FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH (CDER)

Nonprescription Drugs Advisory Committee (NDAC)
Hilton Hotel - The Ballrooms
620 Perry Parkway
Gaithersburg, Maryland
March 23, 2005

QUESTIONS FOR THE COMMITTEE

1. Please discuss the use of surrogate markers for the assessment of the effectiveness of healthcare antiseptics.

2. Has compelling evidence been provided to change the currently used threshold log reduction standard? Please vote on each product category separately.

		Industry Bacterial Reduction (log_{10})	**FDA TFM Bacterial Reduction (log_{10})**
Healthcare Personnel Handwash	Wash 1	1.5	2
	Wash 10	----	3
Surgical Hand Scrub*	Wash 1	1	1
	Wash 2	---	2
	Wash 11	---	3
Patient Preoperative Skin Preparation*	Preinjection	1	1
	Abdomen	1	2
	Groin	2	3

* Industry has recommended removal of the 6-hour persistence criteria for these products.

3. Given current standards using surrogate markers to demonstrate efficacy, how should the analysis be conducted?
    i. How should we define "meeting the threshold" (e.g., mean log reduction, median log reduction, % of subjects meeting the threshold)?
    ii. How should we evaluate the variability in the data?
    iii. How do we evaluate the variability in the test method?

4. Current labeling for healthcare antiseptics consists of class labeling that does not include product performance information. What labeling information would be helpful for clinicians to fully understand product efficacy?