

CLIENT ALERT

FDA and TTB Allowing Distilleries to Produce Hand Sanitizers to Combat COVID-19

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To combat the shortage of hand sanitizer, distilleries have started to manufacture this product. The Food and Drug Administration (FDA) recently issued a short-term safe harbor allowing distillers to manufacturer hand sanitizers according to one of the formulas it set forth. The FDA announced that it will not take any action during the COVID-19 emergency against distilleries that manufacturer hand sanitizer according to WHO formula standards.

Alcohol is generally subject to a federal excise tax by The Department of Treasury's Alcohol and Tobacco Tax and Trade Bureau (TTB). TTB, however, is waiving certain provisions of the Internal Revenue Code with regard to distilled spirits, and is providing certain exemptions and authorizations to distilled spirits permittees producing ethanol-based hand sanitizers during this emergency. Further, TTB is exempting alcohol fuel plants (AFPs) and distilled spirits plants (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.

Under the recent guidance, hand sanitizer products are not subject to federal excise tax if made with denatured ethanol. However, if made with undenatured ethanol, federal excise taxes still apply. The TTB measures were authorized under authorities that apply in disaster situations, and were initially approved through June 30, 2020, with the possibility for extension as necessary. The recently passed CARES Act provides that distillers do not have to pay federal excise taxes on alcohol used for hand sanitizer through January 1, 2021, when the sanitizer is made in accordance with FDA guidance.

For more information, please contact the professional(s) listed below, or your regular Crowell & Moring contact.

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