# FDA and TTB Temporarily Lift Regulations Governing Hand Sanitizer in Light of COVID-19, Allowing Distilleries and Unlicensed Manufacturers to Produce Alcohol-Based Hand Sanitizers

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The Coronavirus Disease 2019 ("COVID-19") pandemic has catalyzed a demand for alcohol-based hand sanitizers. As a result, the Food and Drug Administration ("FDA") and the Alcohol and Tobacco Tax and Trade Bureau ("TTB") have recently released guidance regarding the production of hand sanitizers to meet the demand during the pandemic. As discussed below, these agencies have loosened restrictions on the production of hand sanitizers which allow manufacturers, including alcohol beverage manufacturers, to produce these products during this time of need.

Food and Drug Administration

FDA enforces regulations that govern the production of alcohol-based hand sanitizers which are classified as over-the-counter ("OTC") drugs.[1] Prior to the COVID-19 pandemic, FDA's regulations require manufacturers of alcohol-based hand sanitizers to hold a specific drug-manufacturing license that allows them to produce alcohol-based hand sanitizers while abiding by strict ingredient and labeling requirements. Accordingly, prior to the issuance of the FDA enforcement policy outlined below, the unregulated or unlicensed production of alcohol-based hand sanitizers would constitute a violation of Federal Food Drug and Cosmetic Act likely subjecting the violator to penalties and fees.

However, in light of the increased demand for hand sanitizers, the FDA released a guidance document, *Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID-19)*, providing that the agency will exercise enforcement discretion with respect to the production of alcohol-based hand sanitizers.[2] Addressing the FDA's "critical role in protecting the United States from emerging infectious diseases,"[3] the FDA acknowledged that consumers and health care professionals are currently experiencing difficulties accessing alcohol-based hand sanitizers, leading to a nationwide shortage.[4] As a result, FDA's issued non-binding guidance that allows companies, like alcohol beverage manufacturers, that are not registered as OTC drug manufacturers, to prepare alcohol-based hand sanitizers under specific circumstances.

In accordance with the FDA guidance document the following requirements apply to an unlicensed firm that seeks to produce alcohol-based hand sanitizers:

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[1] *See* Sections 501(a)(2)(B), 502(f)(1), 505, and 582 of the FD&C Act, codified as 21 U.S.C. §§ 351(a)(2)(b), 352(f)(1), 355, and 360eee -1.

[2] *See* U.S. Food and Drug Administration, "Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID-19)" at p. 1; accessible online at: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-temporary-policy-preparation-certain-alcohol-based-hand-sanitizer-products-during.

[3] *See* U.S. Food and Drug Administration, "Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID-19)" at page 1.

[4] *See id.* at p. 3.

- The product must be produced in accordance with the World Health Organization ("WHO") recommendations utilizing specific United States Pharmacopeia grade ingredients, no additional active or inactive ingredients may be added;
- records must be kept to ensure the products produced adhere to the formula specified;
- the sanitizer must be prepared under sanitary conditions and with well-maintained equipment;
- The manufacturer must utilize the most accurate method of analysis available at the site for verification of alcohol content;
- the sanitizer must be labeled accordance with the examples provided in the guidance document; and
- the company must register its facility and list the sanitizer in the FDA Drug Registration and Listing System.

In addressing the enforceability of the guidance, FDA explicitly provided that the guidance documents "do not establish legally enforceable responsibilities."[5] Rather, the guidance serve the purpose of FDA's opinion on a topic and therefore should be taken as a recommendation absent citing to statutory authority.[6] Thus, the guidance does not create nor abolish any legal rights, but provides an outlet to temporarily deregulate an area of drug manufacturing that is otherwise narrowly regulated. It is important to note FDA's intention to exercise enforcement discretion in this instance will expire at the end of the duration of the current public health emergency.

Alcohol and Tobacco Tax and Trade Bureau

In addition to the FDA guidance, TTB released guidelines that allow for the temporary production of an ethanol-base hand sanitizer by a TTB permitted Alcohol Fuel Plant (AFP) or, a Beverage Alcohol distillery (DSP) without having to first obtain formula approval from TTB, provided the hand sanitizer is produced according to a prescribed formula. The TTB guidance provides:

> Due to the Coronavirus 2019 (COVID-19) pandemic, the Acting Administrator of the Alcohol and Tobacco Tax and Trade Bureau (TTB) has found that it is necessary or desirable to waive provisions of internal revenue law with regard to distilled spirits, and therefore is providing certain exemptions and authorizations to distilled spirits permittees who wish to produce ethanol-based hand sanitizers to address the demand for such products during this emergency. 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. These measures are generally authorized under authorities that apply in disaster situations, and as a result, are initially approved through June 30, 2020, with the possibility for extension as necessary.[7]

As noted in both the FDA and TTB guidance documents, the hand sanitizers must be produced in accordance with the WHO recommendations. The WHO has issued two formulas for hand sanitizers: (1) using ethanol (distilled spirits) and (2) utilizing isopropyl alcohol. TTB does not regulate formula #2 since there are no taxable alcohols involved. This falls under FDA oversight.

**Materials provided for Small Volume Productions under WHO Formulas**

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[5] *See id.* at p.2.
[6] *See id.*
[7] *See* Alcohol and Tobacco Trade Bureau, "Production of Hand Sanitizer to Address the COVID-19 Pandemic," accessible online at: https://www.ttb.gov/public-guidance/ttb-pg-2020-1.

*FORMULATION 1:*

- Ethanol 96%
- Hydrogen peroxide 3%
- Glycerol 98%
- Sterile distilled or boiled cold water

*FORMULATION 2:*

- Isopropyl alcohol 99.8%
- Hydrogen peroxide 3%
- Glycerol 98%
- Sterile distilled or boiled cold water

The WHO standards for strengths for ethanol (alcohol) at 96%, with a + or – 5% accuracy rate. Therefore, normal commercial beverage alcohols are within WHO tolerance range for ethanol of 91% to 100%. Thus, the formula used may have Federal excise tax implications for alcohol beverage manufacturers.

As noted in the TTB guidance, hand sanitizer products are not subject to Federal excise tax if made with specially denatured alcohol ("SDA"). However, if made with undenatured ethanol, Federal excise tax applies. WHO Formulation #1 is not made with SDA and the ethanol is taxable because the ethanol is undenatured. To release the tax a SDA formula must be used in place of the undenatured ethanol. An example of an SDA formula is *SDA #40-B, § 21.76 Formula No. 40-B.*, which provides: To every 100 gallons of alcohol add: One-sixteenth avoirdupois ounce of denatonium benzoate, N.F., and 1/8 gallon of *tert*-butyl alcohol.[1] Utilizing SDA 40-B in place of ethanol in Formula #1 would ensure the alcohol utilized is not taxable.

As the forgoing summary demonstrates, and as many alcohol beverage manufacturers have already learned, the production of hand sanitizers present an unique opportunity for members of the alcohol beverage industry to quickly pivot and assist communities throughout the U.S. in combating the spread of COVID-19. However, this opportunity also presents many questions for beverage manufacturers including how to adopt proper production methods and recordkeeping requirements to ensure limited Federal excise tax implications associated with the production of hand sanitizers.

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[1] Technically, SDA #40-B requires two denaturants: denatonium benzoate (brand name Bitrix) and tert-butyl alcohol. FDA subsequently exempted the use of tert-butyl alcohol requiring only Bitrix to be used in WHO Formula #1. *See*, FDA, "Temporary Policy for Manufacture of Alcohol for Incorporation Into Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID-19): Guidance for Industry," (Updated August 7, 2020), at p.5; the FDA's guidance is accessible online at: https://www.fda.gov/media/136390/download.

For more information on any of the aforementioned guidance, their impact, or other regulatory alcohol and tobacco compliance, contact GrayRobinson's Nationwide Alcohol Beverage Practice at 866-382-5132. Anna Wiand is a Shareholder, David Bateman and Charles Tull are TTB Government Consultants, and Lauren Voke is a Law Clerk with GrayRobinson's Nationwide Alcohol Beverage Practice. David and Charlie both have decades of experience at TTB working with TTB's requirements for the production and taxation of these types of products.