U.S. FOOD & DRUG ADMINISTRATION

FDA COVID-19 Response

At-A-Glance Summary *as of July 19, 2021*

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, vaccines 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 to Accurate and Reliable Tests

- As of July 16, 396 tests and sample collection devices are authorized by the FDA under **Emergency Use Authorizations (EUAs)**; these include 281 molecular tests and sample collection devices, 85 antibody and other immune response tests and 30 antigen tests. There are 52 molecular authorizations and one antibody authorization that can be used with home-collected samples. There is one molecular prescription at-home test, three antigen prescription at-home tests, five antigen over-the-counter (OTC) at-home tests, and two molecular OTC at-home tests.
- The FDA has authorized 11 antigen tests and seven molecular tests for serial screening programs. The FDA has also authorized 576 revisions to EUA authorizations.
- 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

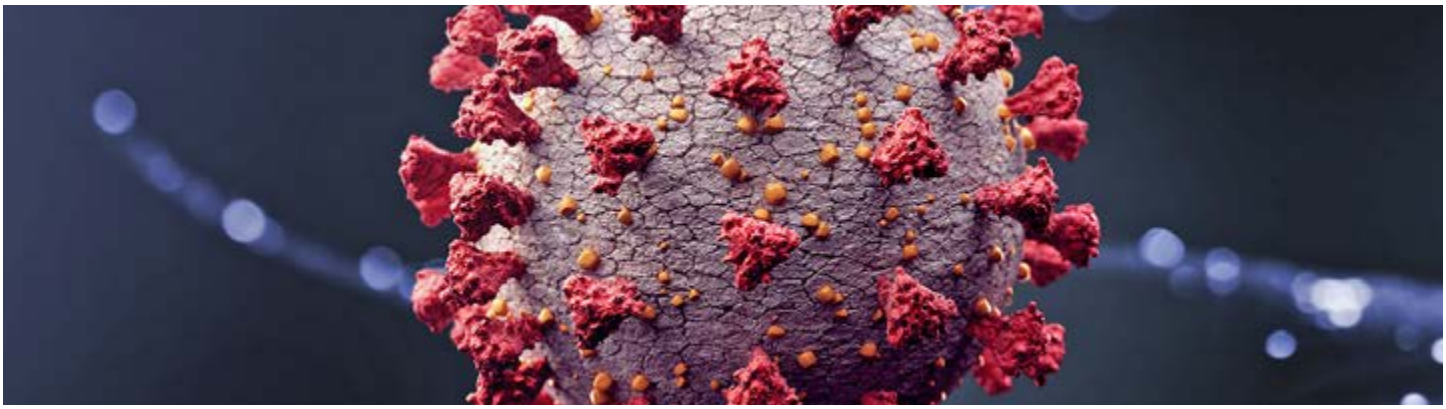
- The FDA added more than 115 **ventilators** and accessories for emergency use to the ventilator EUA and **issued EUAs** for other equipment to treat patients during COVID-19.
- The agency has issued EUAs and policies to help increase the availability of personal protective equipment, such as respirators, gowns, surgical masks, and more.
- **There are now more than 630 drug development programs in planning stages and** 11 EUAs for COVID-19 treatments are currently authorized for emergency use. One treatment is currently approved by the FDA for use in COVID-19.

Facilitating the Development of COVID-19 Vaccines

- There are **three COVID-19 vaccines authorized for emergency use**.

Halting the Sale of Products with Fraudulent Claims Related to COVID-19

- As of July 15, the FDA has received more than 1486 reports of fraudulent 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 more than **180 warning letters** to sellers, more than 312 reports sent to online marketplaces, and more than 299 abuse complaints sent to domain registrars to date.



Recent Actions

- On July 16, the FDA noted that **Pfizer had announced** that the FDA has formally accepted the company's Biologics License Application (BLA) requesting licensure (approval) of the Pfizer-BioNTech COVID-19 Vaccine for the prevention of COVID-19 in individuals 16 years of age and older and has granted the application priority review. Currently, the vaccine is authorized for emergency use to prevent COVID-19 in individuals ages 12 and older.

  The Prescription Drug User Fee (PDUFA) Goal Date of January 2022 reflects the PDUFA deadline for Priority Review and does not mean approval will not happen before that time. Quite to the contrary, the review of this BLA has been ongoing, is among the highest priorities of the agency, and the agency intends to complete the review far in advance of the PDUFA Goal Date.

- On July 15, the announced that the agency has created **new product codes for certain medical devices authorized for emergency use** under EUAs. An applicable product code has been assigned to each authorized device category. The product codes are listed in the tables for each category of devices that have EUAs.

- On July 13, the FDA Center for Drug Evaluation and Research published a **From Our Perspective** on the FDA's Clinical Methodologies Group's recent HHS award, which will fund expansion of the **CURE ID platform**. The platform will allow automated anonymized data collection from electronic health records and clinical disease registries for COVID-19 and eventually other difficult-to-treat infectious diseases.

- On July 13, the FDA authorized the use, under the EUA for the **Janssen COVID-19 vaccine**, of an additional batch of vaccine drug substance manufactured at the Emergent facility. To date, a total of five batches of Janssen drug substance that were manufactured at the Emergent facility have been authorized. The FDA conducted a thorough review of facility records and the results of quality testing performed by the manufacturer. Based on this review and considering the current COVID-19 public health emergency, the FDA has concluded that these batches are suitable for use. While the FDA is not yet ready to include the Emergent BioSolutions plant in the Janssen EUA as an authorized manufacturing facility, the agency continues to work through issues there with Janssen and Emergent BioSolutions management.

- In a July 13 **FDA Voices**, agency leaders explain the progress being made in working toward the goals outlined in the New Era of Smarter Food Safety Blueprint, even in the midst of a pandemic.

- On July 13, the **FDA hosted a webinar** to share information and answer questions about revocation of EUAs for non-NIOSH-approved respirators and decontamination systems. Specifically, the agency presented information about the June 30, 2021, **Update: FDA No Longer Authorizes Use of Non-NIOSH-Approved or Decontaminated Disposable Respirators - Letter to Health Care Personnel and Facilities**.

- On July 12, revisions were made to the Fact Sheet for Healthcare Providers Administering Vaccine and the Fact Sheet for Recipients and Caregivers for the Johnson & Johnson (Janssen) COVID-19 Vaccine to include information pertaining to an observed increased risk of Guillain-Barré Syndrome (GBS)

following vaccination. GBS is a neurological disorder in which the body's immune system damages nerve cells, causing muscle weakness, or in the most severe cases, paralysis. Based on an analysis of Vaccine Adverse Event Reporting (VAERS) data, there have been 100 preliminary reports of GBS following vaccination with the Janssen vaccine after approximately 12.5 million doses administered. Of these reports, 95 of them were serious and required hospitalization. There was one reported death. Each year in the U.S., an estimated 3,000 to 6,000 people develop GBS. Most people fully recover from the disorder.

- A July 12 **FDA Voices** explains the FDA **Regulatory Education for Industry (REdI) Annual Conference**, being held July 19 – 23, to provide an overview of the agency's regulatory operations during COVID-19.
- On July 8, the FDA hosted a Grand Rounds lecture about regulatory science research funded by the FDA: **SARS-CoV-2 Host-Pathogen Interaction, Vaccines & Variants of Concern**. This lecture discussed work from two FDA Medical Countermeasures Initiative (MCMi) projects analyzing coronavirus samples to help inform development of COVID-19 medical countermeasures, conducted by **Public Health England** and the **University of Liverpool**. A **webcast recording** is available.
- On July 8, a joint **CDC and FDA statement** on COVID-19 vaccine boosters was issued. Americans who have been fully vaccinated do not need a booster shot at this time. FDA, CDC, and NIH are engaged in a science-based, rigorous process to consider whether or when a booster might be necessary.
- On June 29, Acting FDA Commissioner Janet Woodcock, M.D. and the Director of FDA's Center for Biologics Evaluation and Research, Peter Marks, M.D., Ph.D., discussed the updates on myocarditis and pericarditis following vaccination with the Pfizer-BioNTech or Moderna COVID-19 Vaccines during a stakeholder call with Vaccinate Your Family and pediatric and healthcare groups. To watch and listen to the call, visit **FDA's YouTube channel**.
- On June 28, the FDA posted its **Report to Congress: Drug Shortages for Calendar Year 2020**, which includes a section on the agency's drug shortage efforts in response to COVID-19.
- On June 25, the FDA announced revisions to the patient and provider fact sheets for the **Moderna** and **Pfizer-BioNTech** COVID-19 vaccines regarding the suggested increased risks of myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the tissue surrounding the heart) following vaccination. For each vaccine, the Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) has been revised to include a warning about myocarditis and pericarditis and the Fact Sheet for Recipients and Caregivers has been revised to include information about myocarditis and pericarditis. This update follows an extensive review of information and the discussion by CDC's Advisory Committee on Immunization Practices.
- On June 25, the FDA issued a supplement to the 2015 safety communication on reprocessed flexible bronchoscopes, reminding health care facilities to follow manufacturer instructions for reprocessing and device maintenance, and providing a new recommendation for health care providers on single-use bronchoscopes. The goal of the recommendations is to reduce potential infection transmission between patients. This communication also includes updated information on medical device adverse event reports.
- On June 24, the **FDA issued an EUA** for the drug Actemra (tocilizumab) for the treatment of hospitalized adults and pediatric patients (2 years of age and older) who are receiving systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO). Actemra is not authorized for use in outpatients with COVID-19.
- On June 16, the FDA issued a **Drug Safety Communication** for hand sanitizers, warning that symptoms such as headache, nausea, and dizziness can occur after applying alcohol-based hand sanitizers to the skin and inhaling the vapors that linger. FDA reviewed case reports submitted to FDA and cases from calls to U.S. poison control centers of adverse events after applying alcohol-based hand sanitizers to the skin. While the majority of cases resulted in minor or minimal effects, some cases resulted in treatment by a health care professional. These reports have occurred after the start of the COVID-19 pandemic. Consumers should use hand sanitizer in a well-ventilated area.

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 325 **news announcements on COVID-19 topics** since January, 2020.
- **Educational Resources** provides links to FDA-produced COVID-19-related resources that help explain the agency's work.
- The FDA web page, **COVID-19 Vaccines**, provides updates and information about the agency's work to facilitate development of COVID-19 vaccines that meet FDA's rigorous scientific standards, and information about authorized vaccines, including fact sheets and FAQs. COVID-19 vaccine fact sheets for recipients are available in more than 25 languages.
- For information about the different types of tests and the steps involved in processing samples, see **Coronavirus Testing Basics** explainer. If you think you have COVID-19 and need a test, contact your health care provider immediately.
- The FDA has provided information on **COVID-19 treatment options**.
- 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.
- **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.
- The FDA has issued more than 75 **guidance documents** to provide updated policies, transparency, and regulatory flexibility to address the food supply, 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 information about **COVID-19 vaccination and the food and agriculture sector**.
- 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.