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5516 '03 AUG 27 A9:53

August 26, 2003

Documents Management Branch HFA-305 Food and Drug Administration 5630 Fishers Lane, Room 1061 Rockville, MD 20852

RE: STERIS Corporation Comments to Healthcare Antiseptic Drug Monograph;

Docket # 75N-183H

Dear Sir or Madam:

Enclosed are STERIS Corporation comments in response to the reopening of the administrative record as published in the Federal Register Notice of May 29, 2003. As directed in the notice, STERIS is including only new information in the attached comments to support the inclusion of 60-95% v/v isopropyl alcohol as a Category I Safe and Effective active ingredient in surgical scrubs and healthcare personnel handwashes.

Please contact Mike Ebers at 314-290-4701 if you have any questions regarding these comments.

Sincerely,

Mike Ebers

Manager, Regulatory Affairs

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