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**
- As of Oct. 22, 2020, 283 tests are authorized by the FDA under Emergency Use Authorizations (EUAs); these include 221 molecular tests, 56 antibody tests and 6 antigen tests.
- 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**
- The FDA added more than 100 ventilators and accessories for emergency use to the ventilator EUA and issued EUAs for other equipment to treat patients during COVID-19.
- The agency has issued EUAs and policies to help increase the availability of personal protective equipment, such as respirators, gowns, surgical masks, and more.
- There are now more than 550 drug development programs in planning stages and as of the end of September, the agency has reviewed more than 350 trials of potential therapies for COVID-19. Five EUAs to treat COVID-19 and serious conditions caused by COVID-19 are currently authorized for emergency use. One treatment is currently approved by the FDA for use in COVID-19.

**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**
- As of Sept. 23, 2020, the FDA has identified more than 1127 fraudulent and unproven medical products related to COVID-19.
- To proactively identify and neutralize threats to consumers, the FDA launched Operation Quack Hack in March 2020. The Operation Quack Hack team has reviewed thousands of websites, social media posts, and online marketplace listings, resulting in over 119 warning letters to sellers, more than 230 reports sent to online marketplaces, and more than 272 abuse complaints sent to domain registrars to date.
Recent Actions

- On Oct. 22, the FDA approved the antiviral drug Veklury (remdesivir) for use in adult and pediatric patients 12 years of age and older and weighing at least 40 kilograms (about 88 pounds) for the treatment of COVID-19 requiring hospitalization. Veklury should only be administered in a hospital or in a health care setting capable of providing acute care comparable to inpatient hospital care.

- On Oct. 22, the FDA Vaccines and Related Biological Products Advisory Committee (VRBPAC) met to discuss, in general, the development, authorization and/or licensure of vaccines to prevent COVID-19.

- On Oct. 21, the FDA held another session in the Virtual Town Hall Series - Coronavirus (COVID-19) Test Development and Validation to help answer technical questions about the development and validation of tests for SARS-CoV-2.

- In an Oct. 20 FDA Voices, entitled the FDA’s Vaccines and Related Biological Products Advisory Committee and its Role in Advising the Agency on COVID-19 Vaccines, Peter Marks, M.D., Ph.D., highlights that being transparent about the data that the FDA will evaluate in support of the safety and effectiveness of these vaccines and discussing this data with members of the VRBPAC in a public forum is critical to build trust and confidence in their use by the public.

- An Oct. 20 Consumer Update, entitled Advisory Committees Give FDA Critical Advice and the Public a Voice, provides a description of how the FDA relies on our many advisory committees to help us make sound decisions based on the best science available. This process is transparent and independent, and open to the public.

- On Oct. 15, the FDA reissued an EUA for certain filtering face-piece respirators that are manufactured in China and are not approved by the Centers for Disease Control and Prevention’s National Institute for Occupational Safety and Health.

- On Oct. 13, the FDA held another session in the Webinar Series - Respirators and Other Personal Protective Equipment (PPE) for Health Care Personnel Use During the COVID-19 Pandemic.

- On Oct. 7, the FDA issued a warning letter to Battelle Memorial Institute for failure to comply with regulatory requirements for medical device reporting as specified in the EUA for the Battelle Critical Care Decontamination System.

- On Oct. 6, the FDA issued guidance with recommendations for vaccine sponsors regarding the scientific data and information that would support issuance of an EUA for investigational vaccines intended to prevent COVID-19.

- On Oct. 3, the FDA announced the awarding of a new research contract to the Stanford University School of Medicine to perform an in-depth analysis of tissue samples to learn more about how SARS-CoV-2—the virus that causes COVID-19—affects different systems in the body, and identify immune correlates. This regulatory science project could potentially help inform development and evaluation of medical countermeasures for COVID-19.

- On Oct. 2, the FDA posted a transcript and video of FDA Commissioner Stephen M. Hahn, M.D.’s remarks to the National Consumers League earlier about the vaccine review process.

- In a Sept. 29 FDA Voices, entitled A Closer Look at the FDA’s Center for Devices and Radiological Health’s Unprecedented Efforts in the COVID-19 Response, FDA Commissioner Stephen M. Hahn, M.D. highlights how in just a few short months, the agency’s Center for Devices and Radiological Health’s response to the pandemic has been unprecedented in terms of volume, speed and agility – spanning multiple areas, including: regulatory flexibility, EUAs for devices, shortage mitigation activities, Public Health Service Corps deployment and extensive engagement with stakeholders. The FDA also posted an infographic that provides a visualization of data associated with CDRH’s response.
RESOURCES

- The FDA has made information available to the public in both English and Spanish on our COVID-19 website in addition to multilingual COVID-19 resources. 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 200 news announcements on COVID-19 topics since January. In late March, the agency began to issue "Daily Round-ups" to capture its ongoing response efforts each weekday.

- The FDA is warning consumers and health care professionals that the FDA continues to find hand sanitizer products that are labeled as containing ethanol (also known as ethyl alcohol) but have tested positive for methanol or 1-propanol contamination. Methanol and 1-propanol are not acceptable ingredients for hand sanitizer products and can be life-threatening when ingested. The FDA also continues to find hand sanitizers that are subpotent, meaning the product contains less than the required amount of ethyl alcohol, isopropyl alcohol or benzalkonium chloride. Before buying or using hand sanitizer, the FDA recommends checking this list of hand sanitizers consumers should not use. Bookmark www.fda.gov/handsanitizerlist for the latest, and use our step-by-step search guide to find out if your product is on the list.

- 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 60 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.