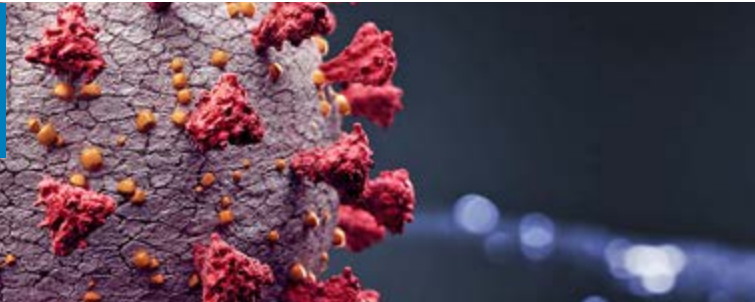


# FDA COVID-19 Response

## At-A-Glance Summary *as of February 28, 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, 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 Feb. 26, 332 tests and sample collection devices are authorized by the FDA under **Emergency Use Authorizations (EUAs)**; these include 248 molecular tests and sample collection devices, 70 antibody tests and 14 antigen tests. There are 37 molecular authorizations that can be used with home-collected samples. There is one molecular prescription at-home test, one antigen prescription at-home test, and one over-the-counter at-home 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

- 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.

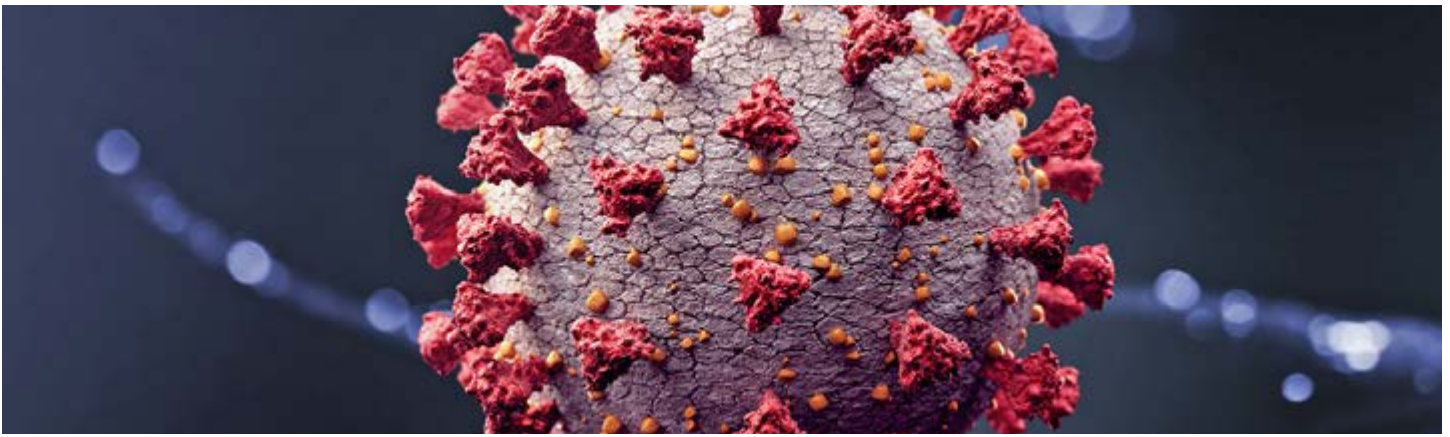
- There are now more than 600 drug development programs in planning stages and as of the end of January**, eight EUAs to treat COVID-19 and serious conditions caused by COVID-19 are currently authorized for emergency use. One treatment is currently approved by the FDA for use in COVID-19.

#### Facilitating the Development of COVID-19 Vaccines

- As of Feb. 27, there are **three COVID-19 vaccines authorized for emergency use**.

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

- As of Feb. 23, the FDA has received more than 1320 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 over **174 warning letters** to sellers, more than 297 reports sent to online marketplaces, and more than 277 abuse complaints sent to domain registrars to date.



## Recent Actions

- On Feb. 27, the **FDA issued an EUA for the third vaccine for the prevention of COVID-19 caused by SARS-CoV-2**. The EUA allows the Janssen COVID-19 Vaccine to be distributed in the U.S for use in individuals 18 years of age and older.
- On Feb. 26, the FDA held a meeting of its **Vaccines and Related Biological Products Advisory Committee** to discuss the request for an EUA for a COVID-19 vaccine from Janssen Biotech Inc.
- On Feb. 22, the **FDA issued guidances for medical product developers**, specifically covering vaccines, diagnostics and therapeutics products, to address the emergence and potential future emergence of variants of SARS-CoV-2, the virus that causes COVID-19.
- In a Feb. 19 **safety communication**, the FDA informed patients and health care providers that pulse oximeters have limitations and a risk of inaccuracy under certain circumstances.
- In a Feb. 18 statement, the U.S. Department of Agriculture, the FDA and the U.S. Centers for Disease Control and Prevention continued to **underscore that there is no credible evidence of food or food packaging associated with or as a likely source of viral transmission of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)**, the virus causing COVID-19.
- On Feb. 11, the FDA revised its guidance, **Investigational COVID-19 Convalescent Plasma and associated web page**, to reflect the reissued **Emergency Use Authorization for COVID-19 convalescent plasma** (issued Feb. 4). Specifically, the guidance provides recommendations to blood establishments on the collection and labeling of high titer COVID-19 convalescent plasma under the EUA. In addition, the revisions address when individuals who have received an investigational COVID-19 monoclonal therapy as a participant in a clinical trial, or received an authorized or licensed COVID-19 monoclonal antibody therapy, qualify as convalescent plasma donors.
- On Feb. 9, the FDA posted the webpage, **COVID-19 Vaccine Safety Surveillance**, which provides an overview of the active and passive systems used to monitor the safety of authorized COVID-19 vaccines.
- On Feb. 9, the FDA issued an **EUA** for a monoclonal antibody combination for the treatment of mild to moderate COVID-19 in adults and pediatric patients (12 years of age or older weighing at least 40 kilograms [about 88 pounds]) who test positive for SARS-CoV-2 and who are at high risk for progressing to severe COVID-19.
- In a Feb. 9 Letter to Health Care Providers on **Using Ventilator Splitters During the COVID-19 Pandemic**, the FDA provided up-to-date information concerning multiplexing ventilator tubing connectors, also known as ventilator splitters, in situations in which no alternatives for invasive ventilatory support are available.
- In a Feb. 4 alert, the FDA notified health care professionals and compounders of **potential risks** associated with compounding remdesivir drug products. The FDA cautions against compounding remdesivir drug products. The agency recommends health care providers utilize the FDA-approved drug for patients who are prescribed remdesivir. Compounded

drugs are not FDA-approved and are not evaluated by FDA for safety, effectiveness, or quality. Compounded drugs should only be used in patients whose medical needs cannot be met by an FDA-approved drug.

- On Jan. 27, the FDA added content to the question-and-answer appendix in its guidance titled, **Conduct of Clinical Trials of Medical Products During the COVID-19 Public Health Emergency**. The updated guidance includes a new question-and-answer regarding whether the FDA considers receipt of medical products authorized under an emergency use authorization for use in clinical care, such as a vaccine to prevent COVID-19, or a monoclonal antibody to treat COVID-19, to be receipt of “investigational” medical products. This information may be relevant when sponsors are considering eligibility criteria that exclude patients from enrolling in clinical trials if they have received certain medical products.
- On Jan. 26, the FDA placed all alcohol-based hand sanitizers from Mexico on a **country-wide import alert** to help prevent entry of products that appear to

be violative and potentially dangerous products from entering the U.S. until the agency is able to review the product’s safety. FDA analyses of alcohol-based hand sanitizers imported from Mexico found 84% of the samples analyzed by the agency from April through December 2020 were not in compliance with FDA’s regulations. The FDA, with its Latin American office, continues to work proactively with regulatory counterparts in Mexico.

- On Jan. 21, the FDA’s Office of Criminal Investigations recently investigated a case that has led to an arrest and the filing of a **criminal complaint** by the U.S. Department of Justice for introducing misbranded drugs into interstate commerce. The criminal investigation found that in a variety of online postings from as early as March 2020, the defendant, Johnny T. Stine, claimed to have a COVID-19 vaccine that he offered to inject in customers for \$400-\$1,000 each. Stine’s company, North Coast Biologics, had previously received a **warning letter** from the agency for promoting an unapproved COVID-19 vaccine product.

## 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 275 **news announcements on COVID-19 topics** since January, 2020.
- A new 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.
- 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](http://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.

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- [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 70 [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 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.