FDA COVID-19 Response  
At-A-Glance Summary as of April 14, 2020

Along with other federal, state, and local agencies and public health officials across the country, the U.S. Food and Drug Administration continues critical work to protect public health during the pandemic of COVID-19. The FDA regulates a wide range of products and plays an important role in the federal government’s response to this virus – protecting and advancing public health through transparency and regulatory flexibilities that address the pandemic. Major focus areas for the FDA’s response activities 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. We are also monitoring the human and animal food supply and taking swift action on fraudulent products.

### Informational Resources

The FDA has made a wide range of information regarding our activities available to the public on our COVID-19 website. This includes regularly updating our Frequently Asked Questions in both English and Spanish. It also includes issuing a number of Consumer Updates, MedWatch alerts, stakeholder updates, webinars, and other resources, including for patients 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.

### Major Activities

- **Medical Products and Equipment:** Since the beginning of the COVID-19 pandemic, the FDA has been working to facilitate the development and availability of medical countermeasures and equipment for use by patients, health care providers, and health care systems as quickly and safely as possible – from tests to respirators to blood products.
  - The FDA has worked with more than 300 test developers who have said they will be submitting Emergency Use Authorizations (EUAs) for tests that detect the virus, including many who have notified the agency that they have been developing serological tests that can help health care professionals identify individuals who have antibodies to the virus from a past or current COVID-19 infection and may have developed an immune response.
  - We regularly update this list of EUAs for devices, and have issued more than 30 EUAs authorizing over 70 products, spanning a range of items essential for the response.

- **Therapeutics:** Currently there are no FDA-approved products for COVID-19. The FDA has created a special expedited pathway for possible therapies, the Coronavirus Treatment Acceleration Program (CTAP). The FDA is using every available authority and regulatory flexibility to facilitate the development as quickly as possible of new products to treat patients, while at the same time examining safety and efficacy. We continue to support clinical trials that are testing new products for COVID-19 to gain valuable knowledge about their safety and effectiveness. See also clinicaltrials.gov, which lists more than 40 U.S. trials underway and more than 300 internationally. To date, the FDA is:
  - Reviewing 19 therapeutic agents in several active clinical trials, such as remdesivir, chloroquine and hydrochloroquine, sarilumab, convalescent plasma, hyperimmune globulin, and others.
Facilitating a multi-sector effort with several partners on convalescent plasma and is helping coordinate a study of hyperimmune globulin that the National Institute of Allergy and Infectious Diseases of the National Institutes of Health will conduct.

Planning to review another 26 agents that are currently in the pre-trial planning phase.

Monitoring medical supplies and working with federal and other partners to mitigate and prevent shortages.

The FDA has also issued an EUA that allows chloroquine and hydroxychloroquine donated to the Strategic National Stockpile to be used to treat certain patients with COVID-19.

**Vaccines:** At this time, there is no FDA-approved vaccine to prevent COVID-19. However, the FDA is working in partnership with vaccine developers and other researchers and manufacturers to help expedite the development and availability of vaccines to prevent COVID-19.

**Fraudulent Products:** The FDA continues to aggressively monitor the market for any individuals or companies promoting products with fraudulent claims that they can diagnose, mitigate, treat, cure or prevent COVID-19 as part of our ongoing efforts to protect the health of both people and animals during this pandemic. To date, the FDA has worked with online retailers to remove more than 90 fraudulent products with claims related to COVID-19, and has issued more than 30 health fraud warning letters to sellers of bogus COVID-19 products.

**Food Safety and Supply:** The FDA continues to monitor the food supply chain for both humans and animals, and is working with federal partners to address supply chain imbalances. While there are no widespread, nationwide shortages of food, there are local reports of shortages of certain products before stores are able to restock, in part because the demand for food at grocery stores significantly increased while demand for food in restaurants and hotels suddenly declined.

**Inspection and Importation:** The FDA continues to screen and monitor millions of domestic and international products in the supply chain, including with our federal partners, to help ensure COVID-19-related supplies coming into the U.S. get to where they need to go. This includes personal protective equipment and other medical devices, medicines, food, and other FDA-regulated products.

### Guidance Documents

The FDA has issued more than 30 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 include:

- **Diagnostics:** Guidelines to help expand the availability of certain validated tests for COVID-19.
- **Personal Protective Equipment (PPE):** Guidelines to help expand the availability of face masks used by the general public and health care professionals; surgical apparel; and surgeon and patient exam gloves.
- **Other Medical Devices:** Guidelines to help expand availability and access to critical medical products, such as ventilators, respirators, sterilizers, air purifiers, electronic thermometers, infusion pumps, medical oxygen and nitrogen, and others.
- **Investigational Treatment with Convalescent Plasma:** Guidance that provides recommendations for collecting and using convalescent plasma collected from patients who have recovered from COVID-19.
- **Conduct of Clinical Trials of Medical Products:** Guidance to assist sponsors in ensuring the safety of trial participants, maintaining compliance with good clinical practice, and minimizing risks to trial integrity during the COVID-19 public health emergency.
- **Hand Sanitizers:** Guidelines to help expand the supply of alcohol-based hand sanitizers produced by non-traditional manufacturers, such as compounding pharmacies, chemical companies, cosmetic companies, and distillers.
- **Food Safety and Supply:** Guidelines to provide flexibility, promote access to the food supply and reduce food waste, including to food producers when onsite audits are not feasible. For example, these guidances help enable restaurants to sell ingredients they are not using directly to consumers; ease menu labeling
requirements for chain restaurants and similar establishments as they switch to online and take-out orders; provide labeling flexibility for shell eggs sold to consumers and help enable certain egg producers to supply consumers to meet increased demand. The FDA has also provided information to help redirect unused food into the animal food supply when it can't be sold for people to eat.

- **Blood Supply**: Guidances to help address critical shortages in the blood supply through increased regulatory flexibility and expanding the eligible donor pool without compromising safety.

- **Telemedicine**: Guidances to help expand non-invasive remote monitoring of patients, and to provide veterinarians greater flexibility in treating animals through telemedicine.

- **Ongoing Programs**: Guidance to provide recommendations and flexibility for ongoing programs affected by the pandemic, such certain Risk Evaluation and Mitigation Strategy requirements.

| • Donate plasma: If you have fully recovered from COVID-19, you may be able to help patients currently fighting the infection by donating your plasma. |
| • Have medical supplies or equipment to donate? [Contact FEMA](#). Also, see additional FEMA information on [how to help](#). |
| • Want to sell medical supplies or equipment to the federal government? [Submit a price quote](#). |
| • Are you a private company wanting to produce a product related to the COVID-19 response? Email nbecn@max.gov. |
| • Are you a therapeutics sponsor wanting to submit a COVID-19 related proposal for review? See [this information](#) and [email](#). |
| • Are you a diagnostic test developer? See [FAQs](#). For additional information on completing the Emergency Use Authorization (EUA) template, submitting your Pre-EUA/EUA submission to FDA, or wish to consider use of an alternative specimen type, please contact the Division of Microbiology Devices at (301) 348-1778 or by [email](#). |
| • Are you a physician who would like to request an Emergency Investigational New Drug (EIND) for antiviral products? Please call 855-543-3784. |
| • Are you an importer with a shipment held up at a port of entry? Visit [Importing COVID-19 Supplies](#) for contact information and instructions, and to find the right office for your shipment. Make sure to provide your 11-digit customs entry number from your filer, the port of entry, and other shipment details, and that you have fulfilled the expectations in the EUA or guidance, as this will facilitate a more timely import process. Please use [this email](#) specific to personal protective equipment or test kits. For information on how to protect yourself from COVID-19 and what to do if you think you are sick, visit [http://www.coronavirus.gov](http://www.coronavirus.gov). |