



April 21, 2020

Janet Woodcock, M.D.  
Director – Center for Drug Evaluation and Research  
U.S. Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993

Dear Director Woodcock:

On behalf of the members of the American Coalition for Ethanol (ACE), I am writing to ask the Food and Drug Administration (FDA) to reconsider the modified guidance it issued on April 15, 2020 relating to alcohol-based hand sanitizer.

COVID-19 has caused staggering damage to the U.S. ethanol industry. Plummeting motor fuel demand has idled more than half of the industry's productive capacity, forcing many producers to shut down entirely. For those still in operation, the ability to devote a portion of their alcohol production for use as sanitizer helps keep some of their workforce employed and enables them to donate to healthcare workers and community organizations.

That's why so many of our members were encouraged by the *Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID-19)* issued by FDA on March 27. While a small number of ethanol plants were previously equipped to supply food (FCC) or pharmaceutical (USP) grade ethanol, the regulatory flexibility in the March 27 guidance signaled to many other ethanol producers they could retrofit and do their part to respond to the public health crisis by supplying alcohol for sanitizer.

Unfortunately, FDA's modified guidance, issued on April 15, has inflicted regulatory whiplash on many of these plants, some of whom are donating this product as a service to their communities. FDA's modified guidance claims that "because of the potential for the presence of potentially harmful impurities due to the processing approach, fuel or technical grade ethanol should only be used if it meets USP or FCC grade requirements and the ethanol has been screened for any other potentially harmful impurities not specified in the USP or FCC requirements." Not only does this directly reverse FDA's March 27 policy, it provides zero evidence regarding what "potentially harmful impurities" may exist. We appreciate FDA suggests a company wanting to use fuel grade ethanol not meeting FCC or USP requirements can submit data on their product for an FDA assessment, but we fear compounders won't bother with this additional regulatory hurdle and will instead look for other sources of alcohol for sanitizer.

We respectfully urge FDA to reconsider the modified policy as it unnecessarily prevents many ethanol producers from providing sanitizer during this pandemic. Thank you for your time and consideration.

Sincerely,

Brian Jennings, CEO  
American Coalition for Ethanol