TTB and FDA Issue Special Guidance: Distilleries Producing Hand Sanitizers to Combat COVID-19

Mar 25, 2020

Categories:

Coronavirus Response Team
Publications

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In response to the coronavirus and a national shortage of hand sanitizer for front-line health care providers, social service agencies, and government agencies providing essential services, several distilleries have stepped up to convert the manufacturing of distilled spirits into making hand sanitizer. Alcohol is a key component in making hand sanitizer, and the Alcohol and Tobacco Tax and Trade Bureau (TTB) gave a nod to permitting the production of hand sanitizer using the formula established by the World Health Organization (WHO).

The Food and Drug Administration (FDA) has also provided a short-term safe harbor for distillers to manufacture hand sanitizers using the WHO formula under certain circumstances.The FDA's guidance states that it will not take action during the public health emergency against manufacturers of hand sanitizers that follow the WHO formula under certain specific circumstances. The TTB issued a special guidance to clarify that permitted distilleries can produce hand sanitizer without obtaining additional permits or bonds in accordance with the following conditions:

- The permitted distiller must produce hand sanitizer based upon an ethanol-based formula.
- Permitted distilleries are authorized to produce hand sanitizer pursuant to an exemption and must keep records of their operations during production.
- Hand sanitizer products that are made with denatured ethanol are not subject to the federal excise tax; but if the process uses undenatured ethanol, then the excise tax applies.
- TTB further states that formula approval is not required if the hand sanitizer is made using a specific mix of undenatured ethanol or denatured ethanol, glycerol and hydrogen peroxide (please see TTB for more specific requirements)

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- The guidance by TTB as indicated is initially approved only through June 30, 2020, and may be extended if necessary, to address the emergent nature of the COVID-19 virus pandemic.

The guidance and links to other regulations should be carefully reviewed by distilleries wanting to produce hand-sanitizer during the COVID-19 crisis.

To provide guidance and support to clients as this global public-health crisis unfolds, Frost Brown Todd has created a Coronavirus Response Team. Our attorneys are on hand to answer your questions and provide guidance on how to proactively prepare for and manage any coronavirus-related threats to your business operations and workforce.

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