

September 7, 2016

U.S. Food and Drug Administration (FDA) Issues Final Rule on Active Ingredients Used in Antibacterial Hand and Body Washes

The FDA issued a final rule pertaining to active ingredients used in over-the-counter (OTC) Consumer Antiseptic Wash (antibacterial rinse off) products, such as hand soaps and body washes, marketed for consumer use or commercial use in public settings. This rule does not apply to Consumer Antiseptic Rub (hand rub or leave on products, such as hand sanitizers or hand sanitizer wipes). It also does not apply to products used in healthcare or food industries.

In the FDA's final ruling issued September 6, 2016, the FDA identified 19 active ingredients that can no longer be used in Consumer Antiseptic Wash products, including triclosan, the most common active ingredient in these products. Manufacturers will have one year to comply with this rule by removing affected products containing these 19 ingredients from the market by the **effective date of September 6, 2017**.

In response to comments submitted by the industry, the FDA has deferred the rulemaking on three other active ingredients to allow additional time for the submission of new safety and effectiveness data for these ingredients. The three ingredients are benzalkonium chloride, benzethonium chloride and chloroxylenol (PCMX). Consumer antibacterial products containing these ingredients can continue to be marketed while this data is being collected.

Safety and Effectiveness of Consumer Antiseptics: Topical Antimicrobial Drug Products for Over-the-Counter Human Use

On or after September 6, 2017, any OTC Consumer Antiseptic Wash containing any of the 19 ingredients listed by the FDA cannot be initially introduced or initially delivered for introduction into interstate commerce unless it is the subject of an approved new drug application.

In its press release, the FDA reinforced the Centers for Disease Control and Prevention's recommendations to wash hands with soap and water to reduce the spread of germs and to use an alcohol-based hand sanitizer that contains at least 60 percent alcohol when soap and water are not available. Click on the link below to read the press release.

[FDA Press Release](#)