March 26, 2020

The Food and Drug Administration
The Honorable Stephen M. Hahn, M.D.
Administrator
The Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993-0002

Dear Dr. Hahn,

I am writing on behalf of the American Craft Spirits Association (ACSA), which represents the interests of craft distillers across the U.S.

As you know, Section 2308 of the CARES Act provided relief from Federal Excise Taxes (FET) for alcohol used to make hand sanitizer, made under FDA Guidance, until the end of 2020.

As you are now well aware, the March 2020 FDA guidance falls short of what is needed to allow craft distillers to make and supply hand sanitizer to their local communities, hospitals, nursing homes, postal service carriers, first responders and many others. The need is great as pleas from multiple parties echo throughout the country. The willingness among the distillers is evident. But, the FDA guidance creates substantial impediments.

We understand this very issue has been brought to your attention and appreciate your efforts to resolve it quickly. It comes in a time of national crisis. As such, many craft distillers are turning to ethanol they have in stock that is not yet denatured. The guidance states that "the alcohol is denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR parts 20 and 21, using the formulas in Appendix C of this document." Denaturants such as isopropyl alcohol are in short supply. It would be helpful to be allowed to manufacture sanitizers from undenatured ethanol only in this time of public health emergency. Alternatively, glycerol is already considered an approved denaturant in 27 CFR 21.151. Could the glycerol in the WHO formula be considered an approved denaturant for the duration of the public health emergency?

The FDA guidance additionally requires that ethanol to be used in hand sanitizers must be distilled to a level of purity of no lower than 94.9% ethanol by volume. This quality of ethanol is

no longer readily available for purchase, and to make it requires a specific kind of still which many small producers do not have. It would be possible to manufacture hand sanitizer to the correct WHO formulation of 80% ethanol using spirits distilled to a lower alcohol by volume. This is the same kind of alcohol small producers make for their beverage products, and is safe for beverage alcohol consumption, but not sufficiently pure for the FDA guidance. As a result, the FDA guidance is currently not helpful.

Additionally, the FDA registration process is cumbersome, particularly with production on short notice for these very small businesses. The guidance states and requires "alcohol production firms register their facility and list these products in the FDA Drug Registration and Listing System." This process is time consuming and difficult, requiring knowledge and time that these small entrepreneurs do not have.

Our craft producers are making hand sanitizers in small quantities, numbering in the thousands, not perhaps as some larger companies will be doing. Most producers have waiting lists for these products in the hundreds, reflecting the desperate needs for these products in their communities across the nation.

We are hopeful your new guidance is reflective of the capabilities of small producers with coordination of the Tax and Trade Bureau (TTB) at Treasury, so we can comply with all relevant guidance and statutes to provide hand sanitizer to our communities who are desperate for product at this time of public health emergency.

Thank you for your immediate attention to this issue. We would be happy to discuss further. I can be reached at (202) 669-3661.

Respectfully,

Margie A.S. Lehrman

Chief Executive Officer