



Congress of the United States
House of Representatives
Washington, DC 20515

Friday, March 27, 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 COVID-relief package that would temporarily remove the Federal Excise Tax on hand sanitizer production as long as the distiller has followed FDA guidance. Through the current guidance, the FDA is standing in the way of hundreds of thousands of gallons of hand sanitizer from being produced and given to those on the front lines battling this pandemic. We have a responsibility to provide more resources to help flatten the

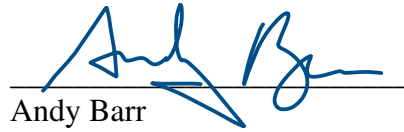
curve and alleviating this burden would allow distilleries the opportunity to step up and help their communities.

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.

Sincerely,

A handwritten signature in black ink, appearing to read 'John Yarmuth', written over a horizontal line.

John Yarmuth
Member of Congress

A handwritten signature in blue ink, appearing to read 'Andy Barr', written over a horizontal line.

Andy Barr
Member of Congress

Members of Congress Urging the FDA to Update Guidance on Hand Sanitizer Production

John Yarmuth

Andy Barr

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