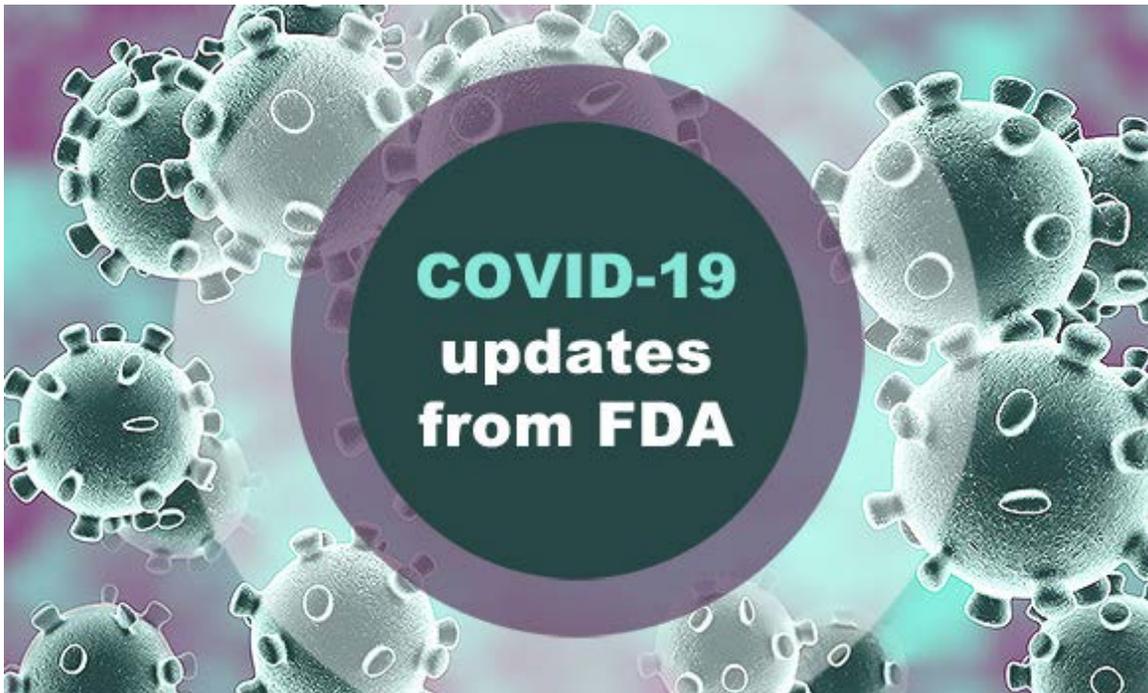


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Medical Countermeasures Initiative Update

February 19, 2020



FDA's Actions in Response to 2019 Novel Coronavirus at Home and Abroad

FDA is an active partner in the Novel Coronavirus (COVID-19) response, working closely with our government and public health partners across the U.S. Department of Health and Human Services, as well as with our international counterparts.

Our work is multifaceted, 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 as we oversee the safety and quality of FDA-regulated products for American patients and consumers.

Read more in the latest statement from FDA Commissioner Stephen M. Hahn M.D., including:

- Active supply chain surveillance
- FDA inspections and monitoring compliance of FDA-regulated products manufactured overseas

- Safety of consumer products
- Efforts to diagnose, treat, and prevent COVID-19
- Next steps

[Read the FDA statement](#)

Related links:

- [Novel coronavirus \(COVID-19\) information from FDA](#)
 - For more updates from FDA, follow [@SteveFDA](#), [@US_FDA](#), [@FDA_Global](#), and [@FDA_MCMi](#) on Twitter
 - [2019 Novel Coronavirus \(CDC\)](#)
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Events

- **March 3, 2020:** Public workshop - [Facilitating End-to-End Development of Individualized Therapeutics](#) (Silver Spring, MD and webcast)
- **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) - Register by **February 28, 2020, 4:00 p.m. ET.**
- **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. [Register](#) by **11:59 p.m. ET, March 2, 2020.**
- **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*)
- **April 20-24, 2020:** [Training Course: Achieving Data Quality and Integrity in Maximum Containment Laboratories](#) (Bethesda, MD) - Apply to attend by **February 28, 2020.**

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

Information for industry

- [Important Information for Human Cell, Tissue, or Cellular or Tissue-based Product \(HCT/P\) Establishments Regarding the 2019 Novel Coronavirus Outbreak](#) - There have been no reported cases of transmission of COVID-19 via these products. Routine screening measures are already in place for evaluating clinical evidence of infection in HCT/P donors. *(February 14, 2020)*
 - **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)*
 - **FDA funding reminder:** Proposers are encouraged to submit white papers to the FDA [Broad Agency Announcement](#) (BAA) by **5:00 p.m. ET, March 2, 2020**, for FY 2020 awards. [MCM-related areas](#) include research and development to support regulatory science and innovation, under Research Area 3: Support new approaches to improve product manufacturing and quality (for example, proposals to support [advanced manufacturing](#) for pandemic preparedness and response, or rapidly scale MCM manufacturing capabilities), and Research Area 7: Facilitate Development of Medical Countermeasures to Protect Against Threats to U.S. and Global Health and Security. In fiscal year (FY) 2020, FDA is encouraging the submission of chemical defense-related topics under Area 7.
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In case you missed it

- From HHS - [HHS Pioneers First Foundry for American Biotechnology](#) - The U.S. Department of Health and Human Services launched the nation's first Foundry for American Biotechnology today to produce technological solutions that help the United States protect against and respond to health security threats, enhance daily medical care, and add to the U.S. bioeconomy. *(February 10, 2020)*



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