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TEXAS HOSPITAL ASSOCIATION

April 10, 2000

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

RE: Docket No. 00D-0053 – FDA draft guidance documents on the reuse of single-use devices

Ladies and Gentlemen:

On behalf of the Texas Hospital Association, I am pleased to provide the following comments regarding the guidance documents drafted by the Food and Drug Administration concerning the reuse of single-use devices. These drafts were published in February 2000 and are entitled "*Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals,*" and "*Reprocessing and Reuse of Single-Use Devices: Review Prioritization Scheme.*"

THA strongly supports the safe use of medical devices. THA also supports the careful stewardship of health care resources. Some devices safely and effectively may be reused after appropriate reprocessing and sterilization. While the FDA has indicated that it may issue further guidance on the labeling of reprocessed devices, there are no current standards to guide the labeling of a device as "single use only." Original equipment manufacturers should be required to follow uniform standards for labeling so that the designation "single use only" is meaningful and standardized. An original equipment manufacturer should not be permitted to label a device for "single use only" if the manufacturer is aware that the device may be safely reused following appropriate sterilization and reprocessing. The device label should include the number of times the device will perform without failure as validated by the original equipment manufacturer. Furthermore, original equipment manufacturers should be required to provide instructions for acceptable, validated methods of sterilization and/or resterilization for all devices.

On behalf of the Texas Hospital Association, I appreciate the opportunity to provide the foregoing comments. Please call me at (512) 465-1538 if you have questions.

Sincerely,

Matthew T. Wall
Associate General Counsel

00D-0053

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