



FAQ: What can I do to provide emergency supplies if I cannot produce 95% ethanol, per the FDA guidance?

March 25, 2020

The FDA is the U.S. authority for regulating hand sanitizers, as hand sanitizers are over-the-counter non-prescription drugs. The FDA has issued new guidance for distilleries that are producing hand sanitizers, indicating that the ingredient used in production must be at 95% ABV. Distilleries that cannot produce ethanol at 95% ABV ([as per FDA guidance](#)) may be able to pursue two options to assist during the COVID-19 public health emergency:

1. If you can gain access to neutral grain spirits (NGS) at 95% ABV, the FDA is allowing you to use it in the production of hand sanitizer.
2. If you are receiving requests for hand sanitizer, but are unable to access or produce alcohol at 95%, a partnership with a compounding pharmacy may be an avenue for you to participate to respond to this emergency.

Compounding pharmacies are under the supervision of a licensed pharmacist. The pharmacist is able to exercise professional judgement on their production of hand sanitizers. A partnership with a compounding pharmacy may be an avenue for you to assist by supplying alcohol that they compound into hand sanitizer for distribution in their hospitals, clinics, or other places in need. You can contact a local partner to see if they can use your products to meet their needs.

Key Considerations:

- It is a good practice to make any compounding pharmacist aware of the [FDA guidance to industry](#), issued on March 23rd.
- Test and certify the ABV of the product you are supplying.
- Any ethanol provided should be clearly labeled to identify the ABV at the point of distillation. The label should also indicate if the alcohol is denatured or undenatured.

[Click here](#) to locate pharmacies near you. Simply click on PCAB Compounding Pharmacy under program type and add your zip code. Finally, please send your questions to legislation@americancraftspirits.org.

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