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FDA ISSUES GUIDANCE ON ALCOHOL-BASED HAND SANITIZER PRODUCTION IN RESPONSE TO COVID-19

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In response to the outbreak of COVID-19, the Food and Drug Administration ("FDA") has issued guidance for industry that will temporarily expand manufacturers' ability to legally produce and sell alcohol-based hand sanitizer. These new measures are intended to address a shortage of alcohol-based hand sanitizer products, as well as reports that consumers have attempted to produce hand sanitizer for their own personal use, which raises serious safety concerns. This Alert summarizes the latest guidance and provides takeaways for consideration.

1. Policy for Temporary Compounding of Certain Alcohol Based Hand Sanitizer Products During the Public Health Emergency (March 2020).

The first guidance to issue is specifically directed at pharmacists in state-licensed pharmacies or federal facilities and registered outsourcing facilities, which the FDA describes collectively as "compounders."

Compounding is a practice in which a licensed pharmacist, physician, or, in the case of an outsourcing facility, a person under the supervision of a licensed pharmacist, combines, mixes, or alters ingredients of a drug to create a tailor-made medication for a patient. In this guidance document, FDA indicates it "does not intend to take action against compounders that prepare alcohol-based hand sanitizers for consumer use and for use as health care personnel hand rubs for the duration of the public health emergency" under the following circumstances:

- The hand sanitizer is compounded using only the specified United States Pharmacopoeia (USP) grade ingredients in the preparation of the product (percentage in final product formulation) consistent with World Health Organization (WHO) recommendations, including either 80% denatured ethanol or 75% isopropyl alcohol, glycerol, hydrogen peroxide, and sterile water;
- The compounder does not add other active or inactive ingredients;
- The compounder takes special care to ensure the alcohol ingredient is correct;

- The hand sanitizer is prepared under the same conditions used by the compounder to produce similar nonsterile drugs; and
- The hand sanitizer is labeled consistent with FDA's proposed draft labels, which are attached to the guidance.

FDA's temporary policy departs from typical compounding practices in that it does not require compounders to obtain a patient-specific prescription under these limited circumstances

2. Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID-19) (March 2020).

The second guidance document, directed to companies that register as over-the-counter (OTC) drug manufacturers to prepare alcohol-based hand sanitizers, provides that FDA will not take enforcement action against entities that prepare alcohol-based hand sanitizers for consumer use and for use as healthcare personnel hand-rubs during the COVID-19 public health emergency. In addition to the requirements set forth for compounding pharmacists discussed above, these companies must also maintain a record to ensure each batch matches the formula developed for the drug product, prepare the hand sanitizer under sanitary conditions, use the most accurate method available to verify the product's alcohol content prior to distribution, register their facility and list these products in the FDA Drug Registration and Listing System (DRLS), and develop a method to collect adverse event reports and relay that data to FDA.

3. Temporary Policy for Manufacture of Alcohol for Incorporation Into Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID-19) Guidance for Industry (March 2020).

The third and most recent guidance is directed at distillers and other entities that manufacture alcohol, are not currently registered drug manufacturers, and would like to produce alcohol for incorporation into alcohol-based hand sanitizers.

In this publication, FDA announces that it "does not intend to take action against alcohol production firms that manufacture alcohol (i.e., ethanol or ethyl alcohol) for use as the Active Pharmaceutical Ingredient (API) in alcohol-based hand sanitizers for consumer use and for use as health care personnel hand rubs for the duration of the public health emergency[.]"

Unlike the guidance for compounders and other manufacturers, this document only applies to ethanol-based hand sanitizer products. Alcohol producers are required to comply with similar requirements in formulating the hand sanitizer, including using USP grade ingredients in the preparation of the product consistent with WHO recommendations. The agency also requires alcohol production firms register their facilities and list these products in the FDA DRLS.

The most significant requirement is that alcohol producers "denature" the alcohol using specified formulas outlined by FDA in order to give the hand sanitizer a bitter taste to discourage oral

consumption. According to the agency, "[t]his is critical because there have been reports of adverse events, including deaths, from unintentional ingestion of hand sanitizer, particularly in young children." If a company distributes the alcohol to another producer, it must label the product in accordance with the samples provided by FDA, which require the label to identify the alcohol content testing method, disclose whether or not the alcohol is denatured, and state the product is "non-potable."

This FDA guidance is consistent with a March 18, 2020 announcement from the federal Alcohol and Tobacco Tax and Trade Bureau (TTB) stating that permitted alcohol fuel and beverage distilled spirits plants "can immediately commence production of hand sanitizer or distilled spirits (ethanol) for use in hand sanitizer, as described below, without having to obtain authorization first." The TTB's regulatory waivers allow whiskey and vodka distillers to produce hand sanitizers, but the distillers tend to produce much smaller volumes of alcohol than an ethanol plant could generate. If made with denatured ethanol, affected alcohol producers are not subject to federal excise tax.

The CARES Act on Alcohol-Based Hand Sanitizer

The Coronavirus Aid, Relief, and Economic Security Act (CARES Act), which the president signed into law on March 27, 2020, establishes a temporary exception from excise tax for alcohol used to produce hand sanitizer. Specifically, section 2308 of the CARES Act amends Section 5214(a) of the Internal Revenue Code of 1986 to read, in relevant part: "Distilled spirits on which the internal revenue tax has not been paid or determined may, subject to such regulations as the Secretary shall prescribe, be withdrawn from the bonded premises of any distilled spirits plant in approved containers… with respect to distilled spirits removed after December 31, 2019, and before January 1, 2021, free of tax for use 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)."

Section 2308 of the CARES Act also provides that alcohol used to produce hand sanitizer after December 31, 2019, and before January 1, 2021 and distributed in a manner consistent with FDA guidance is not subject to any requirements related to labeling or bulk sales under: 1) section 105 or 106 of the Federal Alcohol Administration Act (27 U.S.C. 205, 206) or 2) section 204 of the Alcoholic Beverage Labeling Act of 1988 (27 U.S.C. 215).

Takeaways

While FDA's guidance documents are not legally enforceable, they outline the Agency's current thinking on a topic. These three sets of guidance are notable in that they dramatically relax existing regulation and enforcement relating to a widely popular consumer product – and a product that has been under scrutiny by FDA for years, long before coronavirus put hand sanitizer in the spotlight. As always, we recommend following agency guidance as closely as possible to avoid enforcement action.

We at Bryan Cave Leighton Paisner LLP have extensive experience helping clients with all legal issues arising in the food and agribusiness industries. We will continue to monitor developments amid the COVID-19 pandemic and are happy to address your questions and concerns. Please do not hesitate to reach out to the authors of this Client Alert or any member of BCLP's Food and Agribusiness Team if you have any questions, and you can follow our ongoing COVID-19 coverage at bclplaw.com.

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