STERIS®

March 10, 2005

Ms. Shalini Jain
Center for Drug Evaluation and Research, HFD-21
Food and Drug Administration
5630 Fishers Lane, Rm. 1093
Rockville, MD 20857

RE: STERIS Corporation Comments to NDAC for March 23, 2005 Panel Meeting; Tentative Final Monograph for Healthcare Antiseptic Drug Products (June 1994).

Dear Ms. Jain:

STERIS Corporation is a leading provider of infection control products to healthcare providers in the United States. STERIS has provided safe and effective healthcare antiseptic drug products to hospitals and other healthcare facilities for over 50 years. This includes surgical scrubs, healthcare personnel handwashes and surgical pre-operative skin preparations. In addition, STERIS has played an active role in submitting data and comments to the FDA during the development of the Healthcare Antiseptic Drug Monograph (TFM). The following comments represent STERIS Corporation's position regarding the topics for discussion before the advisory panel on March 23, 2005.

- The publication of a final rule for the Healthcare Antiseptic Drug Monograph should be a high priority for the FDA. Finalization of this regulation will support the use of safe and effective healthcare antiseptic drug products in healthcare facilities to minimize risk of nosocomial infections.
- The currently proposed TFM point estimate surrogate efficacy criteria are appropriate and adequately distinguish healthcare based antimicrobial hand wash products from consumer antimicrobial products.
- The TFM proposed performance criteria are consistent with performance requirements for New Drug Applications for chlorhexidine based products (CHG) to support identical indications as those identified in the TFM.
- When properly formulated, current active ingredients including alcohol based products have the ability to meet the TFM proposed efficacy criteria.
- 12-20 subjects per product arm in controlled surrogate endpoint clinical studies are an appropriate number of subjects to support each indication in the TFM based on an extensive statistical analysis of CHG based products.

Sincerely,

Mike Ebers
Manager, Regulatory Affairs

Jerry Newman
Director of Product Development