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Medical Countermeasures Initiative Update

April 29, 2020



Coronavirus Disease 2019 (COVID-19) Update

FDA is an active partner in the coronavirus disease (COVID-19) response, working closely with our government and public health partners across the U.S. Department of Health and Human Services, and with our international counterparts. Actions by the FDA in our ongoing response to the COVID-19 pandemic since our last MCMi email update on April 22, 2020 include:

Coronavirus (COVID-19) Updates:

- April 28, 2020: [Daily Roundup](#): FDA actions on warning letters, video resources, and more
- More Daily Roundups (Monday - Friday) - Go to www.fda.gov/coronavirus, and select Daily Roundup (Type of Information) under [Latest COVID-19 Information From the FDA](#)
- April 27, 2020: [FDA Continues to Ensure Availability of Alcohol-Based Hand Sanitizer During the COVID-19 Pandemic, Addresses Safety Concerns](#)
- April 24, 2020: [FDA Reiterates Importance of Close Patient Supervision for 'Off-Label' Use of Antimalarial Drugs to Mitigate Known Risks, Including Heart Rhythm Problems](#)

- April 23, 2020: [Court Grants FDA's Request for Extension of Premarket Review Submission Deadline for Certain Tobacco Products Because of Impacts from COVID-19](#)
- *Also see [Emergency Use Authorization Updates below](#)*

COVID-19 Updates from FDA



FDA Provides Flexibility to the Food Industry to Support Food Supply Chain and Meet Consumer Demand During COVID-19

By: Susan Mayne, Ph.D., Director, Center for Food Safety and Applied Nutrition

During these turbulent times of the coronavirus (COVID-19) pandemic, our daily lives have changed, and consumers are understandably worried about what kind of, and how much food is available to feed themselves and their families. We have no nationwide shortages of food, thankfully, but we are seeing a shift in demand for certain foods and other goods that are leading, at times, to temporary shortages on supermarket shelves and other places where consumers shop.

The reasons for this shift are varied. Restaurants may be closed or limited to take-out or delivery only, schools and hotels are closed, and many of us are cooking more at home. This has resulted in an imbalance in the food supply chain with excess quantities of food typically supplied to restaurants and other food service establishments and increased demand for food supplied to supermarkets.

[Read more](#)

What is an EUA?

Emergency use authorizations (EUAs) are one of several tools FDA is using to help make important medical products available quickly during the COVID-19 pandemic. Learn more in this quick [new video](#).



Drug Safety Information: Hydroxychloroquine or Chloroquine for COVID-19

FDA Cautions Against Use Outside of the Hospital Setting or a Clinical Trial Due to Risk of Heart Rhythm Problems

FDA is concerned that hydroxychloroquine and chloroquine are being used inappropriately to treat non-hospitalized patients for coronavirus disease (COVID-19) or to prevent that disease. We authorized their temporary use only in hospitalized patients with COVID-19 when clinical trials are not available, or participation is not feasible, through an [Emergency Use Authorization \(EUA\)](#). These medicines have a number of side effects, including serious heart rhythm problems that can be life-threatening.

[Read more](#)

Related information:

- [Frequently Asked Questions on the EUA for Chloroquine Phosphate and Hydroxychloroquine Sulfate for Certain Hospitalized COVID-19 Patients \(PDF\)](#)
- [Coronavirus \(COVID-19\) Update: FDA Reiterates Importance of Close Patient Supervision for 'Off-Label' Use of Antimalarial Drugs to Mitigate Known Risks, Including Heart Rhythm Problems \(FDA news release\)](#)
- Fact sheets for patients and health care providers for this EUA are [now available](#) in Chinese, Korean, Spanish, and Vietnamese

Emergency Use Authorization (EUA) Updates

Diagnostic test EUAs

During the COVID-19 pandemic, FDA has worked with more than 380 test developers who have said they will be submitting EUA requests to FDA for tests that detect the virus.

To date, FDA has issued 50 individual EUAs for [test kit manufacturers and laboratories](#), including 8 serology tests. In addition, 22 authorized tests have been added to the EUA [letter of authorization \(PDF\)](#) for high complexity molecular-based LDTs.



FDA has been notified that more than 230 laboratories have begun testing under the policies set forth in our [Policy for Diagnostic Tests for Coronavirus Disease-2019 during the Public Health Emergency Guidance](#).

Reminder: FDA Sets up 24/7 Hotline to Help Labs with Diagnostic Test Issues

FDA's 24/7 hotline (1-888-INFO-FDA, choose option *) is available for labs to call regarding difficulties obtaining supplies for collecting patient samples for COVID-19 testing, including swabs and media needed for transport and conservation of the samples.

Virtual Town Hall Series - Immediately in Effect Guidance on Coronavirus (COVID-19) Diagnostic Tests

Today! April 29, 2020: FDA will host a virtual Town Hall for clinical laboratories and commercial manufacturers that are developing or have developed diagnostic tests for SAR-CoV-2, 12:15 p.m. - 1:15 p.m. ET.

New FAQs

This week, FDA posted [FAQs on the EUA for Face Masks \(Non-Surgical\)](#) and [FAQs on EUAs for Medical Devices During the COVID-19 Pandemic](#) - For more FAQs, see: [Coronavirus Disease 2019 \(COVID-19\) Frequently Asked Questions](#)

Related links:

- [FAQs on Diagnostic Testing for SARS-CoV-2](#) (frequently updated)
- [Emergency Use Authorizations \(Devices\)](#)
- [FDA Combating COVID-19 with Medical Devices \(PDF\)](#)
- [Information for Laboratories Implementing IVD Tests Under EUA](#)
- [Policy for Diagnostic Tests for Coronavirus Disease-2019 during the Public Health Emergency](#) (*updated March 16, 2020*)

Information for industry

- **April 30, 2020:** [SBIA Webinar: Conducting Clinical Trials During the COVID-19 Public Health Emergency](#) - 1:00 - 1:45 p.m. ET (Note: This webinar is now full, but the recording will be available shortly after the webinar concludes.)

- Reminder: [FDA-ARGOS SARS-CoV-2 reference grade sequence data now available \(April 1, 2020\)](#)
- The FDA is committed to providing timely recommendations, regulatory information, guidance, and technical assistance necessary to support rapid COVID-19 response efforts. FDA has issued 40 COVID-19-related guidances to date.

COVID-19-Related Guidance Documents

In case you missed it

- [How you can make a difference during the COVID-19 pandemic](#)
- [Donate COVID-19 Plasma](#) - If you have fully recovered from COVID-19, you may be able to help patients currently fighting the infection by donating your plasma.
- Register by **June 5, 2020** for the [FDA Training Course: Achieving Data Quality and Integrity in Clinical Trials Involving High-Consequence Pathogens](#), scheduled for July 27-31, 2020 in Omaha, Nebraska. Professionals who have experience with high-consequence pathogen clinical trials are encouraged to apply to attend.

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