U.S. FOOD & DRUG ADMINISTRATION

FDA COVID-19 Response

At-A-Glance Summary *as of July 1, 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

- To date, the FDA has authorized 161 tests under **emergency use authorizations (EUA)**, which include 135 molecular tests, 25 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.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

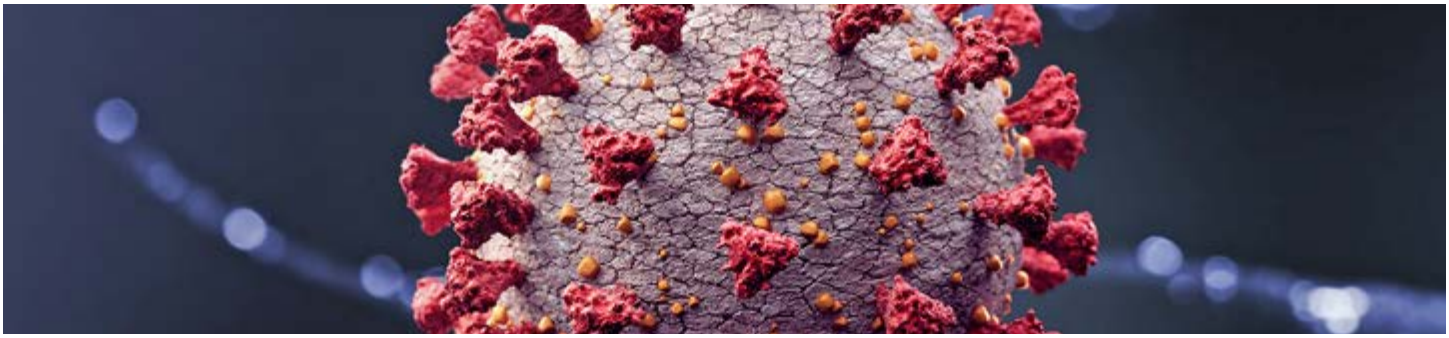
- Added more than 85 **ventilators** and accessories for emergency use to the ventilator EUA and **issued EUAs** for other equipment to treat patients during COVID-19.
- Issued EUAs and policies to help increase the availability of personal protective equipment, such as respirators, gowns, surgical masks, 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

- 193 unapproved, uncleared, or unauthorized products that claimed to diagnose, treat, prevent, or cure COVID-19 have been removed from online marketplaces and the FDA has issued 260 abuse complaints to domain name registrars, of which 189 websites have been taken offline.
- Issued 82 **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.



Recent Actions

- To help facilitate the timely development of safe and effective vaccines to prevent COVID-19, on June 30, the FDA **provided guidance with recommendations** for those developing COVID-19 vaccines for the ultimate purpose of licensure. The guidance, which reflects advice the FDA has been providing over the past several months to companies, researchers, and others, describes the agency's current recommendations regarding the data needed to facilitate the manufacturing, clinical development, and approval of a COVID-19 vaccine.
- On June 30, FDA Commissioner Stephen M. Hahn, M.D., testified at the U.S. Senate Committee on Health, Education, Labor and Pensions hearing, **COVID-19: Update on Progress Toward Safely Getting Back to Work and Back to School**.
- On June 25, in a new FDA Voices, titled **Partnering with the European Union and Global Regulators on COVID-19**, agency leaders explain how the FDA and the European Union, including the latter's European Medicines Agency, have long leveraged each other's expertise and experience. This work has paved the way for critical collaborations on scientific and regulatory fronts as part of the response to the global COVID-19 public health crisis.
- On June 24, U.S. Secretary of Agriculture Sonny Perdue and FDA Commissioner Stephen M. Hahn, M.D., issued a **joint USDA-FDA statement** regarding food export restrictions pertaining to COVID-19.
- On June 23 the first **"FDA Insight" podcast** was launched, featuring FDA Commissioner Stephen M. Hahn, M.D., and FDA Deputy Commissioner for Medical and Scientific Affairs Anand Shah, M.D., discussing FDA's COVID-19 efforts, including the drug development process for a COVID-19 treatment. **The second episode** aired June 30 and focused on COVID-19 testing.
- In a June 23 FDA Voices, titled **FDA maintains the pace of meeting its goals on applications for medical products during the pandemic**, FDA Commissioner Stephen M. Hahn, M.D., explains that one of the challenges facing the FDA during the COVID-19 pandemic is how to ensure the timely reviews of medical product applications despite a surge in volume of work and practical constraints that may impact our ability to conduct on-site inspections. The FDA has maintained the same pace of meeting its goals on review of applications for medical products during the pandemic that it has maintained in recent years.
- On June 23, the FDA announced the partnership with the Critical Path Institute and the National Institutes of Health's National Center for Advancing Translational Sciences on the **CURE Drug Repurposing Collaboratory**, a forum for the exchange of clinical practice data to inform potential new uses of existing drugs for areas of high unmet medical need, advancing research in these areas.
- A June 23 Consumer Update, titled **Getting Smarter about Food Safety: The Pandemic and Lessons Learned**, explains that throughout the COVID-19 pandemic, the experts at the FDA **have learned valuable lessons** that will help shape our work to create a more digital and transparent, as well as safer, food system.
- FDA Commissioner Stephen M. Hahn testified at the June 23 U.S. House of Representatives Committee on Energy and Commerce hearing entitled **Oversight of the Trump Administration's Response to the COVID-19 Pandemic**.
- On June 19, the FDA issued a **Letter to Clinical Laboratory Staff and Health Care Providers** recommending that they stop using COVID-19 antibody tests that are listed on the FDA's **"removed" test**

list. The "removed" test list includes tests for which significant clinical performance problems were identified that cannot be or have not been addressed by the commercial manufacturer in a timely manner, tests for which an EUA request has not been submitted by a commercial manufacturer of the serology test within a reasonable period of time as outlined in the FDA's guidance, and tests voluntarily withdrawn by the respective commercial manufacturers.

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 120 **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 week-day.
- **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 55 **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.