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U.S. FOOD & DRUG ADMINISTRATION

Medical Countermeasures Initiative Update

August 26, 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 19, 2020 include:

Coronavirus (COVID-19) updates

- August 25, 2020: Daily Roundup - FDA actions including updated information for consumers about unsafe hand sanitizers and an Abbreviated New Drug Application approval for an inhaler to treat bronchospasm (narrowing of the airways)
- August 25, 2020: FDA Insight podcast - Drug Shortages and COVID-19, plus listen to previous episodes
- August 23, 2020: FDA Issues Emergency Use Authorization for Convalescent Plasma as Potential Promising COVID–19 Treatment, Another Achievement in Administration's Fight Against Pandemic
- August 21, 2020: FDA revokes Emergency Use Authorization for protective barrier enclosures without negative pressure due to potential risks

- August 20, 2020: Remarks on FDA Leadership to Accelerate the Recovery from COVID-19 to the Alliance for Health Policy, from Anand Shah, MD, Deputy Commissioner for Medical and Scientific Affairs
- *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

Is your hand sanitizer on FDA's list of products you should not use?

One of the best ways to prevent the spread of COVID-19 is to wash your hands with soap and water. If soap and water are not available, the Centers for Disease Control and Prevention (CDC) recommends using an alcohol-based hand sanitizer that contains at least 60 percent ethanol (also known as ethyl alcohol).

The FDA regulates hand sanitizer as an over-the-counter drug, available without a prescription. We test hand sanitizers for quality because it is a product we regulate. We discovered serious safety concerns with some hand sanitizers during recent testing, including:

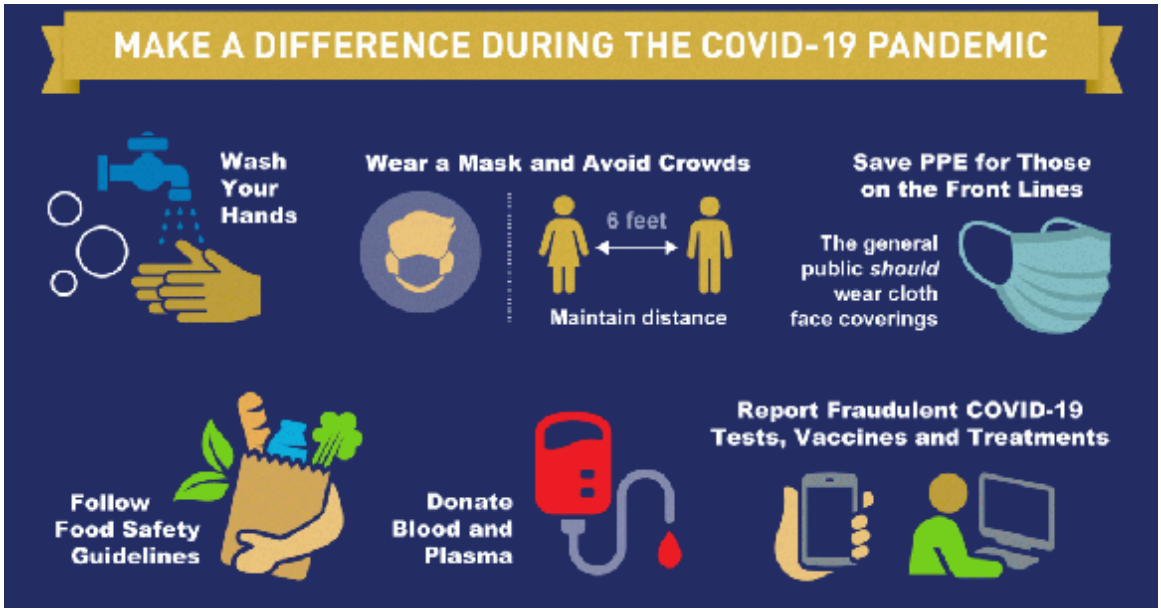
- Contamination with potentially toxic types of alcohol
- Not enough active ingredient (ethyl alcohol or isopropyl alcohol)
- Labels with false, misleading, or unproven claims

Some hand sanitizers have been recalled and there are more than 150 hand sanitizers the FDA recommends you stop using right away.

Before you buy hand sanitizer or use hand sanitizer you have at home, the FDA recommends checking our do-not-use list at www.fda.gov/handsanitizerlist. We update the list regularly as new test

results are released. Bookmark the list in your web browser so that you can check each hand sanitizer before using it.

Read the Consumer Update



Help stop the spread of coronavirus and protect your family

The COVID-19 pandemic requires that we remain vigilant in our everyday lives. We can each take some simple steps to help slow the spread of coronavirus disease and protect ourselves, our families and our communities.

The steps are:

1. **Wash your hands** often with plain soap and water.
2. **Cover your mouth and nose** with a cloth face covering or non-surgical mask when around others.
3. **Avoid crowds and practice social distancing** (stay at least 6 feet apart from others).

Read more tips

Emergency Use Authorization (EUA) updates

FDA issues EUA for convalescent plasma
FDA issued an EUA (PDF) for investigational convalescent plasma for

the treatment of COVID-19 in hospitalized patients as part of the agency's ongoing efforts to fight COVID-19. Based on scientific evidence available, the FDA concluded, as outlined in its decision memorandum (PDF), this product may be effective in treating COVID-19 and that the known and potential benefits of the product outweigh the known and potential risks of the product. *Also see the FDA news release (August 23, 2020)*

FDA revokes EUA for protective barrier enclosures without negative pressure due to potential risks
The FDA has revoked the umbrella EUA for passive protective barrier enclosures (those without negative pressure). We carefully reviewed and considered preliminary evidence showing that there is a potential for adverse events or complications when using these devices while treating patients who are known or suspected to have COVID-19. *Also see: Protective Barrier Enclosures Without Negative Pressure Used During the COVID-19 Pandemic May Increase Risk to Patients and Health Care Providers - Letter to Health Care Providers (August 21, 2020)*

Diagnostic test EUAs
To date, FDA has currently authorized 221 tests under EUAs, which include 179 molecular tests, 39 antibody tests, and 3 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 26, 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.*
- **September 1, 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) - 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 flight flu, along with other public

health partners like CDC and NIH.

Information for industry

Food

- To assist the food industry as it navigates changes to operations related to COVID-19, the FDA has teamed up with the Occupational Safety and Health Administration (OSHA) to develop the Employee Health and Food Safety Checklist for Human and Animal Food Operations During the COVID-19 Pandemic. The checklist pulls from existing guidance provided by the FDA, CDC, and OSHA and serves as a quick reference to help the food industry assess employee health, social distancing, and food safety within workplaces as operations may be impacted by COVID-19. *(August 19, 2020)*

Drug and biological products

- FDA is announcing the availability of a temporary guidance for industry: Manufacturing, Supply Chain, and Drug and Biological Product Inspections During COVID-19 Public Health Emergency Questions and Answers. The questions and answers in this guidance provide information regarding common questions related to inspections for facilities manufacturing pharmaceutical products and sites involved in the conduct of clinical, analytical, and nonclinical studies. *(August 19, 2020)*

Daignostic tests

- FDA has taken steps to encourage the development of tests for screening asymptomatic individuals and for testing pooled samples. This week, the FDA posted a new webpage that provides an overview of available resources related to SARS-CoV-2 screening testing and testing using pooled samples. *(August 24, 2020)*

Hand sanitizer

- FDA is providing a laboratory testing method to assess the quality of finished hand sanitizer products. This testing method can be used to help assure hand sanitizers contain the correct ingredients and do not contain harmful levels of impurities. *(August 24, 2020)*

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.

(select Emergency Preparedness and Response - FDA Medical Countermeasures Initiative (MCMi) News)

U.S. Food and Drug Administration
10903 New Hampshire Avenue, Silver Spring, MD 20993
1-888-INFO-FDA (1-888-463-6332)