modern Distillery Age

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DISCUS Statement in Response to HHS Federal Register Notice on Distillers Making Hand Sanitizer

"This is a terrific outcome that will ease the minds of hundreds of distillers who answered the call to make hand sanitizer during this national public health emergency," DISCUS stated. "We want to thank HHS leadership for listening to our concerns and for their commitment to ensure that distillers who supported their communities are not unfairly charged this fee."

Background

The U.S. Department of Health and Human Services (HHS) has submitted a Notice to the Federal Register stating that those who entered the market to supply hand sanitizer during the Covid-19 public health emergency are not subject to the OTC Drug Monograph Facility Fee. As explained in the Notice, HHS has "concluded that persons that entered the over-the-counter drug market in order to produce hand sanitizers in reliance on the guidance cited above are not "identified as ... OTC drug monograph facilit[ies]" and are thus not subject to the facility fees authorized under section 744M of the FD&CT Act, 21 U.S.C. 379j-72."

HHS provides two reasons for reaching this conclusion:

- First, as the guidance itself acknowledges, the parties at issue are not in the drug manufacturing business. Many of them produce alcoholic beverages. These entities do not hold themselves out to the public as drug makers nor does the public generally encounter them as such. Under the extraordinary circumstances presented by the Covid-19 pandemic, the Department declines to identify these entities as OTC drug manufacturing facilities.
- Second, imposing facility fees on these entities is inconsistent with Congress' stated intent elsewhere in the CARES Act. Section 2308 of the Act provides a temporary exemption from excise taxes for distilled spirits "use[d] in or contained in hand sanitizer produced and distributed in a manner consistent with any guidance issued by the Food and Drug Administration that is related to the outbreak of virus SARS–CoV–2 or coronavirus disease 2019 (Covid-19)." It is unlikely Congress intended to save these entities from excise taxes only to impose tens of thousands of dollars in facility fees from an unfamiliar regulator. The Department declines to discern such a design under these circumstances.

In conclusion, the Department clarifies that persons that were not registered with FDA as drug manufacturers prior to the Covid-19 Public Health Emergency, which then later registered with FDA for the purpose of producing hand sanitizers, are not "identified" as "OTC drug manufacturing facilit[ies]" under section 744M of the FD&C Act, 21 U.S.C. 379j-72, and are thus not subject to the facility fee contained therein. The Department's conclusion does not apply to such persons which (1) manufacture, distribute, and sell over-the-counter drugs in addition to hand sanitizer, or (2) continue to manufacture (as opposed to hold, distribute, or sell existing inventories) hand sanitizer products as of December 31 of the year immediately following the year during which the Covid-19 Public Health Emergency is terminated. In those cases, the Department may identify such persons as OTC drug manufacturing facilities.

Are People Really Drinking More During the Pandemic?

by The IWSR, www.theiwsr.com

In the early days of Covid-19 lockdown, reports of consumers panic buying beverage alcohol led to the impression that people were drinking more than usual during the pandemic. Although pantry loading behavior soon tapered off, many industry watchers were asking themselves, "are consumers drinking more during Covid-19?"

IWSR answered this question with the publication of an in-depth assessment of beverage alcohol consumption and consumer behavior this past year. IWSR's analysis covers 20 key markets (including the global travel retail channel) that drive 75%+ of global alcohol volumes.

Beverage Alcohol Volume Consumption Will Fall by -8% in 2020

IWSR data shows that beverage alcohol volume consumption during the pandemic was down across almost all markets, including Australia, Brazil, China, Colombia, France, Germany, India, Italy, Japan, Mexico, Poland, Russia, South Africa, Spain, Thailand, Turkey, the U.K. and the global travel retail channel. Only the U.S. and Canada will see increases in beverage alcohol volume consumption in 2020 (both at over 2% total volume increases). In total, beverage alcohol volumes across the 19 countries are set to fall by -8% in 2020. Global travel retail volumes are forecast to be down -68% in 2020.

The key reason for this decline is largely down to decreased purchasing in the on-trade. Some countries were able to bear the brunt of the on-trade closures better than others. In Australia, for example, the beverage alcohol market is generally weighted more towards the off-premise, which meant lockdowns did not impact drinking occasions as drastically as in other countries. Australian wine consumers, for example, almost completely transferred on-trade purchasing behaviors to the off-trade. Total beverage alcohol volume consumption in Australia will fall by approximately -1% in 2020. However, in many markets, the increase in at-home consumption did not compensate for the closures of the on-trade.

Longer-to-Consume & Lower Strength Offerings Resonate During Covid-19

In the U.K., IWSR estimates that total beverage alcohol volume consumption will decline by -10% in

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