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HAND HYGIENE TIMES

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Coming Soon!
Regulatory Changes for Hand Soap in Healthcare

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If you haven't already heard, your choice of active ingredients for hand soaps in healthcare may be limited in the 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 aware of these upcoming changes so they can plan for the future.

The FDA released a proposed rule, or an addendum to the Healthcare 1994 Tentative Final Monograph on April 30, 2015. Within the 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, protocol-driven safety framework to ensure that ingredients used by healthcare workers are both safe and effective. The FDA was clear that there was no indication of a potential problem with efficacy or safety; rather because many changes and advances have occurred since the FDA began review of health care antiseptics in the 1970s such as frequency of product use, new technology that can detect low levels of antiseptics in the body, and scientific knowledge about the impact of widespread antiseptic use, the FDA has requested more data on active ingredients.[1] Based on their review of the safety and efficacy studies, the FDA will make a final decision about which actives ingredients will continue to be permitted for use in hand hygiene products. Ethyl alcohol, PCMX, benzalkonium chloride, and benzethonium chloride have been granted deferrals by the FDA in order to provide time for industry to complete additional safety and efficacy testing. It is unclear whether or not these deferred actives will ultimately be approved as part of the monograph. 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.

Other actives such as triclosan will likely be eliminated in the January 2018 ruling by FDA and have a 1-year phase-out period. These upcoming changes may have a significant impact on a healthcare facility's decision about which soap to choose. Triclosan is a common antimicrobial active ingredient used in hand soap today. In fact, 60% of healthcare facilities in the U.S. use an antimicrobial soap, and of those, over half are using a triclosan-based soap.[2] While January 2018 may seem far away, healthcare workers will likely be confused and raise concerns if they know their facility is using a triclosan-based soap once the FDA makes the announcement that Triclosan is no longer permitted. The best course of action a healthcare facility can take is to plan for the future now. This means working with your hand hygiene provider, evaluating other available product options, and having a plan to use up inventory before the January announcement so that healthcare workers feel reassured in January.

For more information about the FDA Healthcare Monograph, regulatory changes ahead, and help with selecting a soap for your facility, visit .

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. Acces sed May 1, 2016.
2. Market share information derived through Global Healthcare Exchange, LLC dataset, 2015.

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1. Exceeds FDA Healthcare Personnel Handwash requirements. 2. GOJO SCLC Study #2015-12-I10484 Antibacterial (CHG-TCS-PCMX-BAK) 4D-48X FCAT II.

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