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Medical Countermeasures Initiative Update

August 12, 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 August 5, 2020 include:

Coronavirus (COVID-19) Updates:

- August 11, 2020: [Daily Roundup](#): FDA actions on issuing warning statements and warning letters; issuing Emergency Use Authorizations for tests; posting new FAQ webpages on the [registration and listing](#), and [importing](#) of medical devices; and more
- August 10, 2020: [The Critical Role of Health Care Professionals During the COVID-19 Pandemic](#), including a video of FDA Commissioner remarks
- *Also see the features and Emergency Use Authorization Updates below*

COVID-19 Updates from FDA

The Critical Role of Health Care Professionals During the COVID-19 Pandemic

"Among the heroes who have emerged from this crisis are the health care professionals who have risked their own health to serve their patients. The nation is indebted to you."

Remarks from FDA Commissioner Stephen M. Hahn, MD to the American Medical Association. *(August 10, 2020)*

[Read Dr. Hahn's remarks](#)



Coronavirus Treatment Acceleration Program (CTAP)

CTAP uses every available method to move new treatments to patients as quickly as possible, while at the same time finding out whether they are helpful or harmful

FDA updated the CTAP webpage with new metrics and FAQs. As of July 31, 2020, 570+ drug development programs are in the planning stages and 270+ trials have been reviewed by FDA.

[CTAP page](#)

Related links:

- [An Update and Behind the Scenes: FDA's Coronavirus Treatment Acceleration Program](#) *(July 14, 2020)*

- [Coronavirus \(COVID-19\) | Drugs](#)
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Emergency Use Authorization (EUA) Updates

FDA issues surgical masks umbrella EUA

FDA [issued an EUA](#) in response to concerns relating to insufficient supply and availability of disposable, single-use surgical masks. As explained in the EUA, surgical masks that meet specific performance requirements are authorized for use in health care settings by health care personnel (HCP) as personal protective equipment (PPE) to provide a physical barrier to fluids and particulate materials to prevent HCP exposure to respiratory droplets and large particles during surgical mask shortages resulting from the COVID-19 pandemic. (*August 6, 2020*)



FDA revokes EUA for Autobio Diagnostics' Anti-SARS-CoV-2 Rapid Test

FDA [revoked the EUA](#) (PDF) of the Autobio Diagnostics Co. Ltd.'s Anti-SARS-CoV-2 Rapid Test for the qualitative detection and differentiation of IgM and IgG antibodies to SARS-CoV-2 in human plasma from anticoagulated blood (Heparin / EDTA / sodium citrate) or serum 2 due to performance concerns with the accuracy of the test. This test may not be distributed.

Diagnostic test EUAs

To date, FDA has currently [authorized](#) 210 tests under EUAs, which include 171 molecular tests, 37 antibody tests, and 2 antigen tests. *Also see: [Coronavirus Testing Basics](#)*

Related links:

- [FAQs on Testing for SARS-CoV-2](#) (frequently updated)
 - [Coronavirus Disease 2019 \(COVID-19\) Emergency Use Authorizations for Medical Devices](#)
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Events

- **Today! August 12, 2020:** [Virtual Town Hall Series - Immediately in Effect Guidance on Coronavirus \(COVID-19\) Diagnostic Tests](#) - 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. FDA will host additional town halls in this series on Wednesdays in August. *There is significant interest in this Town Hall. Connecting early is highly recommended. To ensure you are connected, please dial-in at 12:00 p.m.*
- **August 13, 2020:** FDA Grand Rounds webcast - [Nanotechnology: Over a Decade of Progress and Innovation at FDA](#), 12:00 - 1:00 p.m. ET - *Also see the related [report](#) (PDF), issued July 2020*

- **August 18, 2020:** Save the date for the next event in the [webinar series](#) to share information and answer your questions on respirators and other personal protective equipment (PPE). Printable slides and transcripts from previous events in this series are available.
 - **September 17-18, 2020:** [Considerations for the Use of Real-World Evidence to Assess the Effectiveness of Preventive Vaccines](#) - virtual workshop - [agenda](#) (PDF)
 - **October 2, 2020:** [Vaccines and Related Biological Products Advisory Committee](#) (webcast) - At this meeting the committee will recommend strains for the 2021 Southern Hemisphere influenza vaccines licensed in the U.S., which is part of FDA's year-round efforts to fight flu, along with other public health partners like CDC and NIH.
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Information for industry

Temporary Guidance for Hand Sanitizers

- FDA has taken additional action to help ensure that hand sanitizers produced under the agency's temporary guidances do not contain unsafe levels of methanol. FDA has updated its [guidances](#) to provide clarification that companies test each lot of the active ingredient (ethanol or isopropyl alcohol (IPA)) for methanol, if the ethanol or IPA is obtained from another source. FDA has also included an additional denaturant formula in the temporary guidances. Denaturing alcohol in hand sanitizers is critical to deter children from unintentional ingestion. Consumer and health care personnel safety is a top priority for FDA, and an important part of FDA's mission is to protect the public from harm, especially as we seek to facilitate an increase in the supply of hand sanitizer. *(August 10, 2020)*

Antimicrobial Resistance (AMR)

- FDA is committed to implementing requirements in the [21st Century Cures Act](#) to help encourage the development of safe and effective drugs for serious bacterial and fungal infections in a limited population of patients with unmet needs. Final guidance on the [Limited Population Pathway for Antibacterial and Antifungal Drugs](#) is a part of the larger FDA effort to fight antimicrobial drug-resistant infections and is an integral step in a long-term implementation of the LPAD pathway. *(August 5, 2020)*

An Exciting New Chapter in OTC Drug History: OTC Monograph Reform in the CARES Act

- 240 million Americans use over-the-counter (OTC) drugs every year. OTC drugs are available to consumers without a prescription and can be safely and effectively used without the supervision of a health care provider. The beginning of an exciting new chapter in OTC drug history began in March when the President signed into law H.R. 748, the "Coronavirus Aid, Relief, and Economic Security Act" or "CARES Act." The act includes [important reforms that modernize the way certain OTC drugs are regulated in the United States](#). *(August 6, 2020)*

Information for Health Care Facilities and Providers on "in-use time" - COVID-19

- FDA is aware that some health care facilities and providers are facing challenges in maintaining adequate supplies of certain drugs needed to treat patients with COVID-19. In particular, health care facilities and providers have reported that care of ventilated patients can be complicated by the need to discard containers of medications before they are fully administered because of the in-use time specified on the FDA-approved label. The "in-use time" is the maximum amount of time that can be allowed to elapse between penetration of a container-closure system containing a sterile drug product, or after a lyophilized drug product has been reconstituted, and before patient administration. Some facilities and providers have indicated that they are considering use of certain drugs, for which

supplies may not be consistently available, beyond the labeled “in-use times.”

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 more than 50 COVID-19-related guidances to date.

COVID-19-Related Guidance Documents

Expiration Date Extension Update

Additional Expiration Date Extensions of Certain Lots of Doxycycline Hyclate 100 mg Capsules Held in Strategic Stockpiles

On August 7, 2020, FDA [issued a memo](#) (PDF) to government public health and emergency response stakeholders extending for the second time the expiration dates of certain lots of doxycycline hyclate 100 mg capsules held in strategic stockpiles for anthrax emergency preparedness and response purposes. *Also see: [Expiration date extensions of certain lots of doxycycline hyclate](#)*

In case you missed it

- [Coronavirus Disease 2019 \(COVID-19\) Resources for Health Professionals](#)
- If you have recovered from COVID-19, confirmed by a positive test, you're in a special position to help us fight the virus. [Donate plasma now.](#)
- Questions about methanol contamination in hand sanitizer? Visit FDA's [searchable list](#) to help you identify hand sanitizers that should not be used. In addition, FDA continues to find issues with certain hand sanitizer products. Test results show certain products have concerningly low levels of the active ingredient ethyl alcohol or isopropyl alcohol. Do not use these subpotent products, also on the searchable list.
- Take our [hand sanitizer quiz](#) to test your knowledge!

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