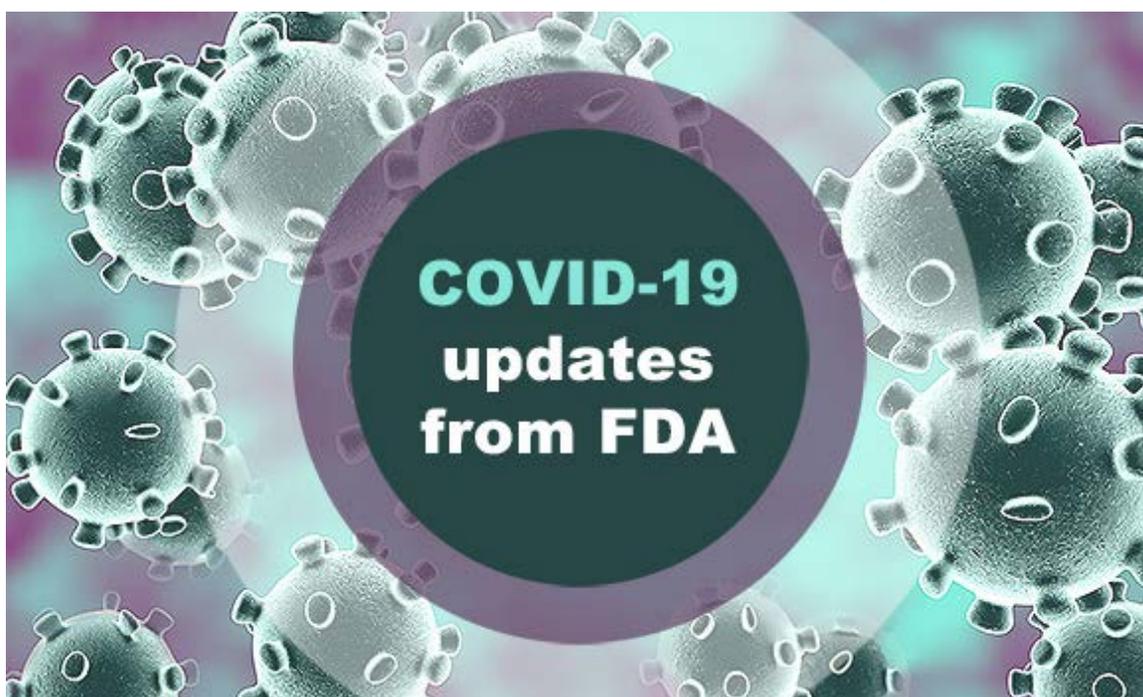


If your email program has trouble displaying this email, [view it as a web page](#).



Medical Countermeasures Initiative Update

March 4, 2020



Update on FDA's Actions in Response to Coronavirus Disease 2019

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 February 19, 2020.

FDA steps to ensure quality of foreign products

FDA continues to take a multi-pronged approach to this public health emergency, including focusing on actively facilitating efforts to diagnose, treat and prevent the disease; surveilling the medical product supply chain for potential shortages or disruptions and helping to mitigate such impacts, as necessary; and leveraging the full breadth of our public health tools, including enforcement tools to stop fraudulent activity. *(February 24, 2020)*

[Read the FDA statement](#)

Supply Chain Update

FDA has been closely monitoring the supply chain with the expectation that the COVID-19 outbreak would likely impact the medical product supply chain, including potential disruptions to supply or shortages of critical medical products in the U.S. A manufacturer has alerted us to a shortage of a human drug that was recently added to the drug shortages list. The manufacturer just notified us that this shortage is related to a site affected by coronavirus. The shortage is due to an issue with manufacturing an active pharmaceutical ingredient used in the drug. It is important to note that there are other alternatives that can be used by patients. We are working with the manufacturer as well as other manufacturers to mitigate the shortage. We will do everything possible to mitigate the shortage. (February 27, 2020)

[Read the FDA statement](#)

Related links:

- [Coronavirus Disease 2019 \(COVID-19\)](#) information from FDA
- 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

- **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). [Additional technical information, including fact sheets](#)
- **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. Currently, the majority of respirators on the market are indicated for use in industrial settings. This action allows certain National Institute for Occupational Safety and Health (NIOSH)-approved respirators not currently regulated by the FDA to be used in a health care setting by health care personnel during the coronavirus (COVID-19) outbreak, thereby maximizing the number of respirators available to meet the needs of the U.S. health care system. *Also see:* [Coronavirus Disease 2019 \(COVID-19\) EUA Information](#)



FDA Issues New Policy to Help Expedite Availability of Diagnostics

On February 29, 2020, as part of FDA's ongoing and aggressive commitment to address the coronavirus outbreak, the agency [issued a new 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.

The [template for these EUA submissions is available](#) (Word doc). If you need additional information completing the template or wish to consider use of an alternative specimen type, please contact the Division of Microbiology Devices at (301) 348-1778 or email CDRH-EUA-Templates@fda.hhs.gov.

[Read the FDA statement](#)

Related link:

- [Information for Laboratories Implementing IVD Tests Under EUA](#)
-

Events

- **New! March 4, 2020:** [Vaccines and Related Biological Products Advisory Committee public meeting](#) (Silver Spring, MD and webcast) - The committee will meet in open session to discuss and make recommendations on the selection of strains to be included in the influenza virus vaccines for the 2020 to 2021 influenza season.
- **March 5, 2020:** Public workshop - [Medical Extended Reality: Toward Best Evaluation Practices for Virtual and Augmented Reality in Medicine](#) (Silver Spring, MD and webcast)
- **March 5, 2020:** [Advancing Animal Models for Antibacterial Drug Development](#) (Silver Spring, MD and webcast) - Hosted by FDA, the National Institutes of Health (NIH), and the Biomedical Advanced Research and Development Authority (BARDA) to discuss progress and challenges in the development and advancement of various animal models for serious infection.
- **New! March 12, 2020:** FDA Grand Rounds - [Modernization of Pharmaceutical Manufacturing through the Adoption of Advanced Technology](#) (Silver Spring, MD and 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*) - FDA staff will present with other federal partners on public health preparedness and response issues including MCM emergency use and stockpiling, diagnostics, and preparedness communication.
- **April 20-24, 2020:** [Training Course: Achieving Data Quality and Integrity in Maximum Containment Laboratories](#) (Bethesda, MD) - Apply to attend by **March 6, 2020 (deadline extended!)**.

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

Information for industry

- On March 2, 2020, FDA hosted a [webinar for laboratories certified to perform high-complexity testing](#) under the Clinical Laboratory Improvement Amendments (CLIA), and others interested in learning more about this guidance. [Slides are available.](#) (PDF, 69 KB) Also see: [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](#)
 - **Reminders for diagnostics manufacturers**, from HHS:
 - The Biomedical Advanced Research and Development Authority (BARDA), a component of the HHS Assistant Secretary of Preparedness and Response (ASPR), is supporting U.S. government market research to identify medical countermeasures with the potential to help address the 2019-nCoV outbreak. **If your company is developing 2019-nCoV diagnostics, therapeutics, vaccines, or other products, submit your ideas to BARDA's online portal.**
 - [HHS Seeks Abstract Submissions for 2019-nCoV Diagnostics Development](#) - Under this [EZ BAA](#), BARDA will review concise abstract submissions for development funding of 2019-nCoV molecular diagnostics. The diagnostics must utilize platforms already cleared by FDA, with a viable plan to meet requirements for the FDA to consider Emergency Use Authorization (EUA) within 12 weeks of an award. (February 5, 2020)
-

In case you missed it

- From NIH - The National Institutes of Health began a [randomized controlled trial](#) for the treatment of COVID-19 patients. While sponsors are usually expected to allow 30 days between submission and initiation of an initial IND protocol to allow for safety review, FDA has been using both pre-IND discussions and highly expedited initial review to allow such trials to begin as soon as possible. We continue to work with interested sponsors to help expedite any additional clinical trials for COVID-19 medical countermeasures that may be appropriate. (February 25, 2020)



Did someone forward you this email? [Subscribe](#)
(select Emergency Preparedness and Response - FDA Medical Countermeasures Initiative (MCMi) News)



Twitter: [@FDA_MCMi](#)
www.fda.gov/medicalcountermeasures

U.S. Food and Drug Administration
10903 New Hampshire Avenue, Silver Spring, MD 20993
1-888-INFO-FDA (1-888-463-6332)
[Privacy Policy](#) | www.fda.gov