FDA NEWS RELEASE

Coronavirus (COVID-19) Update: FDA Warns Seller Marketing Dangerous Chlorine Dioxide Products that Claim to Treat or Prevent COVID-19

Agency Continues Effort to Protect Public Health from Fraudulent and Harmful Products

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Español (/news-events/press-announcements/actualizacion-del-coronavirus-covid-19-la-fda-advierte-empresa-que-comercializa-productos-peligrosos)

The U.S. Food and Drug Administration has issued a warning letter (/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/genesis-2-church-606459-04082020) to a seller that markets fraudulent and dangerous chlorine dioxide products known as "Miracle Mineral Solution" for prevention and treatment of "Novel Coronavirus Disease 2019" (COVID-19). The FDA has previously warned (/consumers/consumer-updates/danger-dont-drink-miracle-mineral-solution-or-similar-products) 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 FDA is taking this action to protect Americans as part of its response to the global COVID-19 pandemic.

"Despite previous warnings, the FDA is concerned that we are still seeing chlorine dioxide products being sold with misleading claims that they are safe and effective for the treatment of diseases, now including COVID-19. The sale of these products can jeopardize a person's health and delay proper medical treatment," said FDA Commissioner Stephen M. Hahn, M.D. "We continue to take action and keep up our efforts to monitor for fraudulent treatments during this public health emergency and remind the public to seek medical help from their health care providers."

The FDA issued a joint warning letter with the Federal Trade Commission (FTC) to the Genesis II Church of Health and Healing for selling chlorine dioxide products that it fraudulently claims can treat or prevent COVID-19 in adults and children. This is especially concerning since children are a vulnerable population that may be at greater risk for adverse reactions from consuming chlorine dioxide. The FDA and FTC requested that the company respond in 48 hours describing the specific steps it has taken to correct the violations. Companies that sell products with unapproved claims to prevent, treat or cure COVID-19 may be subject to enforcement action, including but not limited to seizure or injunction.

Chlorine dioxide products have not been shown to be safe and effective for any use, including COVID-19, but these products continue to be sold as a remedy for treating autism, cancer, HIV/AIDS, hepatitis and flu, among other conditions, despite their harmful effects.

Websites selling chlorine dioxide products typically describe the product as a liquid that is 28% sodium chlorite in distilled water. Product directions instruct consumers to mix the sodium chlorite solution with citric acid – such as lemon or lime juice – or another acid – such as hydrochloric acid – before drinking. In many instances, the sodium chlorite is sold as part of a kit with a citric acid "activator." When the acid is added, the mixture becomes chlorine dioxide, a powerful bleaching agent that has caused serious and potentially life-threatening side effects.

Life-threatening Adverse Events

The FDA has received reports of people experiencing serious adverse events after drinking chlorine dioxide products, including:

• Respiratory failure caused by a serious condition where the amount of oxygen carried through the blood stream is greatly reduced (methemoglobinemia);

- Changes in the electrical activity of the heart (QT prolongation), which may lead to potentially fatal abnormal heart rhythms;
- Life-threatening low blood pressure caused by dehydration;
- Acute liver failure;
- Low blood cell counts, due to the destruction of red blood cells faster than the body can make it (hemolytic
 anemia), which required a blood transfusion;
- · Severe vomiting; and
- · Severe diarrhea.

The FDA is not aware of any scientific evidence supporting the safety or effectiveness of "Miracle Mineral Solution" products, despite claims that the solution has antimicrobial, antiviral and antibacterial properties. The FDA encourages consumers to talk to a health care professional about preventing and treating medical conditions or diseases.

The FDA is particularly concerned that products that fraudulently claim to cure, treat or prevent serious diseases like COVID-19 may cause consumers to delay or stop appropriate medical treatment, leading to serious and lifethreatening harm.

Fraudulent Cure Claims

In addition to following up with companies that fail to make adequate corrections, the FDA will continue to monitor social media, online marketplaces and incoming complaints to help ensure that the companies do not continue to sell fraudulent products under a different company name or on another website. The FDA is closely monitoring for fraudulent products related to COVID-19 and has issued a number of warning letters (/consumers/health-fraud-scams/fraudulent-coronavirus-disease-2019-covid-19-products) since the start of the pandemic.

The FDA reminds consumers to be cautious of websites and stores selling products that claim to prevent, mitigate, treat, diagnose or cure COVID-19. Fraudulent COVID-19 products may come in many varieties, including dietary supplements and other foods, as well as products purporting to be drugs, medical devices or vaccines. Products that claim to cure, mitigate, treat, diagnose or prevent disease, but are not proven safe and effective for those purposes, defraud consumers of money and can place consumers at risk for serious harm. Using these products may lead to delays in getting proper diagnosis and treatment of COVID-19 and other potentially serious diseases and conditions.

The FDA encourages health care professionals and consumers to report adverse events or quality problems experienced with the use of COVID-19 products to the FDA's MedWatch Adverse Event Reporting program (/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program).

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)
- Fraudulent Novel Coronavirus (COVID-19) Products (/consumers/health-fraud-scams/fraudulent-coronavirus-disease-2019-covid-19-products)
- Fraudulent Novel Coronavirus 2019 (COVID-19) Product Photos (https://www.flickr.com/photos/fdaphotos/albums/72157713334402986) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
- FTC Article on Novel Coronavirus (COVID-19) Scams (https://www.consumer.ftc.gov/blog/2020/02/coronavirus-scammers-follow-headlines)
- FDA Health Fraud (/consumers/health-fraud-scams)
- Reporting Unlawful Sales of Medical Products on the Internet (/safety/report-problem-fda/reporting-unlawful-sales-medical-products-internet)

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