



## Distilled Spirits Council Guidance on Distiller Production of Hand Sanitizer to Address COVID-19 Pandemic

**UPDATE – 3/20/20: FDA has just released further guidance, which can be found [here](#). We will be updating this document soon to reflect this guidance, but please note that FDA’s guidance does state that the Agency does not intend to take action against facilities that prepare alcohol-based hand sanitizers for the duration of the public health emergency provided their guidance is followed (please note that the guidance does specify the use of denatured alcohol). **DISCUS** we will continue to seek clarity that distillers may use the product they have on hand, including undenatured ethanol.**

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DISCUS has been working to gain regulatory clarity for distillers wishing to produce hand sanitizer to help address the nationwide shortage during the COVID-19 pandemic.

Included below is an outline of the current available guidance and practices that should be followed when producing hand sanitizer. We will continue to update this guidance as we gain more clarity from TTB and FDA.

**TTB Policy:** TTB issued public guidance on “Production of Hand Sanitizer to Assess the COVID-19 Pandemic,” which is available at <https://www.ttb.gov/public-guidance/ttb-pg-2020-1>.

TTB has initially authorized this activity through June 30<sup>th</sup>, 2020, with the possibility for extension as necessary, under the authority of 26 U.S.C. 5562.

- **No Prior Authorization Required:** “Any existing DSP therefore can immediately commence production of hand sanitizer or distilled spirits (ethanol) for use in hand sanitizer . . . without having to obtain authorization first.” TTB is exempting DSPs from the requirement to obtain additional permits or bonds to manufacture hand sanitizer or to supply ethanol for use in the manufacture of hand sanitizer to other TTB permittees who are authorized to receive such distilled spirits. Please see [TTB Guidance](#) for complete details.
- **Tax Liability:** TTB’s current position is that hand sanitizer products are not subject to Federal excise tax if made with denatured ethanol. **However, if they are made with undenatured ethanol, Federal excise tax would apply.**
  - **NOTE:** We are strongly urging TTB to allow Beverage Alcohol producers to use the resources they have on hand, denatured or undenatured. We are currently pursuing a legislative fix that would waive the FET for hand sanitizer made from undenatured ethanol and are working collaboratively with TTB and Capitol Hill in this endeavor.

*Disclaimer: Nothing in this document constitutes legal advice. We suggest that you consult with your attorney for any specific guidance on legal or regulatory compliance.*



- **Formula Guidance:** TTB has stated that “[i]ndustrial alcohol user permittees may also use denatured ethanol to manufacture hand sanitizer consistent with [World Health Organization \(WHO\) guidance](#) without first obtaining formula approval.” The WHO Formula No. 1 is linked [here](#) in a scalable format, courtesy of the Brown Forman team. (password jb).

**FDA Temporary Policy:** Hand sanitizers are an over-the-counter (OTC) product regulated by the FDA. See [Notice of final rule from April 11, 2019](#).

- The FDA recently issued a [Policy for Temporary Compounding of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency Immediately in Effect Guidance for Industry](#) and it is our understanding that TTB has recommended that DSPs refer to the temporary guidance when producing hand sanitizer.
  - **NOTE:** This FDA policy is specifically directed to pharmacies and pharmacists, not distilled spirits producers. DISCUS is seeking confirmation from FDA that this policy applies to DSPs too and that accordingly FDA “will not take action against [DSPs] that prepare alcohol-based hand sanitizers for consumer use for the duration of the public health emergency.”
  - **Label and Formula:** FDA’s temporary policy references the WHO guidance and also includes the recommended label that should be included on the product.
- For additional actions to consider, see Hyman, Phelps & McNamara, P.C.’s [“A Quick FDA Regulatory Primer for Distilleries Making Hand Sanitizers/Cleansers.”](#)

**Record Keeping:** We urge all DSPs to maintain clear and detailed records of any hand sanitizer produced and distributed.

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