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New FDA Guidances Allowing Preparation of Certain Alcohol-Based Hand Sanitizer Products During COVID-19 Public Health Emergency

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Food, Drugs, and Devices

Today, the United States Food and Drug Administration ("FDA" or "the Agency") published a guidance document[1] that allows, for the duration of the COVID-19 public health emergency, entities that are not currently licensed or registered drug manufacturers to prepare alcohol-based hand sanitizer—either for public distribution or for their own use—provided they register with FDA as manufacturers of over-the-counter ("OTC") drug products and meet certain other conditions that we have outlined below.

In addition, earlier this week, FDA issued a related guidance[2] that similarly describes conditions under which FDA does not intend to take action against compounders for violations of certain provisions of the Food, Drug, and Cosmetic Act (FDCA) when they produce alcohol-based hand sanitizers for consumer or for use as health care personnel hand rubs.[3] This guidance is also effective only for the duration of the public health emergency.

Background

FDA generally regulates hand sanitizer products as drugs, which means that, among other requirements, such products are generally required to be produced in registered drug establishments in accordance with drug current good manufacturing practice ("CGMP") requirements. The Guidances recognize that the United States is currently operating in a public health emergency and that "[h]and hygiene is an important part of the U.S. response" to the

[1] *See* Guidance for Industry: Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID-19) ("Guidance").

[2] *See* Immediately in Effect Guidance for Industry: Policy for Temporary Compounding of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency ("Compounding Guidance").

[3] Compounding Guidance at 2.

ongoing pandemic.[4] The Guidances highlight the recommendation by the Centers for Disease Control and Prevention ("CDC") that consumers apply hand sanitizer with at least 60 percent alcohol when soap and water are unavailable. However, FDA notes that "some consumers and health care professionals are currently experiencing difficulties accessing alcohol-based hand sanitizers."[5]

Guidance

The Guidance describes the conditions under which firms can prepare alcohol-based hand sanitizers for consumer use and for use as health care personnel hand rubs while the public health emergency is ongoing.[6] To qualify for FDA's exercise of enforcement discretion, the manufacturer must:[7]

- Use United States Pharmacopeia grade ingredients, consistent with World Health Organization recommendations, discussed in the Guidance
- Not add other active or inactive ingredients, which FDA asserts could impact quality and potency
- Document key steps and controls to assure each batch matches the formula developed for the drug product
- Prepare the hand sanitizer under sanitary conditions and use equipment that is well-maintained and fit for purpose
- Use the most accurate method of analysis available at the site to verify alcohol content in samples of the finish drug prior to release of each batch
- Label the drug consistent with the relevant Appendix of the Guidance
- Register with FDA as a drug establishment and list the product
- Establish a system for adverse event reporting

[4] Guidance at 2, Compounding Guidance at 2.

[5] Guidance at 3, Compounding Guidance at 3.

[6] Specifically, FDA notes that it does not intend to take action for violations of sections 501(a)(2)(B) (CGMP), 502(f)(1) (labeling with adequate directions for use), 505 (new drug approval), and 582 (drug supply chain security).

[7] Guidance at 3-5.

Compounding Guidance

The Compounding Guidance provides a similar allowance for state-licensed pharmacies, federal facilities, and outsourcing facilities ("compounders").[8] To qualify for FDA's exercise of enforcement discretion, the compounder must:[9]

- Use United States Pharmacopeia grade ingredients, consistent with World Health Organization recommendations, discussed in the Compounding Guidance
- Not add other active or inactive ingredients, which FDA asserts could impact quality and potency
- Prepare the drug under conditions routinely used by the compounder to compound similar non-sterile drugs
- Label the drug consistent with the relevant Appendix of the Compounding Guidance

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To best advise our clients on the rapidly evolving public health situation in the United States, our COVID-19 task force is staying abreast of daily developments and tracking the latest federal, state and local policies related to COVID-19. Please feel free to reach out to our team members listed below with any questions, and to visit Covington's website for our COVID-19: Legal and Business Toolkit.

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[8] Under this policy, FDA does not intend to take action against a state-licensed pharmacy or federal facility for violations of sections 501(a)(2)(B), 502(f)(1), 505, and 582, and does not intend to take action against outsourcing facilities for violations of sections 502(f)(1), 505, and 582.

[9] Guidance at 3.