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Medical Countermeasures Initiative Update

September 2, 2020



Coronavirus Disease 2019 (COVID-19)

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 26, 2020 include:

Coronavirus (COVID-19) updates

- September 1, 2020: [Daily Roundup](#) - FDA's action on a warning letter in its ongoing response to the COVID-19 pandemic
- August 28, 2020: [FDA Broadens Emergency Use Authorization for Veklury \(remdesivir\) to Include All Hospitalized Patients for Treatment of COVID-19](#)
- August 28, 2020: [FDA Announces Advisory Committee Meeting to Discuss COVID-19 Vaccines](#)
- August 28, 2020: [FDA Advises Health Care Providers Not to Use Gowns from Laws of Motion PPE Due to Potential Risk](#)
- August 27, 2020: [FDA Warns Consumers About Hand Sanitizer Packaged in Food and Drink](#)

Containers

- August 26, 2020: [FDA Authorizes First Diagnostic Test Where Results Can Be Read Directly From Testing Card](#)
- Also see the features and Emergency Use Authorization Updates below, and ongoing updates to the list of hand sanitizers consumers should not use at: www.fda.gov/handsanitizerlist

COVID-19 Updates from FDA



FDA warns consumers about hand sanitizer packaged in food and drink containers

The FDA is warning consumers about [alcohol-based hand sanitizers](#) that are being packaged in containers that may appear as food or drinks and may put consumers at risk of serious injury or death if ingested. The agency has discovered that some hand sanitizers are being packaged in beer cans, children's food pouches, water bottles, juice bottles, and vodka bottles. Additionally, the FDA has found hand sanitizers that contain food flavors, such as chocolate or raspberry.

In one recent example of consumer confusion, the FDA received a report that a consumer purchased a bottle they thought to be drinking water but was in fact hand sanitizer. The agency also received a report from a retailer about a hand sanitizer product marketed with cartoons for children that was in a pouch that resembles a snack. Drinking only a small amount of hand sanitizer is potentially lethal to a young child, who may be attracted by a pleasant smell or brightly colored bottle of hand sanitizer.

Consumers are reminded to keep hand sanitizers out of the reach of children and, in case of ingestion, to get medical help or contact a [Poison Control Center](#) immediately. Very small amounts of hand sanitizer can be toxic, even lethal, to young children.



[Read more](#)

Related links:

- [Safely Using Hand Sanitizer](#)
- [Q&A for Consumers: Hand Sanitizers and COVID-19](#)

Emergency Use Authorization (EUA) updates

FDA broadens EUA for Veklury (remdesivir) to include all hospitalized patients for treatment of COVID-19

FDA [broadened the scope](#) of the [existing EUA](#) (PDF) for the drug Veklury (remdesivir) to include treatment of all hospitalized adult and pediatric patients with suspected or laboratory-confirmed COVID-19, irrespective of their severity of disease.

In May 2020, the FDA issued an EUA that authorized Veklury for the treatment of hospitalized adult and pediatric patients with severe COVID-19. As noted in the initial issuance of the EUA, the emergency use of Veklury was limited to those patients with severe disease, which was defined as patients with low blood oxygen levels or needing oxygen therapy or more intensive breathing support such as a mechanical ventilator.

On August 28, 2020, based on the Agency's ongoing review of the EUA, including its review of the totality of scientific information now available, the FDA has determined that it is reasonable to believe Veklury may be effective for the treatment of suspected or laboratory-confirmed COVID-19 in all hospitalized adult and pediatric patients. The Agency's review has also concluded that the known and potential benefits of Veklury outweigh the known and potential risks for these uses. *(August 28, 2020)*

FDA authorizes first diagnostic test where results can be read directly from testing card

FDA [issued an EUA](#) (PDF) for the [first antigen test where results can be read directly from the testing card](#), a similar design to some pregnancy tests. This simple design is fast and efficient for healthcare providers and patients and does not need the use of an analyzer. *(August 26, 2020)*

Diagnostic test EUAs

To date, FDA has currently [authorized](#) 235 tests under EUAs, which include 190 molecular tests, 41 antibody tests, and 4 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](#)



Events

- **Today! September 2, 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 September. *To ensure you are connected, please dial-in at 12:00 p.m.*
- **New! September 10, 2020:** FDA Grand Rounds webcast: [Advancing the Science of Real-World Data to Address the COVID-19 Pandemic](#), presented Amy P. Abernethy, MD, PhD, FDA Principal Deputy Commissioner and Acting Chief Information Officer, 12:00 - 1:00 p.m. ET, CE credit available
- **September 15, 2020:** Save the date for the next event in FDA's [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) - 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.
- **New! October 22, 2020:** [Vaccines and Related Biological Products Advisory Committee](#) (webcast) - The committee will discuss, in general, the development, authorization, and/or licensure of vaccines to prevent COVID-19. No specific application will be discussed at this meeting.

Information for industry

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](#)

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.](#)

Coming soon – FDA is switching to a new email subscription service provider

At FDA, we are constantly seeking ways to enhance your communications experience and to help you stay informed. In the coming weeks, we'll be changing the platform that we use for FDA's free email subscription service.

Rest assured that any subscriptions you have for FDA's Medical Countermeasures Initiative (MCMi) email updates, including these weekly COVID-19 updates from FDA, will continue. The new platform will provide more customized subscription options and make it easier for you to learn about other FDA topics that may interest you. In addition, subscription selections will be more streamlined and user-friendly. We hope that you will find these changes helpful.

Thank you for your continued interest in FDA's public health emergency preparedness and response activities.

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