

“Antibacterial hand and body wash manufacturers did not provide the necessary data to establish safety and effectiveness for the 19 active ingredients addressed in this final rulemaking. For these ingredients, either no additional data were submitted or the data and information that were submitted were not sufficient for the agency to find that these ingredients are Generally Recognized as Safe and Effective (GRAS/GRAE). In response to comments submitted by industry, the FDA has deferred rulemaking for one year on three additional ingredients used in consumer wash products – benzalkonium chloride, benzethonium chloride and chloroxylenol (PCMX) – to allow for the development and submission of new safety and effectiveness data for these ingredients. Consumer antibacterial washes containing these specific ingredients may be marketed during this time while data are being collected.

Washing with plain soap and running water remains one of the most important steps consumers can take to avoid getting sick and to prevent spreading germs to others. If soap and water are not available and a consumer uses hand sanitizer instead, the U.S. Centers for Disease Control and Prevention (CDC) recommends that it be an alcohol-based hand sanitizer that contains at least 60 percent alcohol.”

Reference: <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm517478.htm>