FDA NEWS RELEASE

Coronavirus (COVID-19) Update: Daily Roundup April 8, 2020

For Immediate Release:

April 08, 2020

The U.S. Food and Drug Administration today announced the following actions taken in its ongoing response effort to the COVID-19 pandemic:

- The FDA and Federal Trade Commission (FTC) issued warning letters to three sellers of fraudulent COVID-19 products, as part of the agency's effort to protect both people and pets. With these warning letters, the FDA is exercising its authority to protect consumers and animals from companies selling unapproved products with false or misleading claims during the COVID-19 pandemic. There are currently no approved preventatives or treatments for COVID-19. Consumers should not purchase or take any product to prevent or treat COVID-19 unless it is prescribed by a health care provider and acquired from a legitimate source.
    - The first seller warned (https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-warns-company-marketing-dangerous-chlorine-dioxide-products-claim), Genesis II Church of Health and Healing, sells fraudulent and dangerous chlorine dioxide products known as "Miracle Mineral Solution" for prevention and treatment of COVID-19. The FDA has previously warned consumers not to purchase or drink chlorine dioxide products sold online as medical treatments, as the agency is not aware of any scientific evidence supporting their safety or effectiveness and they pose significant risks to patient health.
    - The second seller warned (/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/savvy-holistic-health-dba-holistic-healthy-pet-605915-04072020), Savvy Holistic Health dba Holistic Healthy Pet, sells fraudulent products with misleading claims about the prevention or treatment of COVID-19 in people and pets.
    - The third seller warned (/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/cbd-online-store-606587-04072020), CBD Online Store, offers unapproved and misbranded CBD products with misleading claims the products are safe and/or effective for the treatment or prevention of COVID-19 in people.

- Today, the FDA issued guidance (/regulatory-information/search-fda-guidance-documents/investigational-covid-19-convalescent-plasma) to provide recommendations to health care providers and investigators on the administration and study of convalescent plasma to patients currently seriously ill with COVID-19. Convalescent plasma is plasma collected from individuals who have recovered from COVID-19, and is referred to as COVID-19 convalescent plasma. The agency's guidance provides recommendations on pathways available to health care providers for use of investigational COVID-19 convalescent plasma; patient eligibility; collection of COVID-19 convalescent plasma, including donor eligibility and donor qualifications; and labeling and recordkeeping. The recommendations included in the guidance are intended to supplement information that FDA previously made available on its web site (/vaccines-blood-biologics/investigational-new-drug-ind-or-device-exemption-ide-process-cber/recommendations-investigational-covid-19-convalescent-plasma).
- Diagnostics update to date:
    - During the COVID-19 pandemic, the FDA has worked with more than 270 test developers who have said they will be submitting emergency use authorizations (EUA) requests to FDA for tests that detect the virus.
    - To date, 31 emergency use authorizations (/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations) have been issued for diagnostic tests.
    - The FDA has been notified that more than 150 laboratories have begun testing under the policies set forth in our COVID-19 Policy for Diagnostic Tests for Coronavirus Disease-2019 during the Public Health Emergency Guidance.
    - The FDA also continues to keep its COVID-19 Diagnostics FAQ (/medical-devices/emergency-situations-medical-devices/faqs-testing-sars-cov-2) up to date.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

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Related Information

- Coronavirus Disease 2019 (COVID-19) (/emergency-preparedness-and-response/counterterrorism-and-emerging-threats/coronavirus-disease-2019-covid-19)

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