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Considerations for Companies Interested in Manufacturing Hand Sanitizer to Fight Against COVID-19

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As the COVID-19 pandemic continues, many businesses are manufacturing essential public health and/or medical supplies that are now in high demand. Companies around the world—from global luxury brands like Dior and Givenchy to local distilleries throughout the United States—have been switching their alcohol-based product lines from the manufacturing of products such as perfume and spirits to the manufacturing of hand sanitizer.

If your company wants to assist in manufacturing critical supplies like hand sanitizer to fight against the spread of COVID-19, there are several regulatory and legal considerations it should be mindful of during these uncertain times.

FDA Guidance for Preparing Hand Sanitizer

The Food and Drug Administration (FDA) has regulatory oversight of over-the-counter drugs, including alcohol-based hand sanitizers, and producers of such products are typically required to register with the FDA. On March 27, 2020, the FDA released updated guidance, entitled Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID-19). The FDA guidance provides that the FDA does not intend to take action against businesses "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[,]" provided that businesses follow certain requirements, including:

- The hand sanitizer is generally manufactured using: (1) alcohol that is not less than 94.9% ethanol by volume or isopropyl alcohol; (2) food grade glycerin; (3) hydrogen peroxide; and (4) sterile water.
- The hand sanitizer is manufactured according to the formula provided in the guidance.
- Records are kept to ensure the correct amount of the active ingredient (alcohol) is used, and that each batch of hand sanitizer matches the provided formula.
- Sanitary conditions and appropriate equipment are used during manufacturing.

- The alcohol content in samples of the finished product is verified before each batch is distributed.
- The hand sanitizer is labeled appropriately.
- Businesses register with the FDA Drug Registration and Listing System (DRLS). Once firms receive confirmation of registration from the FDA, they may begin operations.

Of particular note for distilleries and other companies using consumable alcohol, the alcohol must be "denatured" (by incorporating an additive to make the product unfit for consumption) before the hand sanitizer may be distributed.

Labeling and Marketing Concerns

In addition to following the FDA's guidelines, businesses should be aware of labeling and marketing issues that can lead to enforcement actions, as well as civil or criminal litigation. An instructive case involves GOJO Industries Inc. ("GOJO"), which makes PURELL® hand sanitizer. On January 17, 2020, the FDA issued GOJO a warning letter regarding labeling and marketing statements, including statements that "suggest that PURELL® Healthcare Advanced Hand Sanitizers, which are formulated with ethyl alcohol, may be effective against viruses such as the Ebola virus, norovirus, and influenza." The FDA noted that, given these statements, PURELL® Healthcare Advanced Hand Sanitizers qualify as new drugs under section 201(p) of the FD&C Act, 21 U.S.C. 321(p), and that they may not be distributed or sold in interstate commerce without the FDA's prior approval.

On February 1, 2020, a class action was filed against GOJO in the Southern District of New York, citing the FDA warning letter and bringing claims for negligent misrepresentation, violations of state consumer protection laws, violation of the Magnusson-Moss Act, and fraud and unjust enrichment. *Gonzales v. Gojo Industries, Inc.*, Case No. 1:20-cv-00888 (S.D.N.Y., filed Feb. 1, 2020). *Gonzales* seeks certification of a nationwide class of all purchasers of PURELL® Healthcare Advanced Hand Sanitizers, and similar class actions against GOJO have now been filed in Ohio and California as well.

Businesses may also be criminally liable for producing and/or distributing falsely or misleadingly labeled or advertised products. Under the Federal Food, Drug, and Cosmetic Act of 1938, for example, it is illegal to distribute a covered product (such as hand sanitizer) in interstate commerce that is "misbranded"—that is, if the product labeling does not meet set requirements. *See* 21 U.S.C. § 331(a)-(c).

This serves as a timely reminder that any business producing or distributing hand sanitizer should ensure its labeling and/or marketing claims are true, accurate, and in strict compliance with regulatory requirements. Before undertaking this transition, businesses should consult with an attorney to fully examine their potential exposure. During these unprecedented times, employees should be encouraged to remain vigilant and follow internal protocols on reporting suspected fraudulent activity and/or procedures not adhering to federal requirements.

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