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Regulatory Changes Ahead for Hand Soap in Healthcare: What to Expect in January

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If you haven't already heard, active ingredient choices for hand soaps in healthcare may be limited in the very near future. The Food and Drug Administration (FDA) Division of Over-the-Counter Drug Products regulates the use of antiseptic drug products, like hand sanitizers and antimicrobial soaps, used in healthcare through the Monograph system. The healthcare Monograph has been in a tentative state since 1994, but changes are currently underway that may affect a large percentage of healthcare facilities, and they need to be prepared so they can plan their course of action.

It's helpful to have a bit of background information to better understand the imminent changes. Back in April 2015, the FDA released a proposed rule, or an addendum to the Healthcare 1994 Tentative Final Monograph. Within the 2015 proposed rule, the FDA called for more data on the safety and efficacy of active ingredients used in hand hygiene products and established a new safety framework to ensure that the ingredients are both safe and effective. The request for additional data was not the result of a safety signal and the FDA was clear that healthcare facilities should continue to use these life-saving products[1]. Based on their review of the additional data, the FDA will make a final decision about which actives ingredients will continue to be permitted for use. Chloroxylenol (PCMX), benzalkonium chloride, and benzethonium chloride have been granted deferrals by the FDA to provide time for industry to complete additional safety and efficacy testing. It is unclear whether these deferred actives will ultimately be approved as part of the Monograph.

In addition to the aforementioned soap actives, ethyl alcohol has been deferred from final rulemaking for hand sanitizers. The FDA will not make a final ruling on the deferred ingredients in the upcoming January 2018 ruling and has not provided an expected timeline to do so. Deferred active ingredients can continue to be used while new data is being developed.

Healthcare facilities can expect that the FDA will eliminate triclosan as an eligible active ingredient in January. This change will have significant consequences in healthcare since 40% of facilities in the U.S. are using a triclosan-based soap today[2]. When the FDA makes their announcement, it does not mean facilities must immediately stop using triclosan. There will likely be a 1-year phase-out period where manufacturers will have to remove triclosan from their products. That said, there will likely be questions and concerns among healthcare workers who are a key hand hygiene product stakeholders. Infection Preventionists will be looked to for guidance, recommendations, and to answer questions. To minimize healthcare worker confusion and angst, the best course of action healthcare facilities can take is to plan for these expected changes. To ensure as smooth a transition as possible, facilities should work with their product manufacturer now to evaluate other available product options and develop a plan to use up inventory before the January announcement. It will also be important to develop communications addressing the changes, how the facility is responding, and what healthcare workers can expect.

1. FDA issues proposed rule to address data gaps for certain active ingredients in health care antiseptics: product use should continue in health care setting as additional data are gathered [news release]. Silver Spring, MD: U.S. Food and Drug Administration; April 30, 2015. http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm445002.htm. Accessed May 1, 2016.
2. Market share information derived through Global Healthcare Exchange, LLC dataset, 2015.
3. Augustine Scientific, Newbury OH, Ex Vivo Soil Removal Analysis, August 5, 2017
4. BioScience Laboratories, Inc.; Bozeman, MT, Study# 170398-101, Evaluation of In-Vivo Germ Removal, July 5, 2017.
5. BioScience Laboratories, Inc. Bozeman, MT, Study# 1707304-101, Evaluation of In-Vivo Germ Removal, August 22, 2017.

PRODUCT FEATURE

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