The U.S. Food and Drug Administration, along with other federal, state, and local agencies and public health officials across the country, continues critical work to protect public health during the pandemic of COVID-19. Major focus areas of the FDA’s response include increasing the availability of tests, therapeutics, and other devices such as ventilators and personal protective equipment, and many other important items necessary for the response. The FDA is also monitoring the human and animal food supply and taking swift action on fraudulent COVID-19 products.

### Highlights of FDA Activities

#### Ensuring Timely Availability to Accurate and Reliable Tests
- As of May 7, 370 tests and sample collection devices are authorized by the FDA under *Emergency Use Authorizations (EUAs)*; these include 270 molecular tests and sample collection devices, 76 antibody and other immune response tests, and 24 antigen tests. There are 49 molecular authorizations and one antibody authorization that can be used with home-collected samples. There is one molecular prescription at-home test, two antigen prescription at-home tests, four antigen over-the-counter (OTC) at-home tests, and two molecular OTC at-home tests.
- The FDA has authorized 9 antigen tests and 3 molecular tests for serial screening programs. The FDA has also authorized 483 revisions to EUA authorizations.
- The FDA continues to monitor authorized tests and emerging scientific evidence and may revise or revoke an EUA, when appropriate, including when a test’s benefits no longer outweigh its risks. The FDA provides continuous updates to make clear which tests have been issued EUAs by the agency, and which tests should not be used.

#### Accelerating Availability of Medical Equipment and Products for Treatment
- The FDA added more than 100 ventilators and accessories for emergency use to the ventilator EUA and issued EUAs for other equipment to treat patients during COVID-19.

#### Facilitating the Development of COVID-19 Vaccines
- There are three COVID-19 vaccines authorized for emergency use.

#### Halting the Sale of Products with Fraudulent Claims Related to COVID-19
- As of May 6, the FDA has received more than 1375 reports of fraudulent products related to COVID-19.
- To proactively identify and neutralize threats to consumers, the FDA launched Operation Quack Hack in March 2020. The Operation Quack Hack team has reviewed thousands of websites, social media posts, and online marketplace listings, resulting in more than 170 warning letters to sellers, more than 305 reports sent to online marketplaces, and more than 299 abuse complaints sent to domain registrars to date.
Recent Actions

• On May 10, the FDA expanded the EUA for the Pfizer-BioNTech COVID-19 Vaccine to include adolescents 12 through 15 years of age. For this age group, the Pfizer-BioNTech COVID-19 Vaccine is administered as a series of two doses, three weeks apart, the same dosage and dosing regimen as it is for individuals 16 years and older. The FDA amended the EUA originally issued on Dec. 11, 2020 for administration in individuals 16 years of age and older.

• On May 5, the FDA issued a new report titled, “Resiliency Roadmap for FDA Inspectional Oversight,” outlining the agency’s inspecional activities during the COVID-19 pandemic and its detailed plan to move toward a more consistent state of operations, including the FDA’s priorities related to this work going forward.

• On April 30, the FDA revoked the EUA of the Battelle CCDS Critical Care Decontamination System, which was authorized for use in decontaminating compatible N95 respirators for multiple-user reuse by health care personnel. The FDA revoked the EUA in response to Battelle’s request for voluntary withdrawal of the authorization. In response to changing customer needs, as of March 31, 2021, Battelle has ceased all Battelle CCDS decontamination site operations and marketing activities.

• On April 28, the FDA updated the EUA Authorized Serology Test Performance page on the FDA’s website. The FDA provided information on the expected predictive value of authorized serology tests that have submitted performance data with SARS-CoV-2 antibody prevalence assumptions ranging from 5% to 50%. These estimates may help health care providers interpret these antibody test results for their patients. Additionally, the updated web page clarifies the use of serology tests when assessing a patient’s adaptive immune response.

• On April 23, the FDA and the CDC issued a press release to announce the lifting of the recommended pause on the use of Janssen (Johnson & Johnson) COVID-19 Vaccine following a thorough safety review. The FDA added and updated some questions about resuming the use of this vaccine to the Janssen COVID-19 Frequently Asked Questions webpage. This followed a pause in the use of this vaccine out of an abundance of caution, announced April 13, so that the CDC and the FDA could review data involving six reported U.S. cases of a rare and severe type of blood clot in individuals after receiving the J&J vaccine.

• In an April 21 statement, the FDA provided an update on the agency’s recently completed inspection of Emergent BioSolutions, a proposed manufacturing facility for the Johnson & Johnson COVID-19 Vaccine. The FDA’s inspections are thorough, and these assessments review the quality of manufacturing procedures, including records, staff training, facility operations, drug production and testing and the systems in place to ensure product quality.

• On April 21, the FDA’s Center for Food Safety and Applied Nutrition updated its COVID-19 Vaccination & Food and Agriculture Sector webpage to include the HHS COVID-19 Vaccination Toolkit for agriculture workers.

• On April 20, the FDA authorized an amendment for many molecular diagnostic SARS-CoV-2 tests authorized for diagnosis or screening, which allows emergency use of such tests on pooled specimens for
testing individuals without symptoms or other reasons to suspect COVID-19, when tested at least once per week as part of a serial testing program without prospective FDA review. The amendment applies only to pooling of anterior nasal respiratory specimens. To utilize this approach, EUA holders must submit a notification to FDA with specific required information, including validation data (if requesting to pool more than three specimens) and pooling procedures.

On April 16, the FDA revoked the EUA that allowed for the investigational monoclonal antibody therapy bamlanivimab, when administered alone, to be used for the treatment of mild-to-moderate COVID-19 in adults and certain pediatric patients. Based on its ongoing analysis of emerging scientific data, specifically the sustained increase of SARS-CoV-2 viral variants that are resistant to bamlanivimab alone resulting in the increased risk for treatment failure, the FDA has determined that the known and potential benefits of bamlanivimab, when administered alone, no longer outweigh the known and potential risks for its authorized use. Therefore, the agency determined that the criteria for issuance of an authorization are no longer met and has revoked the EUA. Other antibody treatments remain available under EUA to treat COVID-19.

In an April 12 FDA Voices, FDA leaders explain how the agency is working to address concerns about vaccines among diverse communities and to protect and promote the health of diverse populations by focusing our efforts on strategies that address health disparities. Read more here: Vaccine Ready: Addressing COVID-19 Health Disparities among Racial and Ethnic Minority Communities.

On April 9, the FDA issued a letter to health care personnel and facilities recommending transition from use of decontaminated disposable respirators. The agency is recommending health care personnel and facilities transition away from crisis capacity conservation strategies, such as decontaminating or bioburden reducing disposable respirators for reuse. Based on the increased domestic supply of new respirators approved by the CDC’s National Institute for Occupational Safety and Health currently available to facilitate this transition, the FDA and the CDC believe there is adequate supply of respirators to transition away from use of decontamination and bioburden reduction systems.

On April 6, the FDA announced the issuance of an EUA for the Symbotica COVID-19 Self Collected Antibody Test System, the first antibody test authorized for use with home collected dried blood spot samples. Samples collected at home are then sent to a Symbiotica, Inc. laboratory for analysis.

On April 5, the FDA issued and immediately implemented a new guidance: Development of Abbreviated New Drug Applications During the COVID-19 Pandemic – Questions and Answers. It provides general recommendations to prospective generic drug applicants related to generic drug product development and regulatory submissions in the form of questions and answers that have been received and addressed by the FDA during the COVID-19 public health emergency.

On April 1, the FDA announced two revisions regarding the number of doses per vial available for the Moderna COVID-19 Vaccine. The first revision clarifies the number of doses per vial for the vials that are currently available, in that the maximum number of extractable doses is 11, with a range of 10-11 doses. The second revision authorizes the availability of an additional multi-dose vial in which each vial contains a maximum of 15 doses, with a range of 13-15 doses that can potentially be extracted.

On March 31, the FDA announced actions to get more tests for screening asymptomatic individuals on the market. The FDA authorized several COVID-19 tests for OTC use (without a prescription) when used for serial screening (testing asymptomatic individuals multiple times on a routine basis), such as testing twice a week in schools or other settings. The FDA also authorized serial screening tests for use in a point-of-care setting, such as a doctor’s office.

On March 30, the FDA posted a new web page, SARS-CoV-2 Viral Mutations: Impact on COVID-19 Tests, for clinical laboratory staff and health care providers about the impact of viral mutations on COVID-19 molecular, antigen, and serology tests. This web page builds on the letter the FDA issued January 8 alerting clinical laboratory staff and health care providers to the potential for false negative results due to the impact of viral mutations on molecular SARS-CoV-2 tests.
RESOURCES

- The FDA has made information available to the public in both English and Spanish on our COVID-19 website in addition to multilingual COVID-19 resources. This includes regularly updating our Frequently Asked Questions, issuing Consumer Updates, MedWatch alerts, FDA Voices, stakeholder updates, webinars, and other resources for patients, caregivers and health care providers. The FDA has issued more than 325 news announcements on COVID-19 topics since January, 2020.

- Educational Resources provides links to FDA-produced COVID-19-related resources that help explain the agency’s work.

- The FDA web page, COVID-19 Vaccines, provides updates and information about the agency’s work to facilitate development of COVID-19 vaccines that meet FDA’s rigorous scientific standards.

- For information about the different types of tests and the steps involved in processing samples, see Coronavirus Testing Basics explainer. If you think you have COVID-19 and need a test, contact your health care provider immediately.

- The FDA has provided information on COVID-19 treatment options.

- Before buying or using hand sanitizer, the FDA recommends checking this list of hand sanitizers consumers should not use. Bookmark www.fda.gov/handsanitizerlist for the latest, and use our step-by-step search guide to find out if your product is on the list.

- Innovation to Respond to COVID-19 provides an overview of the FDA’s work to facilitate and accelerate the development of COVID-19 medical products and ways the agency is exercising regulatory flexibility through guidance to industry.

- COVID-19 Resources for Health Professionals provides quick and easy access to FDA information for health care professionals.

- Coronavirus Disease 2019 (COVID-19) Emergency Use Authorizations for Medical Devices provides information on the EUAs for medical devices that the FDA has issued related to COVID-19.

- The FDA has issued more than 75 guidance documents to provide updated policies, transparency, and regulatory flexibility to address the food supply, vital medical products and public health issues facing the U.S. during this pandemic. These guidances are on diagnostics, personal protective equipment, other medical devices, investigational treatment with convalescent plasma, conduct of clinical trials of medical products, blood supply, hand sanitizers, food safety and supply, telemedicine and other topics.

- The FDA has provided information about COVID-19 vaccination and the food and agriculture sector.

- For updated information about COVID-19 clinical trials underway in the U.S. and internationally, see clinicaltrials.gov.

- Subscribe to receive updated COVID-19-related information from the FDA.