american cleaning institute®

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Donald D. Ashley, JD
Director
Office of Compliance
Center for Drug Evaluation and Research
U.S. Food and Drug Administration

Theresa Michele, MD
Director
Office of Nonprescription Drugs
Center for Drug Evaluation and Research
U.S. Food and Drug Administration

Dear Mr. Ashley and Dr. Michele,

I write on behalf of the American Cleaning Institute[1] (ACI) to express our concerns related to the new, increasingly widespread practice of providing hand sanitizers to consumers in public settings. These hand sanitizers are often sold in bulk and used to fill existing dispensers. As explained more below, these practices can create a serious risk to public health and safety. We note that we do support FDA's alcohol testing policy,[2] warnings and recalls due to impurities (e.g., methanol), and import alert[3] as vital actions to ensure that Americans are provided safe and effective hand hygiene products during the COVID-19 pandemic.

However, ACI and its members are concerned about the flood of hand sanitizer products on the market from hand sanitizer manufacturers that do not comply with applicable regulatory requirements. The purpose of this letter is to highlight our concerns and ask that FDA: (1) clarify requirements for hand sanitizer labeling and refilling practices; (2) take enforcement action against certain products that are in violation of legal requirements and raise public health and safety concerns; and (3) issue safety communications to manufacturers and the public about these unsafe and unlawful practices.

As you may know, there are a large number of new entrants into the hand sanitizer market offering bulk hand sanitizer formats (e.g., gallon jugs, 55-gallon drums) and open refillable dispensers. These drug delivery systems are especially prevalent in public locations and are intended to encourage the public to get out and "safely" reopen our communities (e.g., retail shopping, schools, lobbies, community outdoor settings). It is our understanding that in most cases, these bulk systems are either not labeled at all or

[1] The American Cleaning Institute® (ACI – www.cleaninginstitute.org) is the Home of the U.S. Cleaning Products Industry® and its members include the manufacturers and formulators of soaps, detergents, and general cleaning products used in household, commercial, industrial and institutional settings; companies that supply ingredients and finished packaging for these products; and chemical distributors.

[2] The press announcement for the testing policy can be found here: https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-january-19-2021

[3] The press announcement for the import alert can be found here: https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-takes-action-place-all-alcohol-based-hand-sanitizers-mexico-import

not labeled in accordance with FDA drug labeling requirements, and these hand sanitizers and their containers have not been validated for compatibility or stability in those bulk systems. In addition, some businesses that provide hand sanitizer to their employees, patrons, or the general public are purchasing bulk hand sanitizer for use in refilling existing containers, including some dispensers, jugs and bottles that were not intended to be refilled. There are several serious risks to health and safety, as well as legal liabilities, associated with the use of bulk alcohol hand sanitizer products and their use in refilling other containers, including the following:

- Misbranding – misrepresentation of the product to the end user and liability concerns.
- Product integrity – consistency, quality and purity over the lifespan of the product, particularly in instances where bulk alcohol hand sanitizers are used to refill or "top-off" containers not originally sold for that product, which can result in mixing of different products.
- Product stability – loss of antimicrobial efficacy, absence of formulation/package compatibility data, and potential mixing of active ingredients or cross-contamination of different products. Alcohol is highly volatile, which causes a high risk of evaporation to levels below the OTC drug requirement minimum of 60.0% (especially with poorly designed dispensing systems).
- Traceability – loss of connectivity to the batch/lot # and expiry in the event of a safety concern, quality excursions or incidents, and recall notices.

While these practices may not be occurring with malintent, hand sanitizer manufacturers (particularly new entrants into the category and those following the FDA Temporary Guidance) may not be aware that the concerns noted above are, in many cases, in direct violation of legal requirements and FDA guidance, and pose potential risks to health and safety. Furthermore, the act of refilling a container that retains the label from the original manufacturer with an alternative product potentially misleads consumers and likely causes the product to be misbranded and adulterated.

On behalf of ACI members, we respectfully request that FDA take immediate action to address the serious issues related to bulk hand sanitizers produced primarily by new entrants into the realm of hand sanitizer manufacturing, including certain manufacturers following the WHO formula. Specifically, we request that FDA issue appropriate safety communications and guidance to clarify the packaging and labeling requirements for Hand Sanitizer OTC drugs, including with regard to the refilling of primary packaging, and to remind manufacturers and users that certain practices are not permissible. We also encourage FDA to enhance its surveillance to identify bulk products that raise these public health and safety issues and take appropriate enforcement action against companies that fail to comply.

In addition to raising these issues for your awareness, ACI and its members stand ready to assist the FDA as a knowledgeable, helpful resource in addressing these risks. ACI appreciates your leadership on this matter, and the overall engagement of the FDA in response to the COVID-19 pandemic emergency. Please contact me at jkim@cleaninginstitute.org or 202.680.4849 if I can be of further assistance. Thank you.

Best regards,

James Kim, Ph.D.
Vice President, Science & Regulatory Affairs