

May 9, 2002

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Dockets Management Branch
Division of Management Systems and Policies
Office of Human Resources and Management Services
Food and Drug Administration
Room 1061 (HFA-305)
5630 Fishers Lane
Rockville, MD 20852

Ref: Docket #02D-0039

Dear Sir;

Cleaning is an essential element in healthcare sterilization. The draft guidance document fails to mention cleaning as part of the labeling requirement. Please add a cleaning requirement to the following sections:

1. Section II D
2. Section E2
3. Section F
4. Section III
5. Section IV

Without cleaning requires and intended use instructions, the user will not know the recommended methods.

Regards,



Thomas K. "Chip" Moore
Senior Market Manager
Sterilization Products

02D-0039

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