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April 6, 2000

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

To Whom It May Concern:

The American Society for Gastrointestinal Endoscopy (ASGE) appreciates the opportunity to submit these comments on the Food and Drug Administration's (FDA) draft guidance entitled "Reprocessing and Reuse of Single-Use Devices: Review Prioritization Scheme" and the companion document "Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals." In recent months there has been a large public debate over the reuse of single use devices (SUDs). ASGE applauds FDA's effort to listen to all viewpoints, and we concur that the "primary goal is to protect the public health by assuring that the practice of reprocessing and reusing SUDs is based on good science."

ASGE represents more than 6500 physicians who specialize in the use of endoscopy in the diagnosis and treatment of gastrointestinal (GI) diseases and conditions. Our members are committed to providing their patients the most efficacious and efficient medical care. A number of single use devices used in endoscopic procedures are frequently reprocessed either by hospitals or third party reproprocessors. As a result, our members are very interested in, and support the FDA's actions to ensure they are maintaining the highest patient safety standards.

ASGE has closely followed the FDA's actions on this issue, including the Review Prioritization Scheme (RPS) since the original draft was released on December 10, 1999. ASGE has concerns with the risk classification methodology and believes the subjective basis for the RPS needs improvement. ASGE members interpret the algorithms for devices they use in their practices differently than the FDA classifications. As a result, ASGE urges FDA to refine its methodology to produce clearer RPS criteria and less ambiguous classifications. ASGE is prepared to work with FDA to produce workable solutions that will produce the highest patient safety standards and provide the necessary guidance to our members.

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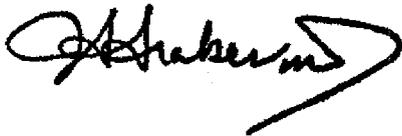
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ASGE applauded the FDA's suggestion for a research program to provide data on the reuse of SUDs, and we continue to express our interest in working cooperatively with FDA on such an effort. ASGE believes data should drive any solution to this issue and believe it is equally critical to any ongoing process to adjust risk classification. As always, ASGE recognizes that if a significant risk of harm to patients is demonstrated, then FDA must act to protect the public health. We strongly urge FDA to begin this research effort now in the best interests of patients and the physicians who rely on this data in their practices.

From start to finish, ASGE believes that the FDA's proposed guidance demonstrate convincingly that better information is needed to regulate reprocessing effectively. Therefore, we urge FDA to place a *priority on scientific study and data collection* to bolster its current regulatory posture. As data are developed, FDA can then adjust its requirements as necessary to ensure continued public and physicians confidence in the use of reprocessed medical devices.

ASGE urges careful consideration of these recommendations. We look forward to continuing to work with FDA and all other interested parties on this important issue.

Sincerely,

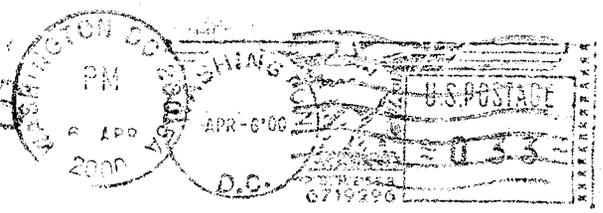
A handwritten signature in black ink, appearing to read "J. Frakes", with a long, sweeping underline that extends to the right.

James T. Frakes, MD, MS
President



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FIRST-CLASS



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