

METHODS AND PERFORMANCE CRITERIA

The Final Monograph for topical antibacterial products will require that all categories of antibacterial products achieve log reductions that are specified in the Monograph. If these log reductions are not achieved the products will fall outside the terms of the Monograph and, therefore, will not be considered as topical OTC antibacterial drugs. It is therefore imperative that methods that are cited in the Final Monograph to measure log reductions are standardized and validated. Without such standardization, the validity of test results, and comparability between products from different companies would be questionable. The Industry Coalition continues to advocate that finished product testing imposed by the Final Monograph should be carried out using standard, peer-reviewed methods developed by the American Society for Testing and Materials (ASTM) that include neutralization of sampling fluids. If FDA cited ASTM methodology in the Final Monograph, this would encourage reliability, reproducibility and comparability of log reductions.

In previous submissions to FDA the Industry Coalition recommended different log reductions for healthcare personnel hand wash products, and non-professional uses of topical antibacterials (e.g. food-handler products, consumer hand and body products) to those currently described in the 1994 Tentative Final Monograph for antiseptic products used in health care settings. It is clear from the discussion at the March 2005 NDAC meeting that FDA's Advisory Panel does not believe that sufficient evidence has been provided to change the log reductions for healthcare antiseptic products.

The Industry Coalition has carefully reviewed log reductions for all products in the Health Care Continuum in light of the March 2005 NDAC position on health care antiseptic products. The Industry Coalition has concluded that the log reductions identified in Table 1 for healthcare personnel hand wash products and non-professional antibacterial products are appropriate, as long as standardized ASTM methods (with neutralization of all sampling fluids) are employed in the Final Monograph. As noted in the SDA/CTFA Industry Coalition letter to FDA, dated 6 October 2005, topical antibacterial products should be effective the first time they are used, and effectiveness should be demonstrated after a single wash. Demonstration of cumulative activity by a tenth wash is a redundant measure that should not be included in the Final Monograph; this position is reflected in Table 1.

Table 1

Proposed log reductions for healthcare personnel hand wash, antiseptic hand wash, and other non-professional use topical antibacterial products

Product Category	Log Reductions in 1994 TFM	Current Revised Industry Proposal for Log Reductions
Healthcare Personnel Hand Wash	2 log ₁₀ after 1st wash 3 log ₁₀ after 10th wash	2 log₁₀ after single wash. (10 th wash is not relevant & should be omitted from the Final Monograph)
Antiseptic Hand Wash and all other non-professional use antibacterial products (e.g. food handler, consumer hand and consumer body products)	2 log ₁₀ after 1st wash 3 log ₁₀ after 10th wash	2 log₁₀ after single wash. (10 th wash is not relevant & should be omitted from the Final Monograph)