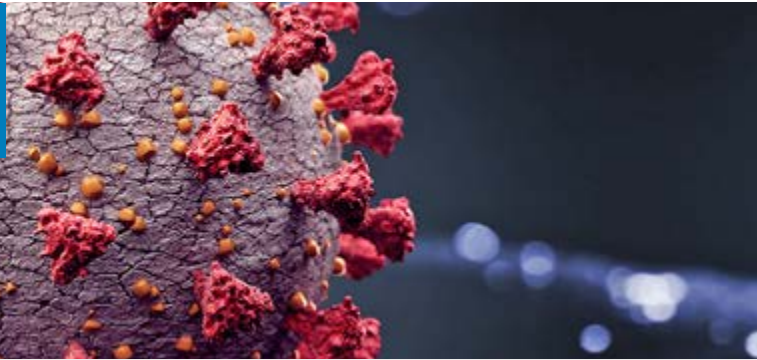


FDA COVID-19 Response

At-A-Glance Summary *as of September 25, 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

- As of Sept. 23, 2020, 252 tests are authorized by the FDA under **Emergency Use Authorizations (EUAs)**; these include 202 molecular tests, 46 antibody tests and 4 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 90 **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 590 drug development programs in planning stages and as of the end of**

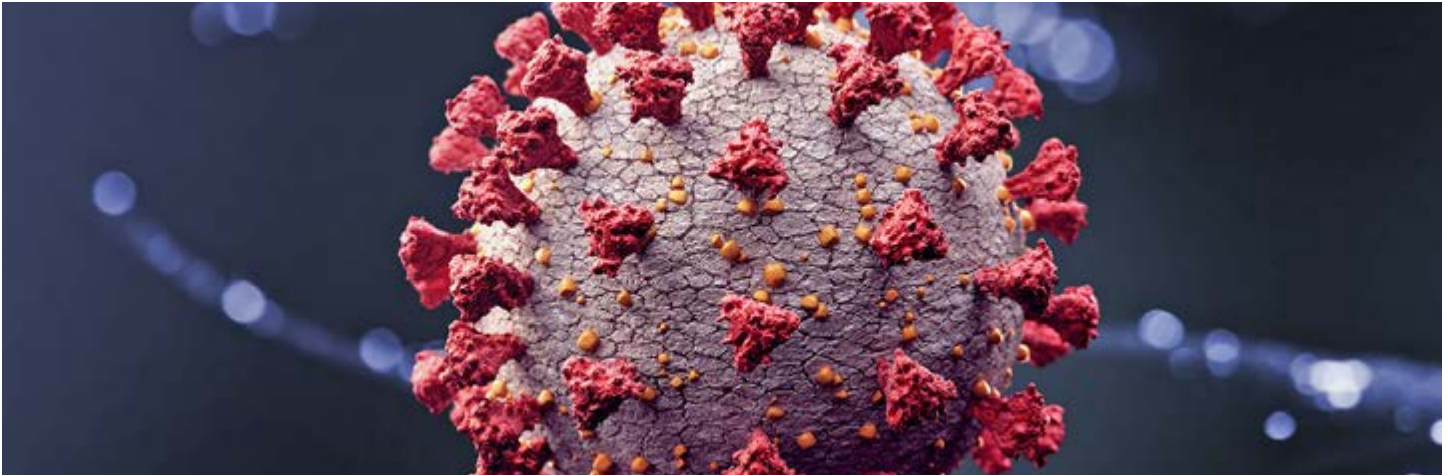
August, the agency has reviewed more than 310 trials of potential therapies for COVID-19. Five EUAs to treat COVID-19 and serious conditions caused by COVID-19 are currently authorized for emergency use.

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 1094 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 **114 warning letters** to sellers, more than 223 reports sent to online marketplaces, and more than 271 abuse complaints sent to domain registrars to date.



Recent Actions

- On Sept. 23, FDA Commissioner Stephen M. Hahn, M.D. testified before the U.S. Senate Committee on Health, Education, Labor and Pensions at a hearing entitled, **COVID-19: An Update on the Federal Response**.
- On Sept. 21, a new video entitled, **Beware of Fraudulent Coronavirus Tests, Vaccines and Treatments**, was posted to inform consumers that products that fraudulently claim to cure, treat, diagnose, or prevent COVID-19 haven't been evaluated by the FDA for safety and effectiveness for such use, and they might be dangerous to you and your family. There are currently no FDA-approved drugs or vaccines to treat or prevent COVID-19.
- On Sept. 16, the FDA held another session in the **Virtual Town Hall Series - Immediately in Effect Guidance on Coronavirus (COVID-19) Diagnostic Tests** to help answer technical questions about the development and validation of tests for SARS-CoV-2.
- On Sept. 15, **the FDA published comparative performance data for some authorized COVID-19 molecular diagnostic tests**. The tables show the Limit of Detection of more than 55 authorized molecular diagnostic COVID-19 tests against a standardized sample panel provided by the FDA. The agency provided these standardized samples, known as a reference panel, to test developers who are required to assess their test's performance against this panel (or other FDA-recommended reference materials) as a condition of their EUA.
- On Sept. 14, the FDA announced a new **research contract** awarded to the University of Liverpool and global partners to sequence and analyze samples from humans and animals to create profiles of various coronaviruses, including SARS-CoV-2, which causes COVID-19. The study will also examine in vitro coronavirus models, such as organs-on-chips. This regulatory science project, awarded in collaboration with the National Institutes of Health, National Institute of Allergy and Infectious Diseases (NIH/NIAID), will hopefully help inform development and evaluation of medical countermeasures for COVID-19.
- On Sept. 11, in a new FDA Voices entitled, **The FDA's Scientific and Regulatory Oversight of Vaccines is Vital to Public Health**, agency leaders explain that they are committed to making decisions that are guided by science and data regarding the authorization or approval of COVID-19 vaccines.
- In a Sept. 10 webcast, **Advancing the Science of Real-World Data to Address the COVID-19 Pandemic**, FDA Principal Deputy Commissioner Amy P. Abernethy, M.D., Ph.D., discusses the potential for diverse, real-world data sources such as electronic health records, insurance claims, patient registries and lab results to further inform our pandemic response.
- In a Sept. 8 Consumer Update entitled **FDA's Food and Cosmetics Information Center Answers Your Questions**, information is provided on how to get answers to questions about nutrition and the safety and labeling of food, dietary supplements and cosmetics.

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.