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 authorized 141 tests under emergency use authorizations (EUA), which include 120 molecular tests, 20 antibody tests and 1 antigen test.
- 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.

Accelerating Availability of Medical Equipment and Products for Treatment
- Added more than 80 ventilators and accessories for emergency use to the ventilator EUA and issued EUAs for other equipment to treat patients during COVID-19.
- Issued EUAs and policies to help increase the availability of personal protective equipment, such as respirators, gowns, surgical masks, and more.
- Monitoring more than 144 active trials of therapeutic agents for COVID-19; another 457 development programs for therapeutic agents are in the planning stages.

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
- Issued hundreds of abuse complaints resulting in online marketplaces removing listings for 260 products that claimed to diagnose, treat, prevent, or cure COVID-19.
- Issued 73 health fraud warning letters to sellers of unapproved, uncleared, and unauthorized products with fraudulent COVID-19 claims to diagnose, treat, prevent, or cure COVID-19, including homeopathic drug products, cannabidiol products, nasal sprays, colloidal silver products, herbal products, chlorine dioxide products, antibody tests, and others.
- Continue to aggressively monitor the market for and take appropriate action against individuals and companies selling products with fraudulent COVID-19 claims.
Recent Actions

- On June 18, the FDA announced its participation in the COVID-19 Diagnostics Evidence Accelerator, a collaborative project to advance the development of diagnostics. The project is organized by the Reagan-Udall Foundation for the FDA in collaboration with Friends of Cancer Research.

- On June 17, the FDA issued a press release about warning letters to three companies for marketing adulterated and misbranded COVID-19 antibody tests. The warning letters are the first set of letters the agency has issued for marketing adulterated or misbranded COVID-19 test kits.

- On June 16, the FDA revoked the EUA of the Chembio Diagnostic System, Inc. DPP COVID-19 IgM/IgG System, a SARS-CoV-2 antibody test, due to performance concerns with the accuracy of the test. Antibody tests, a type of serological test, can help provide information on a person’s and population’s exposure to COVID-19.

- On June 16, the FDA took a meaningful step forward in getting more tests to more Americans more quickly and making that process even easier for developers by posting template updates regarding the validation of molecular diagnostic tests for developers that intend their assay to be used for pooling patient samples or for screening asymptomatic individuals not suspected of having COVID-19.

- On June 15, the FDA revoked the EUA that allowed for chloroquine phosphate and hydroxychloroquine sulfate donated to the Strategic National Stockpile to be used to treat certain hospitalized patients with COVID-19 when a clinical trial was unavailable, or participation in a clinical trial was not feasible. Based on its ongoing analysis of the EUA and emerging scientific data, the FDA determined that chloroquine and hydroxychloroquine are unlikely to be effective in treating COVID-19 for the authorized uses in the EUA. Additionally, in light of ongoing serious cardiac adverse events and other potential serious side effects, the known and potential benefits of chloroquine and hydroxychloroquine no longer outweigh the known and potential risks for the authorized use.

- On June 15, the FDA warned health care providers about a newly discovered potential drug interaction related to the investigational antiviral drug remdesivir, which has received emergency use authorization for the treatment of hospitalized COVID-19 patients with severe disease.

- On June 11, the FDA issued an EUA to Illumina, Inc., for the first COVID-19 diagnostic test utilizing next-generation sequence technology. The FDA authorized the Illumina COVIDSeq Test for the qualitative detection of SARS-CoV-2 RNA from respiratory specimens collected from individuals suspected of a COVID-19 infection by their health care provider.

- On June 10, the FDA and NIH provided updates to the CURE ID crowd-sourcing app to make it easier for health care providers to share — via mobile device or website — their experiences treating COVID-19 patients who are unable to be enrolled in a clinical trial.
CURE ID’s web-based repository lets providers share experiences with novel uses of existing drugs in treating difficult-to-treat infectious diseases.

On June 7, in response to public health and safety concerns about the appropriateness of decontaminating certain respirators, the agency reissued certain EUAs to specify which respirators are appropriate for decontamination by the authorized decontamination systems.

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 115 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 more than 50 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 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.