



Not So Clean After All: FDA Takes Aim at Manufacturer of OTC Hand Sanitizer Product Line Making Disease Prevention Claims from Ebola to the Flu

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With everyone worrying about the coronavirus and the flu this time of year, it is not surprising that last month the Food and Drug Administration issued a Warning Letter against the manufacturer of a well-established over-the-counter hand sanitizer product line.¹ According to the Warning Letter, the hand sanitizers were intended for use as consumer and healthcare antiseptics; however, FDA found that as currently **formulated and labeled**, the hand sanitizers were unapproved new drugs in violation of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

Highlights

Labeling Claims

In the Warning Letter, FDA outlined numerous claims that it observed on the company's websites and social media accounts for the products, which served as evidence of the products' intended use. For example:

"Kills more than 99.99% of most common germs that may cause illness in a healthcare setting, including MRSA & VRE"

"To help prevent transmission, hand hygiene with an alcohol-based hand sanitizer is recommended along with hand washing if hands are soiled. . . ."

". . . the products you need to help prevent the spread of infection this germ season" (Facebook)

". . . What you need to know about Candida auris in the Healthcare Setting." (Blog)

FDA also took exception with statements made in the context of the Frequently Asked Questions section of the company's website. For example:

". . . Ebola virus is an enveloped virus, Enveloped viruses in general are easily killed or inactivated by alcohol. The World Health Organization and the Center for Disease Control and Prevention (CDC) are recommending the use of alcohol-based hand sanitizer as a preventative measure during this outbreak."

"The FDA does not allow hand sanitizer brands to make viral claims, but from a scientific perspective, influenza is an enveloped virus. Enveloped viruses in general are easily killed or inactivated by alcohol. The World Health Organization and the Center for Disease Control and Prevention (CDC) are recommending the use of alcohol-based hand sanitizer as preventative measures for flue prevention."

¹ See Warning Letter dated January 17, 2020, available at <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/gojo-industries-inc-599132-01172020>

The agency noted that these statements “clearly indicate your suggestion that the [hand sanitizer products] are intended for reducing or preventing the Ebola virus, norovirus and influenza. As such, the statements are evidence of your products’ intended uses.” Moreover, FDA said that it was not aware of any “adequate and well-controlled studies demonstrating that killing or decreasing the number of bacteria or viruses on the skin by a certain magnitude produces a corresponding clinical reduction in infection or disease caused by such bacteria or virus.” FDA concluded that the products were “new drugs” because they are not generally recognized as safe and effective for use under the conditions prescribed, recommended, or suggested in their labeling. Because there were no approved new drug applications for these products, they are unapproved new drugs. .

Formulation

As noted by FDA, the company’s website suggested that the products were being marketed under the OTC Drug Review. The active ingredient, ethyl alcohol, is addressed by two separate OTC drug monographs dealing with consumer and healthcare antiseptics. On April 12, 2019, FDA published a final rule for Consumer Antiseptic Rub products in which it deferred consideration of ethyl alcohol as an active ingredient.² On December 17, 2017, FDA published a final rule for Health Care Antiseptics, and announced that it had deferred rulemaking on six active ingredients for specific OTC Health Care antiseptic uses.³ Ethyl alcohol was one of the ingredients deferred in that rulemaking.

In the Warning Letter, the agency stated that it does not generally intend to object to the marketing of products containing ethyl alcohol until it publishes a final rule establishing whether the ingredient is safe and effective for antiseptic uses, **“provided they meet the proposed formulation and labeling conditions described in the relevant tentative final monograph (TFM) . . . and provided that a particular product does not constitute a hazard to health.”** FDA concluded that the hand sanitizer products did not comply with the relevant TFM. Specifically, FDA stated that the labeling claims made by the company (e.g., that the products were effective in preventing disease or infection from pathogens such as Ebola, MRSA, VRE, norovirus, flu, candida auris, and in preventing the spread of infection), “went beyond describing the intended use of a topical antiseptic” The claims also implied that the products were effective in reducing illness going beyond merely describing the intended use. These claims were not described in the applicable monographs.

Based on the above, FDA found that the products, as formulated and labeled, were not covered under any final or tentative OTC monograph. Moreover, no products intended to prevent disease or infection from these specific pathogens is being considered under the OTC Drug Review. Finally, the agency mentioned that it was not aware of any evidence that the products as formulated and labeled “are generally recognized by qualified experts as safe and effective for use under the conditions suggested, recommended, or prescribed in their labeling.”

AGG Observations

- As we often remind our clients, a company must be careful with any information that it includes on its website, social media and marketing materials, as this is all considered “labeling” and evidence of the product’s intended use.
- Companies must be aware of any claims or statements that are posted to Facebook and other social media websites. FDA is reviewing these sites, so a company should be as careful with the information that is posted there as well as any other marketing medium.

² See Safety and Effectiveness of Consumer Antiseptic Rubs; Topical Antimicrobial Drug Products for Over-the-Counter Human Use Final Rule (84 FR 14847) (effective April 12, 2020), available at <https://www.federalregister.gov/documents/2019/04/12/2019-06791/safety-and-effectiveness-of-consumer-antiseptic-rubs-topical-antimicrobial-drug-products-for>

³ See Safety and Effectiveness of Health Care Antiseptics; Topical Antimicrobial Drug Products for Over-the-Counter Human Use Final Rule (82 FR 60474, December 20, 2017) <https://www.federalregister.gov/documents/2017/12/20/2017-27317/safety-and-effectiveness-of-health-care-antiseptics-topical-antimicrobial-drug-products-for>

- While the OTC Drug Review has been ongoing for more than 40 years and many monographs are not yet finalized, as evidenced by this Warning Letter, FDA will not allow the marketing of a product that falls outside of a Tentative Final Monograph (where it typically exercises enforcement discretion), either because of a labeling claim or the status of the active ingredient, particularly if the claims relate to serious diseases and conditions.
- Companies must continue to closely monitor the OTC Drug Review process and be ready to relabel or reformulate after a monograph is finalized in order to avoid being the subject of an FDA enforcement action.

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