New FDA Guidance to Non-Drug Manufacturers for Alcohol-Based Hand Sanitizers to Combat COVID-19

A. Introduction

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As COVID-19 continues its path across the world, many chemical manufacturers and distillers are wondering how they can assist in efforts to prevent the spread of this virus. This is particularly true when adherence to basic hygienic practices such as washing your hands are critical to limit the spread of the novel virus. Where soap and water are not readily available, consumers and medical personnel increasingly rely on alcohol-based hand sanitizers. Many chemical manufacturers, both traditional and some non-traditional manufactures such as distillers and perfume manufacturers, are evaluating how or whether they can make sanitizer. But in making this evaluation, many manufacturers are concerned about future regulatory and product liability exposure from these new products.

We provide this short update to provide recommendations and guidance on regulatory requirements and product liability exposure for manufacturers who chose to make hand sanitizer.

B. Regulatory Overview

Alcohol based hand sanitizers are regulated by the Food and Drug Administration as drugs. Generally, before any manufacturer may sell a drug, it must first register as a drug manufacturer. The Federal Food, Drug, and Cosmetic Act ("FDCA") then requires that the drug manufacturer first obtain FDA approval prior to marketing or selling any brand-name or generic drug in interstate commerce. 21 U.S.C. § 355(a). The FDA drug approval process can be "onerous and lengthy." *Mut. Pharm. Co., Inc. v. Bartlett*, 570 U.S. 472, 476 (2013).

However, in an attempt to increase the supply of alcohol-based sanitizers, on March 27, 2020, the FDA published multiple temporary policies ("guidance documents") for the production of alcohol-based sanitizer products to expand and incentivize production of hand sanitizer. The guidance documents temporarily suspend normal FDA requirements and waive some FDA enforcement actions. The guidance documents also permit Emergency Use Authorizations (EUA) issued by the FDA, temporarily allowing production of unapproved products or uses of approved products – i.e. alcohol-based hand sanitizers – from manufacturers not currently registered to manufacture and sell drugs. Below is a summary of that FDA guidance.

C. FDA Guidance

i. *Temporary Policy for Manufacture of Alcohol for Incorporation Into Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID-19)*.

The guidance explicitly states the FDA does ***not intend to take action***[1] against "***alcohol producing firms***"[2] that produce ethanol or ethyl alcohol for use as the Active Pharmaceutical Ingredient (API) in alcohol-based hand sanitizers for consumer use ***and*** use by health care personnel for the duration of the emergency declaration. Importantly, the guidance applies only to entities that are ***not*** currently registered drug manufacturers and for the production of ethanol (ethyl alcohol); not isopropyl alcohol or other ingredients included in alcohol-based hand sanitizers.

To follow the guidance and obtain emergency use authorization from the FDA, however, manufacturers must adhere to specific production and process requirements.

The alcohol produced must not be less than 94.9% ethanol by volume.[3] Due to the risk of adverse events – unintentional ingestion by children especially – the guidance requires the alcohol also be denatured ***prior to use***. It may be denatured either by the alcohol producer or at point of production of the finished product.[4] The alcohol producing firm must ensure the ethanol content in the finished API (***before*** being denatured) is at least 94.9% by volume. If the API is being sent to another firm for ultimate production, it must appropriately label at the then-current content so it may be produced at the required and labeled strength of 80% v/v. Beyond alcohol, water, and denaturants, there cannot be any other ingredients added to the product. The alcohol must also be prepared under sanitary conditions and measured accurately.[5]

Alcohol production firms must also register their facility and list these products in the FDA Drug Registration and Listing System.[6] Once registered, firms receive automatic confirmation

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[1] FDA will not take action against alcohol producing firms for the duration of the health emergency for violations of sections 501(a)(2)(B), 501(b), 502(f)(1), 505, or 582 of the FD&C Act (21 U.S.C. 351(a)(2)(B), 351(b), 352(f)(1), 355, and 360eee-1. [2] Whether a firm is a "alcohol producing firm" is not defined but appears to depend the type of alcohol produced. It is noted that *alcohol* as referenced in the guidance is ethanol (ethyl alcohol) as defined in the United States Pharmacopeia and National Formulary (USP-NF) and as ethyl alcohol in the Food Chemical Codex.

[2] Whether a firm is a "alcohol producing firm" is not defined but appears to depend the type of alcohol produced. It is noted that *alcohol* as referenced in the guidance is ethanol (ethyl alcohol) as defined in the United States Pharmacopeia and National Formulary (USP-NF) and as ethyl alcohol in the Food Chemical Codex.

[3] It may be lower; provided, however, it is labeled accordingly and the content produced allows for the finished sanitizer to meet a concentration of 80% v/v. Any water used to adjust this finished ethanol content must be sterile and used as quickly as possible after made sterile or purified. The guidance is clear that the ethanol alcohol is derived from distillation or fermentation typically used for consumer goods. If derived synthetically, it may be used only if it meets United States Pharmacopeia ("USP") or Food Chemical Codex ("FCC") grade.

[4] If the alcohol is ***not*** denatured prior to be sent to producer for ultimate production, the API must be labeled accordingly as undenatured. The FDA provided two separate regulations for guidance on denaturing formulas. Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20 and 21 provide a number of formulas for denaturing alcohol. Formulas for use in hand sanitizers are included in Appendix C of the document and include: Formula 40A or 40B with or without the tert-butyl alcohol Formula 3C (isopropyl alcohol)).

[5] As defined under section 501(a)(2)(A) of the FD&C Act (21 U.S.C. §§ 351(a)(2)(A)). The alcohol production firm must also use the most accurate method of analysis available at the site for verification of ethanol content prior to any distribution or use in ultimate production of hand sanitizer.

[6] DRLS, https://www.fda.gov/drugs/guidance-compliance-regulatory-information/drug-registration-and-listing-system-drls-and-edrls

from FDA and do not need to wait for further communication before they begin to manufacture and distribute these products.

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

To further enhance the availability of hand sanitizer products, the FDA has also issued guidance on the compounding certain alcohol based hand sanitizer products and guidance for firms that register as over-the-counter (OTC) drug manufacturers. In its *Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID-19) (March 2020)*, the FDA issued guidance to firms who register as over-the-counter drug manufacturers to temporarily produce certain alcohol-based hand sanitizer products.

This guidance bears many of the same process and production requirements as the prior policy and industry guidance but applies specifically to the producers of sanitizer itself rather than production of alcohol only. Again, in the guidance, the FDA states it does ***not intend to take action***[7] against ***firms*** that prepare alcohol-based hand sanitizers for both consumers and health care personnel the duration of the health emergency. There are, of course, process and production requirements for participation.

The hand sanitizer must be manufactured using ***either*** ethanol[8] (not less than 94.9% by volume) ***or*** Isopropyl alcohol; Glycerin (USP or FCC "food grade"); Hydrogen Peroxide;[9] and sterile water. The World Health Organization recommends the following formula, which is incorporated into this guidance: Alcohol (ethanol) (80%, volume/volume (v/v)) in an aqueous solution ***or*** Isopropyl Alcohol (75%, v/v) in an aqueous solution; Glycerin (glycerol) (1.45% v/v); Hydrogen peroxide (0.125% v/v); and Sterile distilled water or boiled cold water. No other active or inactive ingredients should be added, especially any ingredients to improve smell or taste due to risk of unintentional or accidental ingestion by children.

Again, the ethanol must either be denatured by the alcohol producer (as stated above) or at the point of production of the finished product. The same formulas (Formula 40A or 40B with or without the tert-butyl alcohol and Formula 3C (isopropyl alcohol)) provided in the policy guidance for alcohol producing firms are again applicable here. The firm must also pay close attention, and document, the active ingredients are at the correct percentages by volume for each batch developed. The product must be produced in sanitary conditions using the most accurate method of analysis available at the site for verification of alcohol.[10]

Product labeling must include the name and contact information of the manufacturer.[11] To the extent you desire to make any representations on the finished product, a note of caution:

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[7] FDA will not take action against firms for the duration of the health emergency for violations of sections 501(a)(2)(B), 502(f)(1), 505, or 582 of the FD&C Act (21 U.S.C. §§ 351(a)(2)(B), 352(f)(1), 355, and 360eee-1).

[8] Alcohol (ethanol) is derived from distillation or fermentation typically used for consumer goods. If derived synthetically, it may be used only if it meets United States Pharmacopeia ("USP") or Food Chemical Codex ("FCC") grade.

[9] Hydrogen Peroxide Concentrate USP, Hydrogen Peroxide Topical Solution USP, or technical grade if concentration is within either of the foregoing USPs.

[10] As defined in section 501(a)(2)(A) of the FD&C Act (21 U.S.C. § 351(a)(2)(A)).

[11] The following labeling options are available according to formula, contents, and intended use: (Labeling for Ethyl Alcohol Formulation Consumer Use), (Labeling for Isopropyl Alcohol Formulation Consumer Use),

lawsuits have recently been brought against FDA approved and regulated manufacturers and distributors for unsubstantiated claims. For example, both Target[12] and Germ-X[13] have been sued for claims that their hand sanitizers kill 99.9% of germs.[14] Accordingly, any representation of effectiveness must be supported by scientific testing and research.

Firms must also register their facility and list these products in the FDA Drug Registration and Listing System.[15] Once registration is complete, firms will receive automatic confirmation from the FDA and do not need to wait for a further communication from FDA before they begin to manufacture and distribute these products. Firms must also have a way to accept adverse event reports as required by Section 760 of the FD&C Act (21 U.S.C. § 379aa). Importantly, the policy explicitly states that it does not apply to all hand sanitizer products.[16]

D. PREP Act Declaration

As discussed at length in a previous update,[17] the Public Readiness and Emergency Preparedness Act (PREP Act), enacted in 2005, authorized the Secretary of the Department Health and Human Services (HHS) to issue a Declaration immunizing "Covered Persons" from liability associated with the use of certain medical "Covered Countermeasures." The HHS March 17, 2020 Declaration extends broad statutory liability immunity for the duration of the emergency and for the following "Recommended Activities": the manufacture, testing, development, distribution, administration, and use of the "Covered Countermeasures," subject to the other conditions in the Declaration and PREP Act. 85 FR 15198[18]

"Covered Persons" are "***manufacturers***," "***distributors***," "program planners," "qualified persons," and their officials, agents, and employees, as those terms are defined in the PREP Act.

(Labeling for Ethyl Alcohol Formulation Health Care Personnel Handrub Use), or (Labeling for Isopropyl Alcohol Formulation Health Care Personnel Handrub Use). Appendices are attached as example.

[12] https://www.classaction.org/news/target-facing-class-action-lawsuit-over-germ-killing-claims-for-store-brand-hand-sanitizer

[13] https://www.law360.com/articles/1251207

[14] The suits allege that claim is not backed by any reliable scientific studies and cite a January 2020 letter sent by the FDA to Purell-maker GOJO Industries concerning its representations that the alcohol-based product can kill 99.99 percent of germs and prevent against the flu and other viruses. In the case of the Germ-X case, the plaintiffs allege Germ-X either explicitly says the sanitizer counteracts coronavirus and other communicable viruses or imply "this misrepresentation with the use of wording, images, and links."

[15] DRLS, https://www.fda.gov/drugs/guidance-compliance-regulatory-information/drug-registration-and-listing-system-drls-and-edrls

[16] *See Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID-19) (March 2020)* "This policy does not extend to other types of products, such as: products (1) that use different active ingredients; (2) whose potency falls above or below the formulation described above; (3) that are marketed with claims that do not conform to the "Topical Antimicrobial Drug Products for Over-the-Counter Human Use; Tentative Final Monograph for Health-Care Antiseptic Drug Products, 59 FR 31402-01 (e.g., pathogen-specific disease claims): (4) that are surgical hand rubs; or (5) whose labeling is false or misleading in any particular."

[17] *See "Navigating Product Liability and Regulatory Issues as Manufacturers Rush to Combat COVID-19"* https://www.bowmanandbrooke.com/insights/medical-products-to-combat covid19?utm_source=hs_email&utm_medium=email&utm_content=85622098&_hsenc=p2ANqtz-9apKpp5MUO_wq50U70pFEVgD3NLeFVqrfSlWre-CjkWRpLs7R5Fn_qaiDrwBS3OAfG5YinjsuCzeZhc2d63lJmlvD_3ZZ8dn0zVU2O5Q6jfgk5DnM&_hsmi=85622098

[18] *Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19*, 85 FR 15198, at 15, 85 FR 15198-01, at 15.

85 F.R. at 15201. "Covered Countermeasures," moreover, are "any antiviral, any other drug, any biologic, any diagnostic, ***any other device***, or any vaccine, used to treat, diagnose, cure, ***prevent, or mitigate COVID-19, or the transmission of SARS-CoV-2*** or a virus mutating therefrom, ***or any device used in the administration of any such product***, and all ***components*** and ***constituent materials*** of any such product." 85 F.R. at 15202. "Covered Countermeasures" must also meet the statutory definition under the PREP Act, which incorporate various regulatory requirements such as being a "qualified pandemic or epidemic product,"[19] "security countermeasure,"[20] or "biological product"[21] as authorized for emergency use in accordance with section 564, 564A, or 564B of the FD&C Act. § 247d(i)(1)(C). Manufacturers of alcohol-based hand sanitizer or its component parts are "Covered Persons," and alcohol-based sanitizers are "Covered Countermeasures" under the Declaration.

The liability immunity created in the Declaration precludes any liability if they allege an injury caused by a countermeasure, or if the claims are due to manufacture, delivery, distribution, dispensing, or management and operation of countermeasure programs at distribution and dispensing sites. If a plaintiff were to allege a manufacturer's alcohol-based hand sanitizer failed to prevent that plaintiff from contracting COVID-19, those claims are barred. The Declaration also provides broad geographic and use immunity for manufacturers of Covered Countermeasures. Liability immunity extends whether the alcohol-based hand sanitizers are donated or commercially sold, extends across the country, and extends for sanitizers provided to the federal government or provided in accordance with state/local public health initiatives. It is important to note that liability immunity is a defense that can be raised and does not necessarily bar the filing of an action against a manufacturer.

But while the PREP Act extends broad immunity to "Covered Persons" developing "Covered Countermeasures," there are limitations. The PREP Act does not immunize a manufacturer from willful misconduct or unsubstantiated claims. It will not bar a cause of action against an otherwise "Covered Person" for death or serious injury proximately caused by willful misconduct as stated in 42 U.S.C. § 247d-6d.[22] Additionally, the PREP Act does not extend liability immunity for marketing or communications regarding Covered Countermeasures. There is no liability immunity that extends to claims of misrepresentation, false advertising, or unfair and deceptive trade practices.

E. Recommendations

For manufacturers looking to manufacture and distribute alcohol-based hand sanitizers to combat COVID-19 and want to ensure the protections afforded by the FDA guidance documents and the PREP Act Declaration, our recommendations are as follows:

- Monitor FDA guidance documents related to the production and distribution of alcohol-based hand sanitizers on a periodic basis. These documents are subject to change and FDA can modify these documents as the COVID-19 situation warrants.

[19] *See* 42 U.S.C § 247d-6d(i)(7)(A); § 247d-6d(i)(1)(B).
[20] *See* 42 U.S.C. § 247d-6b(c)(1)(B).
[21] *See* 42 U.S.C. § 262(i)).
[22] *See* 42 U.S.C. § 247d-6d(c)(1) "Willful misconduct" under the statute means "an act or omission that is taken intentionally to achieve a wrongful purpose; knowingly without legal or factual justification; and in disregard of a known or obvious risk that is so great as to make it highly probable that the harm will outweigh the benefit."

- Comply with FDA guidance document recommendations and ensure registration with FDA. This can be done in parallel with converting manufacturing capacity for sanitizer production.

- Follow PREP Act directives on distribution and sale of the product. Commercially reasonable sales should provide liability immunity.

- Maintain robust recordkeeping for each production lot. Should future regulatory or liability actions occur, having robust recordkeeping will help reduce future exposure.

- Ensure product labeling and advertisements comply with regulations and do not make unfounded/unsubstantiated claims about the efficacy of the product or the ability of the product to protect against infection.

F. Conclusion

As the United States and the world continues to weather the storm of COVID-19, Bowman and Brooke remains committed to providing accurate, relevant legal and regulatory updates to help our clients navigate these uncharted waters. We further welcome the opportunity to discuss any specific questions are clients may have.