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CINCINNATI, OH 45242-2839

March 19, 2002

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

**RE: Docket No. 01D-0514  
Medical Devices; Guidance on Labeling of Reprocessed Single Use Devices; Request  
for Comments and Information**

To Whom It May Concern:

Ethicon Endo-Surgery, Inc. is respectfully submitting comments in response to an open request by FDA on December 20, 2001 (FR Vol. 66, No. 245) regarding the labeling of reprocessed single use devices.

Ethicon Endo-Surgery, Inc. would first like to emphasize that it does not support the reprocessing of single-use devices. Single-use devices were not designed or validated to support reprocessing, and therefore reprocessing could lead to increased health hazards.

Regarding the specific issue of labeling, Ethicon Endo-Surgery, Inc. firmly believes only the name of the legal manufacturer (i.e., reprocessor or remanufacturer in this case) should appear on reprocessed single-use devices, not the names of both the reprocessor and the original equipment manufacturer (OEM) as suggested by FDA in the above Federal Register Notice. Accordingly, Ethicon Endo-Surgery, Inc. wants its name physically removed from all reprocessed devices, as well as, from all levels of labeling.

Once a device is reprocessed, the OEM is no longer the legal manufacturer of record, and as such, bears no legal responsibility for the safe/effective use of the device. Keeping the name of the OEM on the labeling of a reprocessed device is a frank violation of the misbranding provisions of Food, Drug, and Cosmetic Act. In addition, this violates U.S. Trademark law giving rise to serious trademark infringement issues while placing the reputation of the OEM at risk.

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### Misbranding Violation

The Food, Drug, and Cosmetic Act §502 (352) states that a product is misbranded (a) if its labeling is false or misleading in any particular and (b) unless it bears a label containing the name and place of business of the manufacturer, packer or distributor. Relatedly, 21CFR 801.1(a) states "The label of a device in package form shall specify conspicuously the name and place of business of the manufacturer, packer, or distributor".

Reprocessing of a single-use device creates a new legal manufacturer. FDA clearly acknowledges this in a final guidance document issued on August 14, 2000 where it is stated that reproprocessors of single-use devices are subject to all the same requirements as OEMs. In the Federal Register notice of December 20, 2001, FDA refers to reproprocessors as "remanufacturers". Thus, it follows that the reproprocessor's name (not the OEM's) should be specified conspicuously on all labeling. Neither the Food, Drug and Cosmetic Act nor 21 CFR 801 allows for the names of multiple manufacturers to be listed. In fact, multiple legal manufacturers do not exist. Suggesting that both names be listed in labeling is a clear violation of the law. Thus, only the name of the legal manufacturer (reprocessor) should be included in labeling.

### Trademark Violation

FDA's intent to include both the reproprocessor and OEM name on the labeling of reprocessed single-use devices is a direct violation of U.S. Trademark law. Specific laws impacted include 15 United States Code Section 1127 concerning trademarks and trade names; Section 1114 pertaining to infringement; and Section 1125 that pertains to false designation of origin and false description.

According to the law, whether the name on the device is the company identifier or the product identifier, the name is legally reserved to the **exclusive use of the owner**, Ethicon Endo-Surgery, Inc. For this reason, Ethicon Endo-Surgery, Inc. wants to exercise its legal right to have its name removed from all reprocessed single-use devices and associated labeling. Given the well known and documented performance/safety problems associated with reprocessing, the reputation of Ethicon Endo-Surgery, Inc. is at risk if its name remains on the product.

Thus, FDA's desire to include the name of both the remanufacturer and OEM on a reprocessed single-use device is in clear violation of two laws, Federal Food, Drug and Cosmetic Act and U. S. Trademark law. Respectfully, Ethicon Endo-Surgery, Inc. takes serious issue with this and asks that FDA amend its position to require only the name of the remanufacturer (not both names) on reprocessed single use devices. Continued violation of these laws, in light of some of the known problems associated with reprocessed single-use devices, places the reputation of the OEM at significant risk.

In closing, Ethicon Endo-Surgery, Inc. appreciates the opportunity to comment on the issue of labeling of reprocessed single use devices. Should you have any questions regarding these comments, please call me at 513-337-8205.

Respectfully submitted,



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