Division of Public and Behavioral Health
Technical Bulletin

Topic: Antimicrobial Soaps in Health Care Settings
Section/Program: Division of Public and Behavioral Health/Office of Public Health Informatics and Epidemiology
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To: Health Care Providers

The U.S. Food and Drug Administration (FDA) recently released a final rule regarding the safety and effectiveness of antibacterial soaps. It is important for health care facilities to know this final rule is in reference to consumer antiseptic wash products only. The rule does not affect consumer hand “sanitizers” or wipes, or antibacterial products used in health care settings.

When requested by the FDA, consumer manufacturers did not demonstrate that the ingredients are both safe for long-term daily use and more effective than plain soap and water. The same safety and effectiveness request is currently being made by the FDA of health care product manufacturers.

At this time, the FDA is recommending that health care providers continue to use health care antiseptics consistent with infection control guidelines until a final rule is released on these products. These products are an important component of infection control strategies in health care settings, and remain a standard of care to prevent illness and the spread of infection. There is currently no estimate on a final rule for these products in the health care setting.

To review the FDA’s final rule on the safety and effectiveness of antibacterial soaps in the consumer setting:
http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm517478.htm

To review the FDA’s recommendation on the continued use of antibacterial soaps in health care settings:
http://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm445062.htm

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