

FDA NEWS RELEASE

Coronavirus (COVID-19) Update: FDA Continues to Ensure Availability of Alcohol-Based Hand Sanitizer During the COVID-19 Pandemic, Addresses Safety Concerns

Agency Additionally Warns Consumers about Hand Sanitizer Sold with Fraudulent Claims

For Immediate Release:

April 27, 2020

[Español \(/news-events/press-announcements/actualizacion-sobre-el-coronavirus-covid-19-la-fda-continua-garantizando-la-disponibilidad-del\)](#)

Today, the U.S. Food and Drug Administration provided an update on its efforts to ensure the availability of alcohol-based sanitizer to help meet the demand for hand sanitizer during the COVID-19 pandemic. As a result of the agency's significant flexibility, more than 1,500 additional manufacturers have registered with the agency to produce hand sanitizer. At the same time, the agency is addressing safety concerns related to products being sold that are not in line with the FDA's policy and others being marketed with unproven claims.

"We appreciate industry's willingness to help supply alcohol-based hand sanitizer to the market to meet the increasing demand for these products and are grateful for their efforts," said FDA Commissioner Stephen M. Hahn, M.D. "With this increased supply comes our continued mission to ensure safety of these products. It is important that hand sanitizer be manufactured in a way that makes them unpalatable to people, especially young children, and that they are appropriately labeled to discourage accidental or intentional ingestion. Additionally, hand sanitizers are not proven to treat COVID-19, and like other products meant for external use, are not for ingestion, inhalation, or intravenous use."

Following the FDA's guidance aimed at increasing availability of alcohol-based hand sanitizers, the agency has received feedback and questions over the past few weeks from industry and congressional members, particularly regarding the need to use denatured alcohol for these products. Adding these denaturants to the alcohol renders the product more bitter and less appealing to ingest, particularly for young children. While the agency understands the economic and business reasons behind foregoing this step in the manufacturing process, such an approach undermines the agency's mission of helping to ensure the safety of FDA-regulated products for consumer use, which is the FDA's top priority. This approach is consistent with the FDA's policies prior to the COVID-19 pandemic on including denatured alcohol in hand sanitizer and is even more important now as more consumers rely on its use as a mitigation tool against the deadly virus.

To illustrate the importance of using denatured alcohol and, according to an FDA analysis of data provided by the U.S. Centers for Disease Control and Prevention and the American Association of Poison Control Centers surveillance team, calls to the National Poison Data System last month related to hand sanitizer increased by 79% compared to March 2019. The majority of these calls were for unintentional exposures in children 5 years of age and younger. Every year, there are hundreds of calls to poison control centers regarding exposure to hand sanitizer, many of which result in adverse events, including death. Unfortunately, ingestion of only a small amount of hand sanitizer may be potentially lethal in a young child.

This month, the agency received an adverse event report of a 13-year-old child drinking hand sanitizer packaged in a liquor bottle from a distiller. The sanitizer was not denatured and was reported to taste like normal drinking alcohol. To protect consumers, especially children, it is important to make hand sanitizer unpalatable.

The FDA also found that the product ingested by the 13-year-old child was not consistent with the labeling component of the agency’s temporary policy— underscoring the importance that these products include a Drug Facts Label, warnings to keep the product out of reach of children, information to get medical help or call a poison control center right away if swallowed and to supervise use in children under 6 years of age to prevent accidental swallowing. These safety measures apply regardless of where the product is intended to be used, as it can easily be distributed beyond the original intended setting.

The FDA is also concerned about hand sanitizer products being sold by some manufacturers during the COVID-19 pandemic with unproven claims. Last week, the agency issued its first warning letter for a hand sanitizer product marketed with unproven COVID-19-related claims, in violation of federal law. The letter was issued to Prefense LLC (/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/prefense-llc-605488-04232020) for selling their product with misleading claims, for example, “Prefense...protects you from germs with just one application per day! It’s like wearing an invisible glove.” The company’s webpage also states that Prefense can, “protect you from pathogens up to 24 hours or for 10 hand washes.” The FDA is not aware of any evidence that hand sanitizer products can protect consumers for 24 hours or after multiple hand-washings. These types of claims may put consumers at risk by leading to a false sense of security and resulting in infrequent hand washing or hand sanitizing. The agency urges consumers to be vigilant of products sold with misleading, unproven claims, by following our updates on our website (/consumers/health-fraud-scams/fraudulent-coronavirus-disease-2019-covid-19-products).

The FDA remains committed to working with manufacturers, compounders, state boards of pharmacy and the public to increase the safe supply of alcohol-based hand sanitizer available to Americans, as well as continuing to take appropriate action against manufacturers making unproven claims.

Consumers, manufacturers or distributors who have questions for the FDA regarding hand sanitizers should email COVID-19-Hand-Sanitizers@fda.hhs.gov (mailto:COVID-19-Hand-Sanitizers@fda.hhs.gov).

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.

###

Inquiries

Media:

✉ [Jeremy Kahn \(mailto:jeremy.kahn@fda.hhs.gov\)](mailto:jeremy.kahn@fda.hhs.gov)

☎ 301-796-8671

Consumer:

☎ 888-INFO-FDA

✉ Amanda Turney (mailto:amanda.turney@fda.hhs.gov)

☎ 301-796-2969

Related Information

Coronavirus Disease 2019 (COVID-19) (/emergency-preparedness-and-response/mcm-issues/coronavirus-disease-2019-covid-19)

🔗 [More Press Announcements \(/news-events/newsroom/press-announcements\)](/news-events/newsroom/press-announcements)