August 3, 2022

The Honorable Xavier Becerra
Secretary
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Robert M. Califf, M.D., MACC
Commissioner Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Secretary Becerra and Commissioner Califf,

It has come to our attention that a number of craft distillers in several states, including California, are currently being audited by the Food and Drug Administration (FDA) regarding the hand sanitizer they produced during the height of the pandemic.

As you may recall, early in the pandemic in 2020, hundreds of small distillers stepped forward to produce hand sanitizer for those in dire need, including their local communities, state, and federal government. There was a severe shortage of hand sanitizer, and distillers stopped their production lines for manufacturing spirits in order to produce hand sanitizer to help individuals and businesses across the nation. In many cases they donated the product, absorbing a financial burden just to satisfy an unmet supply of hand sanitizer that could ultimately help stop the spread of the coronavirus.

Our Association worked with multiple agencies and departments, including the FDA, to make sanitizer with the appropriate efficacy and to transport sanitizer compliant with government regulations. We had ongoing talks with the FDA to ensure our industry members knew about and followed the emergency guidance which was revised numerous times throughout the early stages of the pandemic, causing these small businesses to navigate lots of changes. We obeyed the FDA guidance and encouraged our members to register in the early phase and then both deregister and later dispose of product in March of this year. Again, many encountered a severe financial loss but knew helping communities in this unprecedented time mattered more than their bottom line.

As a result of that registration, however, in late 2020, many producers were informed that they would owe over 14,000 dollars in user fees to the federal government. Upon hearing this news, the Secretary, in early January 2021, quickly reversed this order and limited any fees until after the pandemic was declared over. Following this series of events, the FDA sent an order asking our distillers to discontinue making hand sanitizer.

Unfortunately, those that complied with initial registration, finished producing sanitizer, sold it or disposed of inventory, and timely deregistered, are still being subjected to audits, testing and possible recalls. We believe this is unreasonable and punitive to small businesses. This is especially true since the testing and notification could be up to 18 months after the samples were collected, and most of these distilleries have long since exited any connection with the sanitizer business.

Members have spent upwards of $25,000 on legal fees to protect their reputation and brand, the very small businesses who have already suffered greatly at the hands of the pandemic.

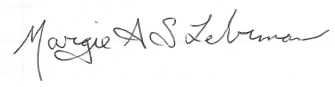
As stated, many of these distillers stepped up to do a patriotic duty by making hand sanitizer when this country faced an acute shortage. Because of the FDA's actions, few if any would do it again. FDA's audits are causing a chilling effect, with these small businesses questioning why their heroic efforts are now being rebuked, with potential erosion of their business reputations, fines, and associated legal fees. Being asked to produce customer records and sales reports is both arbitrary and capricious. The chain of custody and times associated with testing of the product is unclear. Also, the degradation of the product over the span of two plus years is quite possibly a normal course of events.

Furthermore, few if any of our members are making hand sanitizer anymore. They were eager to return to the reasons they opened their distilleries: production of craft spirits.
Finally, and perhaps most importantly, it is unclear if there is truly any danger posed by the hand sanitizer products that remain in circulation. To request a recall is absurd.

We would request that the FDA cease and desist any more audits of craft distillers.

Thank you for your attention to this time-sensitive request. We would welcome the opportunity to discuss further how we can resolve this situation expediently before more distillers suffer harm from this latest round of FDA action.

Sincerely,



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