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CLIENT ALERT

FDA Reminds Companies Manufacturing Hand Sanitizer of the Importance of Using Denatured Alcohol and Continues to Closely Monitor COVID-19 Claims

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During the COVID-19 pandemic, there are two paths for companies seeking to make hand sanitizer: follow the U.S. Food and Drug Administration's (FDA's) temporary policy or follow the monograph for antiseptic hand rubs. On April 27, FDA issued a press release reminding companies manufacturing hand sanitizer under the temporary policy that they must comply with its manufacturing and labeling requirements.

The temporary policy, which FDA has updated throughout the pandemic, has resulted in more than 1,500 new manufacturers registering with the agency to produce hand sanitizer. One appeal of the temporary policy is that companies may bypass FDA's independent testing requirements for effectiveness, provided that they follow the prescribed formula. This week's press release reminds companies that, despite the Agency's flexibility, they must not forego necessary safety measures, including requirements to use denatured alcohol in these products, and to label them with Drug Facts and appropriate warnings. The Agency's statement appears to have been sparked by an April adverse event report of a 13-year old ingesting hand sanitizer packaged in a liquor bottle from a distiller – the product was not denatured and reportedly tasted like drinking alcohol. FDA requires manufacturers to use denatured alcohol so that hand sanitizer is unpalatable and less likely to be consumed, especially by children.

In addition to efforts to ensure product safety, FDA continues to monitor claims, particularly those about COVID-19. This applies to hand sanitizer manufactured under either the temporary policy or antiseptic monographs. FDA's recent press release highlights an April 23rd warning letter issued to Prefense, LLC. The Agency maintains that Prefense made claims for its hand sanitizer on its website and social media pages, which FDA deemed misleading, unproven, and in violation of federal law. While FDA's temporary policies emphasize the importance of hand sanitizer to its COVID-19 response, the Agency remains concerned that certain claims could give consumers a false sense of security, reducing how often they wash or sanitize their hands.

In short, while FDA has relaxed some of its typical rules, it maintains key safety requirements. Companies operating under the temporary policy or the monograph for antiseptic hand rubs should be familiar with—and vigilant about following—these key safety rules.

For more information, please contact the professional(s) listed below, or your regular Crowell & Moring contact.

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