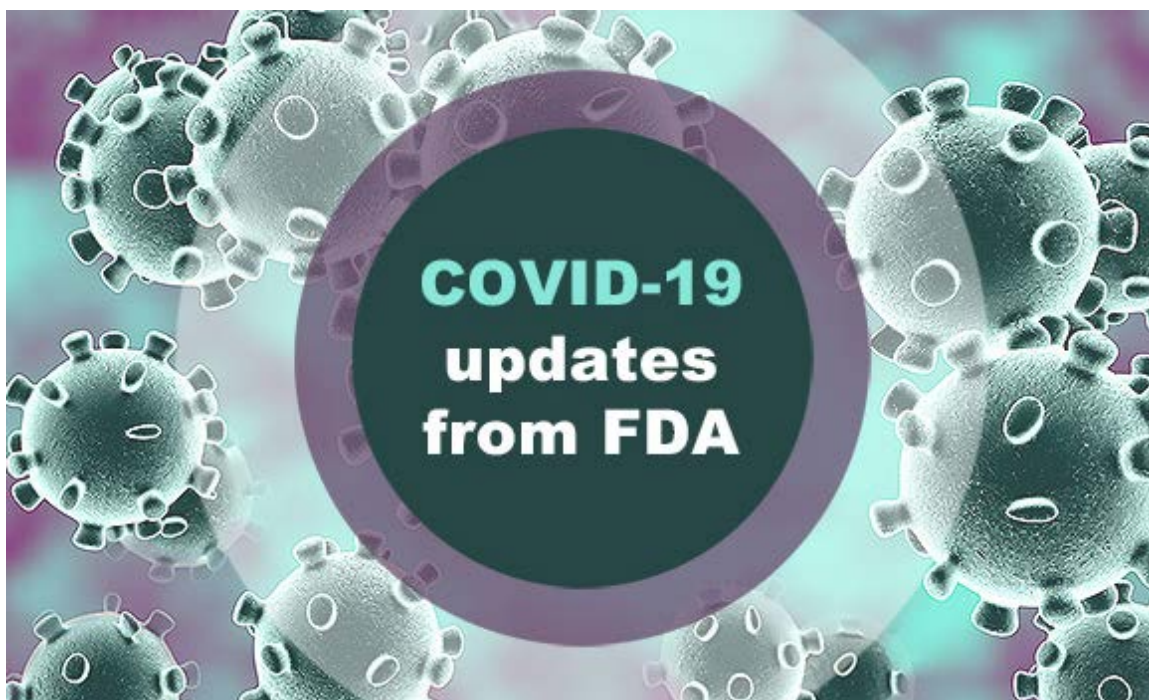


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Medical Countermeasures Initiative Update

March 11, 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. Here's what's new since our last MCMi email update on March 4, 2020.

FDA and FTC Warn Seven Companies Selling Fraudulent Products that Claim to Treat or Prevent COVID-19

The U.S. Food and Drug Administration (FDA) and the Federal Trade Commission (FTC) issued warning letters to seven companies for selling fraudulent COVID-19 products. These products are unapproved drugs that pose significant risks to patient health and violate federal law. The FDA and FTC are taking this action as part of their response in protecting Americans during the global COVID-19 outbreak. The warning letters are the first to be issued by the FDA for unapproved products intended to prevent or treat "Novel Coronavirus Disease 2019" (COVID-19).

The FDA is particularly concerned that products that claim to cure, treat or prevent serious diseases like

COVID-19 may cause consumers to delay or stop appropriate medical treatment, leading to serious and life-threatening harm. (March 9, 2020)

[Read the FDA statement](#)

Foreign Inspections

Statement from FDA Commissioner Stephen M. Hahn, M.D.

On March 10, 2020, we provided an update on FDA inspections outside of the U.S. in response to the COVID-19 outbreak. After careful consideration, the FDA is postponing most foreign inspections through April, effective immediately. Inspections outside the U.S. deemed mission-critical will still be considered on a case-by-case basis.

The FDA based this decision on a number of factors, including State Department Level 4 travel advisories in which travel is prohibited for U.S. government employees, Centers for Disease Control and Prevention travel recommendations, access restrictions being imposed on foreign visitors by certain countries, guidance from the Office of Personnel Management and the importance of the health and safety of our employees. Another critical factor in taking this action is the confidence we have in our ability to maintain oversight over international manufacturers and imported products using alternative tools and methods.

[Read the FDA statement](#)

Related links:

- [Coronavirus Disease 2019 \(COVID-19\) information from FDA](#)
- [Coronavirus Disease 2019 \(COVID-19\) Frequently Asked Questions \(new page!\)](#)
- [White House Press Briefing COVID-19 update by FDA Commissioner Stephen M. Hahn, M.D. \(March 7, 2020\)](#)
- [Remarks by FDA Commissioner Hahn to the American Clinical Laboratory Association - The Commissioner's remarks highlighted the role of diagnostic testing in the COVID-19 response. \(March 4, 2020\)](#)
- [Fraudulent Coronavirus Disease 2019 \(COVID-19\) Products \(new page!\)](#)
- Flickr Album: [Fraudulent Coronavirus Disease 2019 \(COVID-19\) Products](#)
- For more updates from FDA, follow [@SteveFDA](#), [@US_FDA](#), [@FDA_Global](#), and [@FDA_MCMi](#) on Twitter
- [2019 Novel Coronavirus \(CDC\)](#)

Emergency Use Authorization (EUA) Updates

- **Reminder:** [Policy for Diagnostics Testing in Laboratories](#)

Certified to Perform High Complexity Testing under CLIA prior to Emergency Use Authorization for Coronavirus Disease-2019 during the Public Health Emergency (*effective February 29, 2020*) - The templates for these EUA submissions are available:

- [“Accelerated” Template for Laboratories Certified to Perform High-Complexity Testing Under CLIA: EUA Template \(Word doc, updated March 6, 2020\)](#)
- [Test Kit Manufacturer: EUA Template \(Word doc, updated March 6, 2020\)](#)
- **March 6, 2020:** FDA posted new [FAQs on Diagnostic Testing for SARS-CoV-2](#)
- **March 10, 2020:** On February 29, 2020, FDA granted an EUA to two public health laboratories in New York for a diagnostic test to identify COVID-19 (New York SARS-CoV-2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic Panel). On March 10, 2020, on request from the New York State Department of Public Health, FDA re-issued the EUA with amendments incorporated to add : (1) additional authorized laboratories, (2) additional extraction methods, and (3) minor updates to intended use. *Additional technical information, including fact sheets and the instructions for use have also been updated to reflect these changes*
- **Personal Protective Equipment (PPE) update:** On March 2, 2020, in a **joint effort**, FDA and CDC **took action** (PDF, 129 KB) to make more respirators, including certain N95s, available to health care personnel. FDA has posted two documents related to this EUA.
 - [Appendix A: NIOSH-approved FFRs \(Excel file\)](#)
 - [Appendix B: Authorized Respirators \(PDF, as of March 6, 2020\)](#)



Related links:

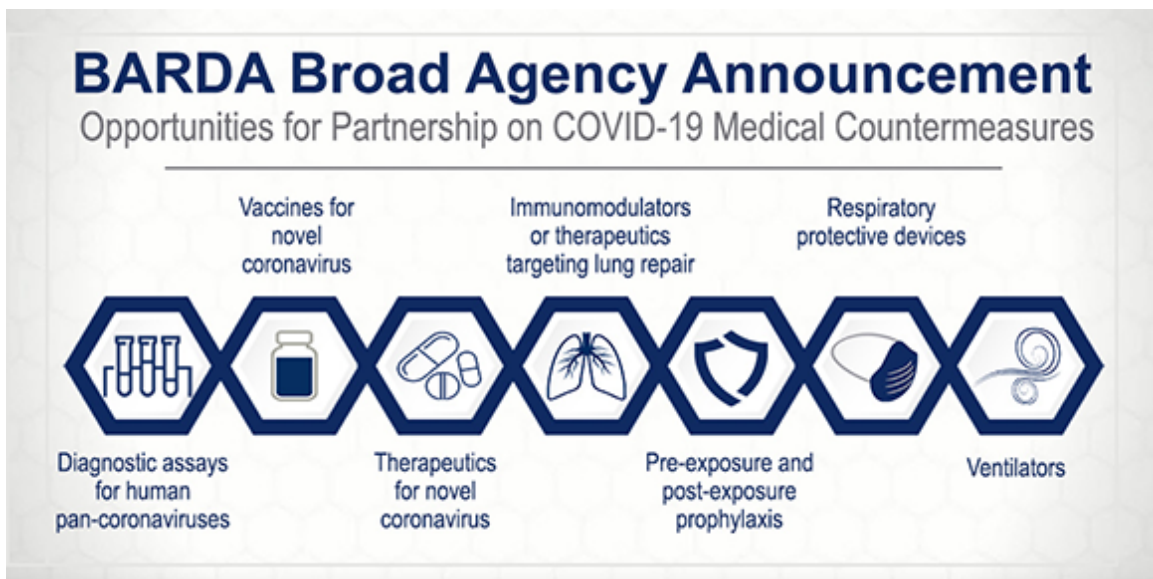
- [Information for Laboratories Implementing IVD Tests Under EUA](#)
 - [FDA Issues New Policy to Help Expedite Availability of Diagnostics \(February 29, 2020\)](#)
 - [Policy for Diagnostics Testing in Laboratories Certified to Perform High Complexity Testing under CLIA prior to Emergency Use Authorization for Coronavirus Disease-2019 during the Public Health Emergency - March 2, 2020 webinar transcript added](#)
-

Events

- **March 12, 2020:** FDA Grand Rounds - [Modernization of Pharmaceutical Manufacturing through the Adoption of Advanced Technology](#) (webcast)
- **March 18-19, 2020:** [Joint Civil & DoD CBRN Symposium](#) (Alexandria, VA) - Hosted by the Defense Strategies Institute (*fee*)
- **March 31 - April 3, 2020:** [Preparedness Summit](#) (Dallas, TX) - Hosted by the National Association of County & City Health Officials (NACCHO) (*fee*)

You can find more information about these and other events on the [MCMi News and Events](#) page.

Information for industry (BARDA BAA)



From HHS - BARDA is investing in an array of medical countermeasures to diagnose, treat, or protect against the 2019 novel coronavirus under the BARDA Broad Agency Announcement (BAA-18-100-SOL-00003).

Specifically, BARDA is pursuing the following products or technologies: diagnostic assays for human pan-coronaviruses; vaccines for novel coronavirus; therapeutics for novel coronavirus; ventilators; immunomodulators or therapeutics targeting lung repair; pre-exposure and post-exposure prophylaxis for novel coronavirus exposure; and respiratory protective devices. To learn more, including targets for product maturity under this announcement, see the newly revised [BARDA Broad Agency Announcement](#).

In case you missed it

- From HHS - [HHS to Procure N95 Respirators to Support Healthcare Workers in COVID-19 Outbreaks](#) - As part of the government-wide efforts to respond to the global outbreak of the 2019 novel coronavirus infection (COVID-19), the U.S. Department of Health and Human Services intends to

purchase 500 million N95 respirators over the next 18 months for the Strategic National Stockpile (SNS). (March 4, 2020)



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