By Jon Hernan, Patrick Cleary, and Ryan McCarthy

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

Manufacturers considering re-tasking resources to assist in producing hand sanitizer to help battle the COVID-19 pandemic should take heed of the FDA product requirements to avoid future liability.

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 nontraditional manufacturers, such as distillers and perfume manufacturers, are evaluating how or whether they can

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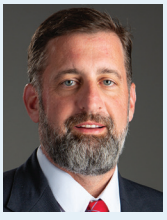
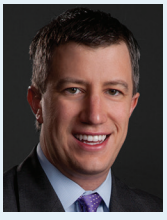


make sanitizer. But in making this evaluation, many manufacturers are concerned about future regulatory and product liability exposure from these new products.

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

Regulatory Overview

Alcohol-based hand sanitizers are regulated by the U.S. Food and Drug Administration (FDA) 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 secure FDA approval before marketing or selling any brand-name or generic drug in interstate commerce. 21 U.S.C. §355(a). The FDA drug approval process normally 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 (referred to here collectively as "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 the FDA to issue Emergency Use Authorizations (EUAs), temporarily allowing production of unapproved products or uses of approved products, such as alcohol-based hand sanitizers, from manufacturers not currently registered to manufacture and sell drugs. Below is a summary of that FDA guidance.

FDA Guidance

The FDA has issued guidance for firms that are not currently registered drug manufacturers but that wish to produce alcohol for incorporation into alcohol-based hand sanitizers, *Temporary Policy for Manufacture of Alcohol for Incorporation into Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID-19)*, and guidance for entities that are not currently licensed or registered drug manufacturers that wish to prepare alcohol-based hand sanitizers, for public distribution or for their own internal use, *Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID-19)* (March 2020).

Temporary Policy for Manufacture of Alcohol for Incorporation into Alcohol-Based Hand Sanitizer Products

The *Temporary Policy for Manufacture of Alcohol for Incorporation into Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID-19)* guidance explicitly states that the FDA does not intend to take action against "*alcohol **producing** firms*" that produce ethanol or ethyl alcohol for use as the active pharmaceutical ingredient (API) in alcohol-based hand sanitizers for consumer use *and* for use by healthcare personnel for the duration of the emergency declaration under of sections 501(a)(2)(B), 501(b), 502(f)(1), 505, or 582 of the FDCA. 21 U.S.C. §§351(a)(2)(B), 351(b), 352(f)(1), 355, & 360eee-1. Importantly, the guidance applies only to entities that are *not* currently registered drug manufacturers and for the production of ethanol (ethyl alcohol), not for 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 percent ethanol by volume. It may be lower, provided that it is labeled accordingly and the finished sanitizer meets a concentration of 80 percent volume per volume (v/v). Any water used to adjust this finished ethanol content must be sterile. The guidance is clear that the ethanol alcohol is to be derived from the distillation or fermentation processes typically used for consumer goods. If it is derived synthetically, it may be used only if it meets United States Pharmacopeia (USP) or Food Chemical Codex (FCC) grade.

Due to the risk of adverse events—unintentional ingestion by children especially—the guidance requires the alcohol also to be denatured *before use*. It may be denatured either by the alcohol-producing firm, or if the alcohol-producing firm is not producing the finalized sanitizer, at the point of production of the finished product. If the alcohol is *not* denatured before being sent to a producer for ultimate production, the API must be labeled accordingly as undenatured. The FDA has also issued guidance on formulas for denaturing (Formula 40A or 40B with or without the tert-butyl alcohol, and Formula 3C (isopropyl alcohol)).

In either event, the alcohol-producing firm must ensure that the ethanol content in the finished API *before* being denatured is at least 94.9 percent by volume. If the API is being sent to another firm for ultimate production, it must appropriately label according to the then-current content so that it may be produced at the required and labeled strength of 80 percent 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 as defined under section 501(a)(2)(A) of the FDCA. 21 U.S.C. §351(a)(2)(A).

Alcohol production firms must also register their facility and list these products in the FDA Drug Registration and Listing System. Once registered, firms receive automatic confirmation from the FDA and do not need to wait for further communication before they begin to manufacture and distribute these products.

Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products

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 *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 that register as over-the-counter drug manufacturers to produce certain alcohol-based hand sanitizer products temporarily.

This guidance bears many of the same process and production requirements as the policy and industry guidance discussed above, but it applies specifically to the producers of sanitizer itself rather

than production of alcohol only. Again, in the guidance, the FDA states that it does *not intend to act* against *firms* that prepare alcohol-based hand sanitizers for both consumers and healthcare personnel for the duration of the health emergency under sections 501(a)(2)(B), 502(f)(1), 505, or 582 of the FDCA. 21 U.S.C. §§351(a)(2)(B), 352(f)(1), 355, and 360eee-1. There are, again, process and production requirements for participation.

The hand sanitizer must be manufactured using *either* ethanol (not less than 94.9 percent by volume, and if synthetic, USP and FCC grade), *or* isopropyl alcohol; glycerin (USP or FCC "food grade"); hydrogen peroxide; and sterile water. The World Health Organization recommends the following formula, which is incorporated into this guidance: alcohol (ethanol) (80 percent, v/v), in an aqueous solution, *or* isopropyl alcohol (75 percent, v/v), in an aqueous solution; glycerin (glycerol) (1.45 percent, v/v); hydrogen peroxide (0.125 percent, 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. A firm must also pay close attention, and document, that 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, as defined in section 501(a)(2)(A) of the FDCA. 21 U.S.C. §351(a)(2)(A).

Product labeling must include the name and contact information of the manufacturer and clarify the intended use (i.e., ethyl or isopropyl alcohol for consumer use, ethyl or isopropyl alcohol for healthcare personnel). To the extent that a firm desires to make any representations on the finished product, a note of caution: lawsuits have recently been brought against FDA-approved and regulated manufacturers and distributors for unsubstantiated claims. For example, citing a January 2020 letter sent by the FDA to Purell-maker GOJO Industries, questioning germ-killing efficacy claims, both Target and Germ-X have been sued for claims that their hand sanitizers kill 99.9 percent of germs. Accordingly, any representation of effectiveness must be supported by scientific testing and research.

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Firms must also register their facility and list these products in the FDA Drug Registration and Listing System. Once registration is complete, firms will receive automatic confirmation from the FDA and do not need to wait for a further communication from the 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 FDCA. 21 U.S.C. §379aa. Importantly, the policy explicitly states that it does not apply to all hand sanitizer products. *See Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID-19)* (March 2020).

PREP Act Declaration

The Public Readiness and Emergency Preparedness Act (PREP Act), enacted in 2005, authorizes 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. *See Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19*, 85 Fed. Reg. 15,198, at 15; 85 Fed. Reg. 15,198–01, at 15.

"Covered persons" are "*manufacturers*," "*distributors*," "program planners," "qualified persons," and their officials, agents, and employees, as those terms are defined in the PREP Act. 85 Fed. Reg. at 15,201 (emphasis added). "Covered countermeasures," moreover, are defined this way:

> 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 Fed. Reg. at 15,202 (emphasis added). "Covered countermeasures" must also meet the statutory definition under the PREP Act, which incorporates various regulatory requirements, such as being a "qualified pandemic or epidemic product" (42 U.S.C §§247d-6d(i)(7)(A), 247d-6d(i)(1)(B)), a "security countermeasure" (42 U.S.C. §247d-6b(c)(1)(B)), or a "biological product" (42 U.S.C. §262(i)), as authorized for emergency use in accordance with section 564, 564A, or section 564B of the FDCA. §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 liability if a plaintiff alleges 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 that 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 or 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. 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.

Recommendations

For manufacturers looking to manufacture and distribute alcohol-based hand sanitizers to combat COVID-19 and wanting to ensure that they have 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 the FDA can modify them as the COVID-19 situation warrants.
- Comply with FDA guidance document recommendations and ensure registration with the 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 record keeping for each production lot. Should future regulatory or liability actions occur, having robust record keeping will help reduce future exposure.
- Ensure that product labeling and advertisements comply with regulations and do not make unfounded or unsubstantiated claims about the efficacy of the product or the ability of the product to protect against infection.

Conclusion

To combat COVID-19 and increase the availability of critical supplies such as hand sanitizer, the HHS March 17, 2020, declaration extended broad statutory liability immunity to participating and otherwise non-FDA-regulated manufacturers for the duration of the emergency. In support, the FDA published multiple temporary policies 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, as long as the manufacturers follow the content, production, labeling, and registration requirements stated above. Manufacturers who are, or are considering, manufacturing alcohol-based hand sanitizers should read and heed these guidance documents to reduce future exposure to litigation.