FDA revoked Autobio's Authorization on August 6, 2020, and the Stakeholders' Authorization on July 21, 2020, under the Federal Food, Drug, and Cosmetic Act (FD&C Act). The revocations, which include an explanation of the reasons for each revocation, are reprinted in this document.

**DATES:** Autobio's Authorization is revoked as of August 6, 2020. The

Stakeholders' Authorization is revoked as of July 21, 2020.

**ADDRESSES:** Submit written requests for single copies of 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 revocations may be sent. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the revocations.

**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) 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 April 24, 2020, FDA issued an EUA for Autobio's Anti-SARS-CoV-2 Rapid Test, subject to the terms of the Authorization. On April 28, 2020, FDA issued an EUA to Stakeholders, for certain in vitro diagnostic SARS-CoV-2 Antibody Tests (lateral flow or enzyme-linked immunosorbent assay tests to detect IgG only, IgG and IgM, or total antibodies in human plasma and/or serum) for use at laboratories certified under the Clinical Laboratory Improvement Amendments of 1988, 42 U.S.C. 263a, to perform moderate or high complexity tests. Notice of the issuance of the Authorizations was published in the **Federal Register** on July 14, 2020 (85 FR 42407), as required by section 564(h)(1) of the FD&C Act. Subsequent to the issuance of the Authorization for Autobio's Test, FDA considered new information, including from an independent evaluation of Autobio's Test from the National Institute of Health's Frederick National Laboratory for Cancer Research, part of the National Cancer Institute (the "NCI study"), demonstrating performance below the performance information submitted in Autobio's original EUA request and reflected in the authorized labeling for Autobio's Test. Subsequent

to the Stakeholders' Authorization, FDA considered that no device had been listed under the EUA and that FDA may issue individual EUAs instead.

##### II. EUA Criteria for Issuance No Longer Met and Other Circumstances Make Revocation Appropriate To Protect the Public Health or Safety

Under section 564(g)(2)(B) and (C) of the FD&C Act, the Secretary of HHS may revoke an EUA if, among other things, the criteria for issuance are no longer met or other circumstances make such revocation appropriate to protect the public health or safety. On August 6, 2020, FDA revoked the EUA for Autobio's Test because the criteria for issuance were no longer met and other circumstances make such revocation appropriate to protect the public health or safety. Under section 564(c)(2) of the FD&C Act, an EUA may be issued only if FDA concludes that, based on the totality of scientific evidence available, including data from adequate and well-controlled clinical trials, if available, it is reasonable to believe that the product may be effective in diagnosing, treating, or preventing such disease or condition and that 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.

Given the poor device performance observed in the NCI study since the issuance of the Authorization for Autobio's Test, FDA has concluded it is not reasonable to believe the product may be effective in detecting antibodies against SARS-CoV-2 or that the known and potential benefits of the device outweigh its known and potential risks. In addition, based on the same information and the risks to public health from false test results, FDA has concluded under section 564(g)(2)(C) of the FD&C Act that other circumstances make revocation appropriate to protect the public health or safety. Accordingly, FDA has revoked EUA200349 for Autobio's Anti-SARS-CoV-2 Rapid Test, pursuant to section 564(g)(2)(B) and (C) of the FD&C Act. On July 21, 2020, FDA revoked the EUA for Stakeholders' certain in vitro diagnostic SARS-CoV-2 Antibody Tests because other circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the FD&C Act), considering that no device has been listed under the EUA, and FDA can issue individual EUAs instead.

##### III. Electronic Access

An electronic version of this document and the full text of the revocations are available on the internet