U.S. FOOD & DRUG ADMINISTRATION

FDA COVID-19 Response

At-A-Glance Summary *as of May 21, 2020*

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 105 tests under EUAs, which include 92 molecular tests, 12 antibody tests and 1 antigen test.

Accelerating Availability of Medical Equipment and Products for Treatment

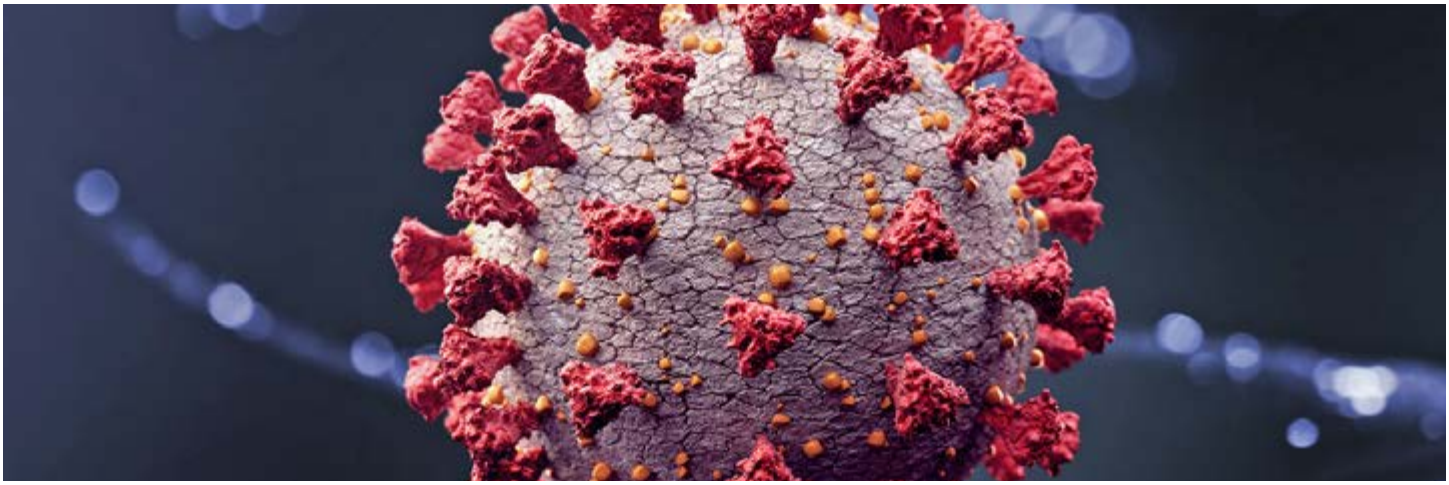
- Added more than 60 ventilators and accessories for emergency use to the ventilator EUA and **issued EUAs** for other equipment to treat patients during COVID-19.
- Authorized EUAs and issued policies to help increase the availability of personal protective equipment, such as respirators, gowns, surgical 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 56 **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 May 21, the **FDA posted a list of antibody tests** that are being removed from the "notification list" of tests being offered under the **Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency**. Antibody tests on this new removal list include those voluntarily withdrawn from the notification list by the test's commercial manufacturer and those for which there is not a pending EUA request or issued EUA. The FDA expects that the tests on the removal list will not be marketed or distributed. Antibody tests offered by commercial manufacturers as outlined under the policy, which was issued on March 16 and updated on May 4, continue to be located on the notification list pending review of their EUA request.
- On May 19, the **U.S. Department of Agriculture and the FDA announced a Memorandum of Understanding (MOU)** to help prevent interruptions at FDA-regulated food facilities, including fruit and vegetable processing. As the COVID-19 pandemic response continues, the USDA and the FDA have been working around the clock on many fronts to support the U.S. food and agriculture sector so that Americans continue to have access to a safe and robust food supply.
- On May 19, the **FDA outlined collaborative efforts** to promote rigorous analyses of real-world data to inform pandemic response. Evaluation of real-world data has the potential to provide a wealth of rapid, actionable information to better understand disease symptoms, describe and measure immunity and understand available medical product supplies to help mitigate potential shortages. These data can also inform ongoing work to evaluate potential therapies, vaccines or diagnostics for COVID-19. This work includes a recent agreement with Aetion to collaborate on advanced analytical techniques to answer urgent COVID-19 research questions. The FDA is also a proud participant in the COVID-19 Evidence Accelerator, organized by the Reagan-Udall Foundation for the FDA in collaboration with Friends of Cancer Research.
- On May 18, the FDA issued a new FDA Voices titled, **COVID-19 Supply Chain Update: Importation of Vital Food and Medical Products**. It provides details on the FDA's work to ensure the safety and security of the U.S. supply of food and medical products. Many of the medical products our health care workers and hospitals need to battle COVID-19 come from overseas, which makes the **FDA's Office of Regulatory Affairs** work imperative to ensure legitimate products are moving as quickly as possible through the ports of entry. At the same time, ORA imports staff also screens for, and blocks the entry of, unproven products that falsely claim to prevent, diagnose, treat or cure COVID-19.
- On May 15, the FDA issued **an EUA for the Everlywell COVID-19 Test Home Collection Kit**, the first standalone at-home sample collection kit that can be used with certain authorized tests. The kit is authorized to be used by individuals at home who have been screened using an online questionnaire that is reviewed by a health care provider. This allows an individual to self-collect a nasal sample at home using Everlywell's authorized kit.

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 about 100 **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**. If you think you have COVID-19 and need a test, contact your health care provider immediately.
- The FDA has issued more than 45 **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**.
- 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**.