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Phone: +1 646 783 7100 | Fax: +1 646 783 7161 | customerservice@law360.com

Cos. Must Heed FDA Warnings On Hand Sanitizers

By **Raymond Williams and Jae Kim** (August 13, 2020, 5:00 PM EDT)

Raymond Williams

Jae Kim

In recent weeks, the U.S. Food and Drug Administration has issued several public statements that include warnings about certain hand sanitizer products with methanol contamination or subpotent levels of alcohol. The FDA has described these products as dangerous and toxic to human health, because there have been reports of consumers experiencing serious and even life-threatening side effects.

Given the FDA's current regulatory treatment of hand sanitizers during the COVID-19 pandemic, companies face unique challenges in determining potential liability exposure and developing appropriate compliance measures.

Hand sanitizer products are traditionally regulated as over-the-counter drug products by the FDA, which means that they are not subject to prior approval by the agency before entering the market, but are required to meet standards set forth in the tentative final monograph for hand sanitizers and meet OTC drug regulatory requirements.

However, recognizing the critical need for increasing the supply of hand sanitizers during the pandemic, the FDA has temporarily waived some (but not all) of these regulatory burdens so that more companies can readily manufacture hand sanitizer products.

The FDA's temporary enforcement discretion policy is outlined in its guidance, "Guidance for Industry: Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID-19)," initially issued in March and updated on June 1.

Under this temporary policy, companies are required to meet several conditions relating to, among other things, formulation, labeling and adverse event reporting, as well as registration and listing. Notably, the FDA expressly stated in its guidance that this enforcement discretion does not apply to the following types of products:

- Hand sanitizers that use active ingredients other than isopropyl alcohol or ethyl alcohol, also known as ethanol;
- Hand sanitizers whose potency falls above or below the formulation described in the guidance;
- Hand sanitizers that are marketed with claims that do not conform to the tentative final monograph for hand sanitizers;
- Hand sanitizers that are marketed with superiority claims;
- Hand sanitizers that are intended to be used as surgical hand rubs or patient antiseptic skin preparations; or
- Hand sanitizers with labeling that is false or misleading in any particular.

With respect to product ingredients and formulation, the temporary policy provides that companies must only use 80% ethanol or 75% isopropyl alcohol as the active ingredient. The only inactive ingredients that can be used are glycerin, hydrogen, peroxide and purified water.

The temporary policy clarified that companies cannot add other active or inactive ingredients to the hand sanitizers to improve the smell or taste, since these ingredients may impact the quality and potency of the product. Further, the finished product must be an aqueous solution, and cannot be in the form of a gel, foam or aerosol spray.

Consistent with this temporary policy, the FDA has closely scrutinized companies that have manufactured hand sanitizers that do not meet these standards. In a series of alerts, the agency has cautioned consumers that exposure to hand sanitizers containing methanol can result in methanol poisoning.

Among the serious side effects associated with methanol exposure are nausea, vomiting, headache, blurred vision, permanent

blindness, seizures, coma, permanent damage to the nervous system and even death. The FDA's testing has shown that certain hand sanitizers are labeled as containing ethanol as the active ingredient, but in fact contain undeclared methanol. Indeed, one of the hand sanitizer products tested by the agency was found to contain 81% methanol and no ethanol.

In the FDA's July 2 press release, the agency advised the public that it has seen an increase in hand sanitizers that are labeled as containing ethanol but that test positive for methanol contamination. According to this press release, state officials have reported that adults and children who have ingested hand sanitizer products contaminated with methanol have suffered blindness, hospitalizations and death.

The agency reiterated its warnings about hand sanitizers with methanol contamination or subpotent levels of alcohol in a July 27 press release and a July 31 update.

The FDA has also established a do-not-use list, which identifies dangerous hand sanitizer products by manufacturer name, distributor name, product name and/or National Drug Code number. Currently, there are over 100 hand sanitizer products on the do-not-use list, which continues to be regularly updated.

For many of these products, the agency has recommended the initiation of recalls and/or has added these products to Import Alert 66-78. This import alert allows the FDA to detain and refuse admission of these products at the border. On July 23, one of the hand sanitizer manufacturers listed on the do-not-use list received a warning letter due to methanol contamination.

Given the serious health risks associated with these violative products, the growing scrutiny by regulators and the potential exposure to liability, companies are encouraged to carefully consider their potential liability exposure, and develop appropriate compliance measures to ensure the safety and efficacy of their hand sanitizer products.

Potential Liability Considerations

Given the widespread use of hand sanitizers by consumers, the potential for product liability suits against hand sanitizer manufacturers and distributors is not insignificant, when a product contains methanol, has subpotent levels of alcohol or is otherwise noncompliant with the FDA's regulatory requirements.

While certain products may have immunity protection under the Public Readiness and Emergency Preparedness, or PREP, Act, this may not be the case for hand sanitizers, due to the way that the U.S. Department of Health and Human Services has defined covered countermeasures.

On March 17, HHS Secretary Alex Azar issued a declaration pursuant to the PREP Act. Generally speaking, persons that meet the requirements of the declaration have immunity protection against any federal or state claim of loss caused by, arising out of, relating to or resulting from the manufacture, testing, development, distribution, administration and use of a covered countermeasure.

As defined in the PREP Act, covered countermeasures are:

> [A]ny 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.[1]

In addition to the product having to be used for COVID-19 purposes, the product's regulatory status must meet one of the following:

- The product is approved, cleared or licensed by the FDA;
- The product is authorized under an emergency use authorization, or EUA;
- The product is described in emergency use instructions issued by the U.S. Centers for Disease Control and Prevention;
- The product is being researched as an investigational new drug, or is covered by an investigational device exemption; or
- The product is a respirator approved by the National Institute for Occupational Safety and Health.[2]

On April 14, the Office of the General Counsel at the HHS issued an omnibus advisory opinion regarding the scope of the PREP Act immunity during the COVID-19 pandemic. The advisory opinion stated that a strict liability standard should not be used to determine if a product is a covered countermeasure.

Rather, if a covered person or entity "reasonably could have believed that the product was a covered countermeasure" then it should not lose that immunity, even if the product was not, in fact, a covered countermeasure. The advisory opinion provided the following example on counterfeit respirators to illustrate this principle:

> For example, FDA has issued EUAs for certain COVID-19 tests and PPE. A covered person purchases 500,000 tests or respirators that appear to be authorized under an EUA. The covered person has taken reasonable steps — under the current, emergent circumstances — to substantiate the authenticity of the products. But it turns out that some or all

> of the products are counterfeit. Under those circumstances, we believe that the person would be immune against a claim arising out of the use of a counterfeit test or respirator.

It is important to note, however, that the products in the above example would presumptively fit under the covered measure definition because of existing EUAs for testing kits and respirators.

To date, the FDA has not issued an EUA for hand sanitizers, nor has the agency approved, cleared or licensed a hand sanitizer product, since they are regulated as OTC drugs. It remains to be seen whether a hand sanitizer company could successfully seek protection under the PREP Act.

Compliance Takeaways

Hand sanitizer manufacturers and distributors are encouraged to regularly monitor for regulatory developments and take steps to assess their compliance with federal laws, regulations and policies. Checking the FDA's do-not-use list prior to purchasing hand sanitizer products from a new vendor is wise, but should not be the only preventive measure taken.

Importantly, the FDA has expressed concerns with the fact that many of the hand sanitizer products with issues were found to contain undeclared methanol and/or low levels of alcohol. Therefore, relying on the label alone may not be enough to ensure the quality of the products.

In instances where a company is not directly engaged in the manufacture of the hand sanitizer product, and does not have a clear line of sight into the actual ingredients used in the product, it may be prudent to take additional diligence measures with respect to third-party suppliers. For instance, the company may conduct analytical testing on samples to confirm if there are issues with its current inventory or incoming shipments.

Given the growing concerns and potential safety hazards associated with certain hand sanitizers, companies are encouraged to consider proactively undertaking a risk assessment, to determine an appropriate compliance strategy for ensuring that their hand sanitizer products are compliant and safe for use.

Raymond M. Williams is a partner and Jae Yeon Kim is an associate at DLA Piper.

DLA Piper summer associate Samuel Son, a law student at Villanova University Charles Widger School of Law, also contributed to this article.

[1] 85 Fed. Reg. 15,198, 15,202 (March 17, 2020).

[2] Respirators were added to definition of Covered Countermeasure by the Coronavirus Aid, Relief, and Economic Security Act.
