

United States Senate

WASHINGTON, DC 20510

April 2, 2020

The Honorable Stephen Hahn
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Hahn:

We write regarding the U.S. Food and Drug Administration's (FDA) guidance to manufacturers who are producing hand sanitizer as part of the COVID-19 crisis. As you know, hundreds of distilled spirits producers across the country have immediately responded to the current health crisis by halting their regular operations and quickly turning to the production of hand sanitizer. These distillers are fulfilling a critical need in their communities and providing the hand sanitizer to health care professionals, first responders, and local and state governments. They have diligently followed the guidance released by their regulator, the Alcohol, Tobacco Tax and Trade Bureau (TTB), and are producing hand sanitizer according to the World Health Organization's (WHO) formula.

Unfortunately, the FDA's "Temporary Policy for Manufacture of Alcohol for Incorporation Into Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID-19): Guidance for Industry" does not acknowledge the reality that these distillers have stepped up in a time of crisis to produce hand sanitizer using the alcohol they have readily available, which is undenatured. Undenatured alcohol is food grade alcohol that is compliant with the WHO's hand sanitizer formula and has the same effectiveness as denatured alcohol. The United States largely differentiates between the two types of alcohol for tax purposes – with undenatured alcohol incurring the distilled spirits Federal Excise Tax (FET) and paid to the federal government.

A provision was included in the recently-passed *CARES Act* that would temporarily remove the Federal Excise Tax on hand sanitizer production as long as the distiller has followed FDA guidance. Therefore, any FDA guidance should help facilitate both the production of hundreds of thousands of gallons of hand sanitizer and the distribution to those on the front lines battling this pandemic while simultaneously protecting consumers. We have a responsibility to provide more resources to help flatten the curve and alleviating this burden would allow distilleries the opportunity to step up and help their communities.

We strongly urge the agency to update its guidance to recognize the use of undenatured alcohol in the production of hand sanitizer during the COVID-19 health crisis and work with industry on reasonable safeguards to keep hand sanitizer out of the hands of children. This will ensure distillers do not face a tax bill for filling a vital need in their communities.

Thank you for your consideration of this change. Please do not hesitate to contact our offices if we can be of additional assistance.

Sincerely,

Gary C. Peters
United States Senator

Roy Blunt
United States Senator

Marsha Blackburn
United States Senator

Rand Paul, M.D.
United States Senator

Debbie Stabenow
United States Senator

Ted Cruz
United States Senator

Kirsten Gillibrand
United States Senator