The American Consumer Institute
Center for Citizen Research

July 6, 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,

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.

It is with this mission in mind that we are writing to you today to inform you of a serious and timely issue that concerns us – namely, the need for guidance and regulation of alcohol-based hand sanitizers.

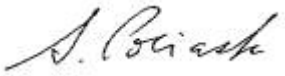
First and foremost, ACI is not in favor of unnecessary regulation and intervention that inevitably puts burdens and costs on the consumer. However, when regulation is necessary for public health, we do encourage relevant decision makers to issue clear and consistent guidance, rather than imprecise messages that only serve to confuse and endanger consumers. Unfortunately, we have been seeing the latter when it comes to this issue.

At the beginning of the COVID-19 pandemic, companies were fighting to keep their heads above water to provide the necessary tools and resources to keep Americans safe. In response to that, the FDA issued emergency, temporary guidance that lowered standards for hand sanitizer products, which the CDC recommended to curb the spread of the virus. While a valiant effort, it unfortunately has resulted in confusion, inconsistency, and the presence toxic products for sale online and on store shelves.

Hundreds of hand sanitizer products that came out in 2020 have now been found to be unsafe or ineffective, including products with methanol and benzene. Moreover, the FDA recently released a warning on the side effects of inhaling vapors of alcohol-based hand sanitizers in response to an uptick of adverse effects that correlate with the release of temporary guidance. Clearly, the root of the problem is the persistent supply of toxic hand sanitizers, but the FDA has yet to rescind the emergency guidance and take these products off the market.

Consumers deserve to know the products they are purchasing and using are safe, effective, and free of toxic ingredients. The COVID-19 pandemic and the government's frantic response has permeated into every facet of society, but it is time to recover and rebuild. With sufficient and proper, approved hand sanitizer products back on the market, we are urge the FDA to pull back the emergency guidance and allow the free market to produce safe and useful germ-fighting products.

Thank you for your time and consideration.



Respectfully,

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