

Congress of the United States
U.S. House of Representatives
Committee on Small Business
2561 Rayburn House Office Building
Washington, DC 20515-6515

April 9, 2020

The Honorable Stephen Hahn, M.D.
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) March 27, 2020 guidance that requires manufacturers to use denatured alcohol in their production of hand sanitizer. This unnecessary requirement is endangering the lives of tens of thousands of first responders and health care professionals responding to the COVID-19 epidemic across the United States of America. We strongly urge the FDA to immediately update its guidance to permit the use of undenatured alcohol to produce hand sanitizer during this public health emergency.

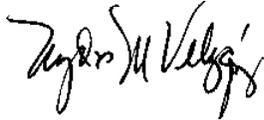
Given the nationwide shortage of hand sanitizer, 598 distilled spirits producers—located in every state in the country, plus the District of Columbia—have begun producing hand sanitizer. Their production, which is in compliance with standards set by the World Health Organization (WHO) and the regulations proposed by the Alcohol, Tobacco Tax and Trade Bureau (TTB) at the U.S. Department of Treasury. This production has allowed these businesses to meet the needs of their local first responders and health care professionals. They were able to do this because they utilized the alcohol that they had on hand, which is undenatured.

Undenatured alcohol is food grade alcohol that is compliant with the WHO's hand sanitizer formula. It has the same effectiveness as denatured alcohol. However, the FDA is still requiring the use of denatured sprits in its most recent guidance. By requiring denatured alcohol in hand sanitizer, the FDA is preventing the immediate distribution of hundreds of thousands of gallons of hand sanitizer to first responders and health care professionals in every state and the District of Columbia.

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 public health emergency. Further we request that the FDA work with the distilled spirits producers to help keep our first responders

and health care professionals supplied with the hand sanitizer that they need, while developing reasonable safeguards that minimize the risk of hand sanitizer to children.

Sincerely,



Nydia M. Velázquez, Chairwoman

/s/ Angie Craig

Angie Craig, Member of Congress

/s/ Judy Chu

Judy Chu, Member of Congress

/s/ Sharice L. Davids

Sharice Davids, Member of Congress

/s/ Antonio Delgado

Antonio Delgado, Member of Congress



Jim Hagedorn, Member of Congress

/s/ Chrissy Houlahan

Chrissy Houlahan, Member of Congress

/s/ Amata Coleman Radewagen

Aumua Amata Coleman Radewagen,
Member of Congress

/s/ Ross Spano

Ross Spano, Member of Congress

/s/ Pete Stauber

Pete Stauber, Member of Congress