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 testing, therapeutics, and 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 of Accurate and Reliable Tests
- Worked with more than 385 test developers who have said they will be submitting Emergency Use Authorizations (EUAs) for tests that detect the virus.
- Issued 63 individual EUAs for test kit manufacturers and laboratories. In addition, 25 authorized tests have been added to the EUA letter of authorization for high complexity molecular-based laboratory developed tests (LDTs).
- Been notified that more than 245 laboratories have begun testing under the policies set forth in our Policy for Diagnostic Tests for Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency Guidance.
- Among the individual EUAs are 12 serology tests that have been authorized to date.

Accelerating Availability of Medical Equipment and Products for Treatment
- Authorized more than 50 ventilators and accessories for emergency use 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 nearly 80 COVID-19 drug development programs that are in progress, with multiple candidates under investigation that may be able to effectively treat patients before a vaccine is developed.

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.
- Worked with federal partners to ensure the delivery of 3.1 million cloth face coverings to over 1,000 grocery store chains and small grocery stores for employee use.

Halting Individuals or Companies Selling Products with Fraudulent Claims Related to COVID-19
- Issued hundreds of abuse complaints resulting in the marketplaces removing listings for 260 products that claimed to diagnose, treat, or even cure COVID-19.
- Issued 42 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 action against individuals or companies selling products with fraudulent claims to mitigate, prevent, treat, diagnose or cure COVID-19.
Recent Actions:

- On May 7, the FDA provided an update on the agency’s efforts to combat the extremely concerning actions by companies and individuals that are exploiting or taking advantage of widespread fear among consumers during the COVID-19 pandemic. In response to scammers on the internet selling unproven medical products, the FDA continues to seek out and stop those selling unapproved products that fraudulently claim to mitigate, prevent, treat, diagnose or cure COVID-19.

- On May 6, the FDA issued an immediately in effect guidance Notifying the Center for Devices and Radiological Health of a Permanent Discontinuance or Interruption in Manufacturing of a Device Under Section 506J of the Federal Food, Drug, and Cosmetic Act During the COVID-19 Public Health Emergency. Among other things, this guidance is intended to assist manufacturers in providing timely, informative notifications about changes in the production of certain medical device products that will help the agency prevent or mitigate shortages of such devices during the COVID-19 public health emergency. On May 11, the FDA will host a webinar for medical device manufacturers and others interested in learning more about the guidance.

- On May 4, the FDA announced important updates to the March 16, 2020 policy on commercial manufacturers’ serology—or antibody—tests for COVID-19. Under the new policy, the FDA expects commercial manufacturers to submit Emergency Use Authorization (EUA) requests, including their validation data, within 10 days of the updated policy publication date, or the date they notify FDA of their test validation, whichever is later.

- On May 1, the FDA issued an emergency use authorization for the investigational antiviral drug remdesivir for the treatment of suspected or laboratory-confirmed COVID-19 in adults and children hospitalized with severe disease. While there is limited information known about the safety and effectiveness of using remdesivir to treat people in the hospital with COVID-19, the investigational drug was shown in a clinical trial to shorten the time to recovery in some patients.

- On May 1, Judge Kathleen M. Williams, in the U.S. District Court for the Southern District of Florida, granted a preliminary injunction against Genesis II Church of Health and Healing of Bradenton, FL, and four of its principals for distributing Miracle Mineral Solution with claims on the defendants’ websites stating the product is intended to cure, mitigate, treat, or prevent COVID-19, in addition to other diseases such as autism, Alzheimer’s, brain cancer, HIV/AIDS, and multiple sclerosis.
RESOURCES

• The FDA has made a wide range of 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.

• The FDA has issued more than 40 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 others.

• 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.