



October 27, 2021

Dr. Theresa Michele
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Nonprescription Drugs
10903 New Hampshire Avenue WO22 Stop 5411
Silver Spring, MD 20993

Dear Dr. Michele:

First and foremost, we want to thank you for your efforts to protect American consumers as we continue to weather this global health crisis.

The American Consumer Institute (ACI) was founded with the mission to promote consumer welfare by improving the understanding and impact that public policies and regulations have on consumers in a free market. That is why we are writing to you about issuing clear guidance regarding hand sanitizer bulk use and distribution.

A year ago, we came to you with our concerns about toxic, underregulated hand sanitizers on the market, which came about after [emergency guidance](#) lowered product standards. Because that emergency guidance was in place much longer than it should have been, we saw [hundreds of hand sanitizer brands](#) reported as toxic, and many more testimonials of inefficacy and poor quality.

Now, almost two years into this pandemic, we are pleased to see you [rescinded](#) the emergency guidance on alcohol-based hand sanitizer products – an important step in ensuring the safety of American consumers. While withdrawing the temporary guidance was a crucial, there is more to be done. Equally important is issuing clear guidance that ensures the safety and efficacy of open refillable or bulk hand sanitizer so that Americans can stay safe and healthy as they return to their daily lives.

Often, many businesses, schools, restaurants, and other public forums provide bulk hand sanitizer dispensers for consumer use. These dispensers are helpful in providing on-the-go sanitizer to consumers in need. However, with these benefits also comes the downside of the unsafe practice of “topping off” dispensers with bulk and potentially unsafe products. As a short cut, employees will fill up the dispenser before it is empty, often with an entirely different product. Not only does that result in mislabeling and consumer confusion, but it leads to the potential for high rates of bacteria growth and lower efficacy as a result of product mixing.

The [CDC lists](#) the following as potential safety risks associated with this practice: “inadvertent contamination, reduced effectiveness from the evaporation of alcohol, and irritant effects from mixing formulations.”

The influx of toxic, underregulated hand sanitizers during the pandemic has worsened this problem tremendously. Consumers are using these mixed products with a false sense of security, thus prolonging our country's fight against COVID-19. It is time to ensure only effective, germ-fighting products end up in consumers' hands.

Thank you again for your efforts to curb the spread of this virus, but please do not slow down. It is imperative that the Biden administration and regulatory officials prioritize consumers and assuage the confusion we have all felt for the past two years.

Respectfully,

Steve Pociask

President, American Consumer Institute