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 Dec. 18, 2020, 305 tests and sample collection devices are authorized by the FDA under Emergency Use Authorizations (EUAs); these include 233 molecular tests and sample collection devices, 62 antibody tests and 10 antigen tests.
- 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 590 drug development programs in planning stages and as of the end of November, the agency has reviewed more than 390 trials of potential therapies for COVID-19. Eight EUAs to treat COVID-19 and serious conditions caused by COVID-19 are currently authorized for emergency use. One treatment is currently approved by the FDA for use in COVID-19.

**Actively Monitoring the Medical Product and Food Supply Chains to Address Imbalances**
- The FDA continues to screen and monitor millions of domestic and international products in the medical supply chain to help ensure COVID-19-related supplies coming into the U.S. are safe and distributed appropriately.

**Facilitating the Development of COVID-19 Vaccines**
- As of Dec. 18, there are two COVID-19 vaccines authorized for emergency use.

**Halting the Sale of Products with Fraudulent Claims Related to COVID-19**
- As of Dec. 17, 2020, the FDA has identified more than 1240 fraudulent and unproven medical 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 over 150 warning letters to sellers, more than 275 reports sent to online marketplaces, and more than 275 abuse complaints sent to domain registrars to date.
Recent Actions

- On Dec. 18, the FDA issued an EUA for the second vaccine for the prevention of COVID-19 caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). The EUA allows the Moderna COVID-19 Vaccine to be distributed in the U.S for use in individuals 18 years of age and older.

- On Dec. 16, the FDA issued a new EUA for the BinaxNOW COVID-19 Ag Card Home Test, authorized for prescription use at home with self-collected nasal swab samples from individuals ages 15 years or older who are suspected of COVID-19 by their health care provider within the first seven days of symptom onset.

- On Dec. 15, the FDA issued an EUA for the first over-the-counter (OTC) fully at-home diagnostic test for COVID-19. The Ellume COVID-19 Home Test is a rapid, lateral flow antigen test, a type of test that runs a liquid sample along a surface with reactive molecules and uses an analyzer that connects with a software application on a smartphone to help users perform the test and interpret results. The test detects fragments of proteins of the SARS-CoV-2 virus from a nasal swab sample from any individual 2 years of age or older.

- On Dec. 15, a new FDA Insight podcast was released, featuring a discussion on advanced manufacturing, including how these technologies support emergency preparedness and response, including COVID-19.

- On Dec. 11, the FDA issued the first EUA for a vaccine for the prevention of COVID-19 caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 16 years of age and older. The EUA allows the Pfizer-BioNTech COVID-19 Vaccine to be distributed in the U.S.

- On Dec. 14, the FDA posted a video on safely using hand sanitizer, with tips for consumers and their families on how to use and store hand sanitizer, as an alternative when handwashing with soap and water isn’t possible.

- On Dec. 9, the FDA issued an EUA to LabCorp for its Pixel COVID-19 Test Home Collection Kit for use with LabCorp’s COVID-19 RT-PCR Test. The Pixel COVID-19 Test Home Collection Kit is the first COVID-19 direct-to-consumer (non-prescription) test system, allowing a person to self-collect a nasal sample in their home and then send the sample to LabCorp for testing. It can be used by anyone aged 18 or over and purchased online or in a store without a prescription.

- On Dec. 8 a new FDA Insight podcast, featuring a discussion with the head of the FDA’s Office Minority Health and Health Equity, was released.

- On Dec. 7 the FDA issued a safety communication, Wear Face Masks with No Metal During MRI Exams, to inform patients and health care providers that patients may be injured if they wear face masks (such as surgical or non-surgical masks and respirators) with metal parts and coatings during a Magnetic Resonance Imaging (MRI) exam.

- On Dec. 4, the FDA authorized the first diagnostic test for use with home-collected patient samples to detect both COVID-19 and influenza A and B (flu). The FDA authorized Quest Diagnostics RC COVID-19 +Flu RT-PCR Test for prescription use with the Quest Diagnostics Self-Collection Kit for COVID-19 +Flu by individuals who are suspected of respiratory viral infection consistent with COVID-19 when home collection is determined to be appropriate by an individual’s healthcare provider. Under a health care provider’s order, patients can self-collect a nasal sample at home and then ship it to Quest Diagnostics for analysis, using the instructions in the collection kit.
• On Dec. 3, to protect consumers from fraudulent products and as part of the FDA’s COVID-19 Operation Quack Hack, the U.S. Attorney’s Office in the Southern District of California recently issued a press release to announce that a San Diego physician was indicted by a federal grand jury earlier this month for selling COVID-19 “treatment kits,” which he advertised to one potential customer as a “miracle cure.”

• On Dec. 2, the FDA updated the SARS CoV-2 reference panel comparative data on our website to reflect the latest information. The FDA SARS-CoV-2 reference panel is an independent performance validation step for diagnostic tests of SARS-CoV-2 infection that are being used for clinical purposes.

• On Nov. 25, the FDA issued guidance on the use of dry heat to help support the single-user reuse of certain particulate filtering facepiece respirators, such as N95 respirators, by health care personnel when there is a limited supply of respirators during the COVID-19 public health emergency.

• On Nov. 24, the FDA published Face Masks, Including Surgical Masks, and Respirators for COVID-19, a comprehensive new page on FDA.gov with answers to frequently asked questions about face masks, surgical masks, and respirators.

• On Nov. 21, issued an EUA for casirivimab and imdevimab, administered together by intravenous (IV) infusion, for the treatment of mild to moderate COVID-19 in adults and pediatric patients [12 years of age or 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 progressing to severe COVID-19.

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 225 news announcements on COVID-19 topics since January.

• A new 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.

• The FDA is warning consumers and health care professionals that the FDA continues to find hand sanitizer products that are labeled as containing ethanol (also known as ethyl alcohol) but have tested positive for methanol or 1-propanol contamination. Methanol and 1-propanol are not acceptable ingredients for hand sanitizer products and can be life-threatening when ingested. The FDA also continues to find hand sanitizers that are subpotent, meaning the product contains less than the required amount of ethyl alcohol, isopropyl alcohol or benzalkonium chloride. 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. Educational Resources provides links to FDA-produced COVID-19-related resources that help explain the agency’s work.

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

• To learn more about keeping your pets safe during the coronavirus (COVID-19) pandemic, watch this video.

• The FDA has issued more than 65 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 a retail food re-opening checklist for previously closed retail food establishments or those that have been open with limited service related to the COVID-19 pandemic, see Best Practices for Re-Opening Retail Food Establishments During the COVID-19 Pandemic.

• If you have fully recovered from COVID-19, you may be able to help patients currently fighting the infection by donating your plasma.

• For updated fact sheets for the Emergency Use Authorizations the FDA has issued, see therapeutics and devices.

• 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.