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, vaccines and 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 June 11, 384 tests and sample collection devices are authorized by the FDA under Emergency Use Authorizations (EUAs); these include 275 molecular tests and sample collection devices, 81 antibody and other immune response tests and 28 antigen tests. There are 52 molecular authorizations and one antibody authorization that can be used with home-collected samples. There is one molecular prescription at-home test, three antigen prescription at-home tests, five antigen over-the-counter (OTC) at-home tests, and two molecular OTC at-home tests.
- The FDA has authorized 11 antigen tests and three molecular tests for serial screening programs. The FDA has also authorized 532 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.
- The agency has issued EUAs and policies to help increase the availability of personal protective equipment, such as respirators, gowns, surgical masks, and more.
- There are now more than 620 drug development programs in planning stages and ten EUAs for COVID-19 treatments are currently authorized for emergency use. One treatment is currently approved by the FDA for use in 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 1445 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 231 warning letters to sellers, more than 310 reports sent to online marketplaces, and more than 299 abuse complaints sent to domain registrars to date.
Recent Actions

- On June 11, following careful review and deliberation, the FDA took important steps that will allow a critically needed supply of the Janssen (Johnson & Johnson) COVID-19 Vaccine to be made available. The agency authorized for use, under the EUA for the Janssen COVID-19 vaccine, two batches of vaccine drug substance manufactured at the Emergent BioSolutions facility in Baltimore.

- On June 10, the FDA’s Vaccines and Related Biological Products Advisory Committee met to discuss, in general, data needed to support authorization and/or licensure of COVID-19 vaccines for use in pediatric populations.

- On June 8, the White House, the U.S. Department of Health and Human Services Office of the Assistant Secretary for Preparedness and Response and the FDA released a series of policy recommendations to address the vulnerabilities in U.S. pharmaceutical supply chains. Led by HHS, the White House report and its recommendations have been accepted by President Biden.

- A Wisconsin man was sentenced on June 8 to three years in prison, followed by three years of supervised release, for purposefully tampering with and attempting to spoil COVID vaccine doses at the hospital where he worked. The matter was investigated by the FDA’s Office of Criminal Investigations.

- On June 8, the FDA Office of Minority Health and Health Equity published a new Health Equity Forum podcast, A conversation with the FDA Chief Scientist: Learn about the Emergency Use Authorization (EUA) Process.

- On June 3, the FDA posted an update to the SARS-CoV-2 Viral Mutations: Impact on COVID-19 Tests web page to share the latest information. The update added new information about a potential impact on the performance of the Mesa Biotech Inc. Accula SARS-CoV-2 Test due to a genetic mutation at positions 28877-28878 (AG to TC) in patient samples.

- On June 3, the FDA reissued the Letter of Authorization for REGEN-COV (Casirivimab and Imdevimab) treatment for COVID-19 to authorize:
  - A dosage change from 1200 mg of casirivimab and 1200 mg of imdevimab to 600 mg of casirivimab and 600 mg of imdevimab;
  - A new coformulation presentation that contains 600 mg of casirivimab and 600 mg of imdevimab in a single vial, and
  - Addition of subcutaneous (under-the-skin) injection as an alternative route of administration when intravenous (administered into a vein) infusion is not feasible and would lead to delay in treatment.

- On May 28, the FDA issued a safety communication to warn the public to stop using the Lepu Medical Technology SARS-CoV-2 Antigen Rapid Test Kit and the Leccurate SARS-CoV-2 Antibody Rapid Test Kit (Colloidal Gold Immunochromatography) because the FDA has serious concerns about the performance of the tests and believes there is likely a high risk of false results when using these tests. Neither test has been authorized, cleared, or approved by the FDA. The FDA has identified this issue as a class I recall, which is the most serious type of recall. The FDA is
aware that these unauthorized tests were distributed to pharmacies to be sold for at-home testing by consumers, as well as offered for sale directly to consumers.

- As part of the FDA’s effort to protect consumers, on May 27, the agency issued a warning letter jointly with the Federal Trade Commission to Oclo Nanotechnology for selling unapproved chlorine dioxide products with unproven COVID-19 claims. FDA continues to warn consumers not to drink chlorine dioxide products including “OCLO 3000.” Drinking any chlorine dioxide product can cause nausea, vomiting, diarrhea and symptoms of severe dehydration. Consumers concerned about COVID-19 should consult with their health care provider.

- On May 27, 2021, the FDA issued an Update: FDA Recommends Transition from Use of Non-NIOSH-Approved and Decontaminated Disposable Respirators - Letter to Health Care Personnel and Facilities. The FDA is recommending health care personnel and facilities transition away from crisis capacity conservation strategies, such as using non-NIOSH-approved disposable respirators, including imported respirators such as KN95s. This recommendation is a follow-up to the April 9, 2021, letter in which the FDA recommended a transition away from decontamination or bioburden-reduction systems for cleaning and disinfecting disposable respirators which were being reused by health care personnel.

- On May 26, the FDA released the Medical Countermeasures Initiative Program Update report which showcases the FDA’s work each year to prepare for all types of public health emergencies, including COVID-19. This report, covering fiscal year 2020, includes a snapshot of the agency’s COVID-19 response during the reporting period.

- On May 26, the FDA issued an EUA for the investigational monoclonal antibody therapy sotrovimab for the treatment of mild-to-moderate COVID-19 in adults and pediatric patients (12 years of age and older weighing at least 40 kilograms [about 88 pounds]) with positive results of direct SARS-CoV-2 viral testing and who are at high risk for progression to severe COVID-19, including hospitalization or death. This includes, for example, individuals who are 65 years of age and older or individuals who have certain medical conditions.

- On May 25, the FDA updated its guidance, Emergency Use Authorization for Vaccines to Prevent COVID-19, to include a new section that clarifies how the agency intends to prioritize review of EUA requests for the remainder of the COVID-19 public health emergency. As noted in the guidance, for the remainder of the current pandemic, the FDA may decline to review and process further EUA requests other than those for vaccines whose developers have already engaged with the agency as described in the agency’s guidance, “Emergency Use Authorization Vaccines to Prevent COVID-19.”

- On May 25 a report describes some of the approaches used by the South Korean government to address COVID-19, particularly regarding development, authorization and use of diagnostic tests. Numerous sources around the world declared South Korea’s response strategy had successfully “flattened the curve” of COVID-19. As South Korea’s experience may be informative for future considerations, the FDA reviewed information, including reports in the press and information made publicly available by the South Korean government, about their COVID-19 response strategy.

- The FDA issued a safety communication on May 19 to remind health care providers and the public that results from currently authorized SARS-CoV-2 antibody tests should not be used to evaluate a person’s level of immunity or protection from COVID-19 at any time, and especially after the person received a COVID-19 vaccination. The FDA also updated the Serology/Antibody Tests: FAQs on Testing for SARS-CoV-2 and the Antibody (Serology) Testing for COVID-19: Information for Patients and Consumers web pages to provide updated information on the use of SARS-CoV-2 antibody test results.

- On May 14, the FDA updated the definition of high risk for COVID-19 to include additional medical conditions and factors associated with increased risk for progression to severe disease. This update applies to the emergency use authorizations (EUAs) for REGEN-COV (Casirivimab and Imdevimab) and Bamlanivimab and Etesevimab.

- As part of the FDA’s effort to protect consumers, on May 19, the agency issued a warning letter jointly with the Federal Trade Commission to BGP, LLC for selling an unapproved product with unproven COVID-19 claims. Consumers concerned about
COVID-19 should consult with their health care provider.

- On May 19, based on a review of data submitted by Pfizer Inc., the FDA authorized undiluted, thawed Pfizer-BioNTech COVID-19 Vaccine vials to be stored in the refrigerator at 2°C to 8°C (35°F to 46°F) for up to 1 month. Previously, thawed, undiluted vaccine vials could be stored in the refrigerator for up to 5 days.

- On May 19, the FDA issued a safety communication informing the public that results from SARS-CoV-2 antibody tests should not be used to evaluate immunity or protection from COVID-19 at any time, and especially after the person received a COVID-19 vaccination.

- On May 17, the FDA provided summary information about the status of CytoDyn, Inc.’s development program for the monoclonal antibody investigational drug, leronlimab, for the treatment of COVID-19. The data currently available from recent CytoDyn clinical trials do not support the clinical benefit of leronlimab for the treatment of COVID-19.

- On May 11, Director of the FDA Center for Biologics Evaluation and Research, Peter Marks, M.D., Ph.D. testified for the FDA at a hearing before the U.S. Senate Committee on Health, Education, Labor and Pensions. View written testimony.

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, and information about authorized vaccines, including fact sheets and FAQs.

- 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.