



## 2.0 Log reduction requirements for surgical scrubs

We propose that the wording in Sub-Section: Testing of health-care antiseptic drug products (b) Specific testing criteria of a surgical scrub be changed. Currently it states; :

[333.470 (b)(1) iii ]

“When tested, in-vivo, by the test procedure...reduces the number of bacteria 1-  $\log_{10}$  on each hand within 1 minute and the bacterial count on each hand does not subsequently exceed baseline within 6 hours on the first day, and produces a 2-  $\log_{10}$  reduction of the micro flora on each hand within 1 minute of product use by the end of the second day of enumeration, a 3-  $\log_{10}$  reduction of the micro flora on each hand within 1 minute of product use by the end of the fifth day when compared to the established baseline.”

This wording has led to confusion as to what exactly are the 6-hour log reduction requirement as demonstrated by the attached product labeling technical reports. From our discussions with the FDA, and demonstrated by the reference standard used, we understood the criteria to be 1- $\log_{10}$  at 1 minute and 6 hours on the first day, 2-  $\log_{10}$  at 1 minute and 6 hours on the second day, and 3-  $\log_{10}$  at 1 minute and 6 hours on the fifth day.