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**
- To date, the FDA has currently authorized 240 tests under Emergency Use Authorizations (EUAs); these include 193 molecular tests, 43 antibody tests and 4 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 90 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.

**Actively Monitoring the Medical Product and Food Supply Chains to Address Imbalances**
- Continue 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.

**Halting the Sale of Products with Fraudulent Claims Related to COVID-19**
- As of Sept. 1, 2020, the FDA has identified more than 1068 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 111 warning letters to sellers, more than 220 reports sent to online marketplaces, and more than 266 abuse complaints sent to domain registrars to date.

- There are now more than 570 drug development programs in planning stages and as of the end of July, the agency has reviewed more than 270 trials of potential therapies for COVID-19.
Recent Actions

- On Sept. 2, the FDA updated its guidance, Investigational COVID-19 Convalescent Plasma, to provide additional information related to the recently issued EUA for the use of COVID-19 convalescent plasma to treat hospitalized patients with COVID-19. This update includes a discussion regarding the FDA’s intent to exercise temporary enforcement discretion regarding the IND requirements for the use of this product when blood establishments, hospitals and health care providers collect plasma that does not meet the Conditions of Authorization of the EUA. The revised guidance continues to provide recommendations for health care providers who wish to administer and study convalescent plasma under an Investigational New Drug Application.

- Three new “FDA Insight” podcasts were posted.
  – Sept. 1: The Opioid Epidemic and COVID-19 Pandemic
  – Aug. 25: Drug Shortages and COVID-19
  – Aug. 18: Health Fraud and COVID-19

- On Aug. 28, the FDA broadened the scope of the existing emergency use authorization (EUA) for the drug Veklury (remdesivir) to include treatment of all hospitalized adult and pediatric patients with suspected or laboratory-confirmed COVID-19, irrespective of their severity of disease.

- On Aug. 28, the FDA issued a press release to announce that a public meeting of the Vaccines and Related Biological Products Advisory Committee will be held on Oct. 22, 2020, to discuss the general matter of the development, authorization, and/or licensure of vaccines indicated to prevent COVID-19.

- On Aug. 27 the FDA warned consumers about alcohol-based hand sanitizers that are being packaged in containers that may appear as food or drinks and may put consumers at risk of serious injury or death if ingested. Some hand sanitizers are being packaged in beer cans, children’s food pouches, water bottles, juice bottles and vodka bottles.

- On Aug. 26 the FDA issued an EUA for the first antigen test where results can be read directly from the testing card, a similar design to some pregnancy tests. This simple design is fast and efficient for health care providers and patients and does not need the use of an analyzer.

- On Aug. 25 the FDA issued a new Consumer Update entitled, Is Your Hand Sanitizer on FDA’s List of Products You Should Not Use?, available in English and five other languages. Before buying hand sanitizer or using hand sanitizer you have at home, the FDA recommends checking its do-not-use list at www.fda.gov/handsanitizerlist. The agency updates the list regularly as new test results are released.

- On Aug. 24 the FDA posted a new webpage that provides an overview of available resources related to SARS-CoV-2 screening testing and testing using pooled samples.

- On Aug. 23, the FDA issued an EUA for investigational convalescent plasma for the treatment of COVID-19 in hospitalized patients as part of the agency’s ongoing efforts to fight COVID-19. Based on scientific evidence available, the FDA concluded, as outlined in its decision memorandum, this product may be effective in treating COVID-19 and that the known and potential benefits of the product outweigh the known and potential risks of the product.

- On Aug. 19, the FDA, in partnership with OSHA, developed the Employee Health and Food Safety Checklist for Human and Animal Food Operations During the COVID-19 Pandemic. The checklist will assist the food industry with operational changes it may have as a result of COVID-19.

- On Aug. 19 the FDA issued the third EUA for a COVID-19 antigen test for LumiraDX UK Ltd.’s LumiraDx SARS-CoV-2 Ag Test, and authorized the test for use in high and moderate complexity laboratories certified Under the Clinical Laboratory Improvement Amendments (CLIA), as well as at the point-of-care (i.e., patient care settings) operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.

- On Aug. 19, the FDA posted frequently asked questions for consumers about UV lights and lamps.
The FDA is providing answers to consumers’ questions about the use of these lamps for disinfection during the COVID-19 pandemic.

- On Aug. 18, the FDA updated its COVID-19 Resources for Health Professionals page to include the CURE ID app. CURE ID allows clinicians to quickly and easily share their experiences treating COVID-19 patients and patients with other difficult-to-treat infectious diseases.
- On Aug. 15 the FDA issued Yale School of Public Health an EUA for its SalivaDirect COVID-19 diagnostic test, which uses a new method of processing saliva samples when testing for COVID-19 infection.

RESOURCES

- The FDA has made information available to the public in both English and Spanish on our COVID-19 website. 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 185 news announcements on COVID-19 topics since January. In late March, the agency began to issue “Daily Roundups” to capture its ongoing response efforts each weekday.

- 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 60 guidance documents to provide updated policies, transparency, and regulatory flexibility to address the vital medical products and public health issues facing the U.S. during this pandemic. These guidelines 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.