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**
- During the COVID-19 pandemic, the FDA has worked with more than 400 test developers who have already submitted or said they will be submitting emergency use authorization (EUA) requests to the FDA for tests that detect the virus or antibodies to the virus.
- To date, the FDA has authorized 120 tests under EUAs, which include 104 molecular tests, 15 antibody tests and 1 antigen test.

**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.
- Authorized EUAs and issued 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.
- Signed a MOU with USDA as another preparedness measure to help prevent interruptions at FDA-regulated food facilities, including fruit and vegetable processing during the national emergency.

**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 65 health fraud warning letters to sellers of unapproved products with bogus COVID-19 claims, including homeopathic drug products, cannabidiol products, nasal sprays, colloidal silver products, herbal products, chlorine dioxide products, and others.
- Continue to aggressively monitor the market for and take appropriate action against individuals and companies selling products with fraudulent claims to diagnose, treat, prevent, or cure COVID-19.
Recent Actions

- On June 4, the FDA posted test performance data from four more antibody test kits on open.fda.gov from its independent performance validation study effort with the National Institutes of Health’s National Cancer Institute. These results are among the first to come from a collaborative effort by the FDA, NIH, CDC and BARDA.

- On June 3, the FDA announced a new Testing Supply Substitution Strategies web resource for labs performing COVID-19 tests that are authorized. This resource includes information on validated supply alternatives for labs to continue performing testing when there is a supply issue with some components of a test. To use this resource, download the file (PPT – 1.5MB), open it, and click Slide Show > From Beginning.

- On June 3, the FDA published a new web page about the FDA Center for Drug Evaluation and Research’s work to protect public health during the COVID-19 public health emergency. Efforts include: Making safe and effective drugs to treat COVID-19 patients available as soon as possible; Monitoring the nation’s supply of medicines and taking action to mitigate or prevent drug shortages; and Working to help ensure the health of all patients.

- On June 2, the FDA testified before the U.S. Senate Committee on Finance on COVID-19 and Beyond: Oversight of the FDA’s Foreign Drug Manufacturing Inspection Process. Read the FDA testimony.

- In a June 2 FDA Voices, titled Pandemic Challenges Highlight the Importance of the New Era of Smarter Food Safety, the authors explain that in March, the FDA was days away from announcing the release of the New Era of Smarter Food Safety Blueprint when the FDA’s focus turned to the COVID-19 pandemic. The FDA will release the blueprint in the coming weeks, outlining plans to create a more digital and traceable food system. The pandemic has illustrated the need for measures outlined in the blueprint.

- On June 2, FDA created a new web page, Coronavirus Disease 2019 (COVID-19) Resources for Health Professionals, to provide quick and easy access to FDA information. FDA recognizes the vital role of health professionals in the fight against COVID-19.

- On June 1, the FDA took additional action to help ensure widespread access to hand sanitizers during the COVID-19 public health emergency. The agency has updated guidances to provide additional clarification on the manufacturing and compounding of certain alcohol-based hand sanitizer products to help ensure that harmful levels of impurities are not present in ethanol used in hand sanitizer.

- On May 29, the FDA took steps to further support the development of COVID-19 tests for at-home self-collection by providing on its website a template that may be used to facilitate submission of requests for EUAs for at-home sample collection kits. As explained in FDA’s guidance, Policy for COVID-19 Tests During the Public Health Emergency (Revised), this template reflects the FDA’s current thinking on the data and information that developers should submit to facilitate the EUA process.
• On May 29, the FDA issued a Consumer Update, Understanding the Regulatory Terminology of Potential Preventions and Treatments for COVID-19.

• In a May 29 FDA Voices, titled Bringing a Cancer Doctor’s Perspective to FDA’s Response to the COVID-19 Pandemic, FDA Commissioner Stephen M. Hahn, M.D. offers insight into the FDA’s role in facilitating treatment options during the public health response to the COVID-19 pandemic.

• On May 27, the FDA took a new step to support the agency’s evaluation of diagnostic tests for COVID-19, by providing a SARS-CoV-2 reference panel. Reference panels are an additional step to help ensure the quality of the tests, validation of new assays, test calibration, and monitoring of assay performance.

**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 healthcare providers. The FDA has issued more than 110 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.

• 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.

• 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.

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

• If you have fully recovered from COVID-19, you may be able to help patients currently fighting the infection by [donating your plasma](http://www.fda.gov).

• For updated fact sheets for the Emergency Use Authorizations the FDA has issued, see [therapeutics](http://www.fda.gov) and [devices](http://www.fda.gov).

• For updated information about COVID-19 clinical trials underway in the U.S. and internationally, see [clinicaltrials.gov](http://www.fda.gov).