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From: Sullivan, Ted [tsullivan@AKINGUMP.COM]
Sent: Tuesday, April 11, 2000 2:04 PM
To: 'fdadockets@oc.fda.gov'
Subject: Docket Number 00D-0053 Comments to Guidance on Disposable Medical Devices



Comments to OEM
Guidance.DOC

ATTN Docket Number 00D-0053

Attached are comments submitted by Tri-State Hospital Supply Corporation on two FDA guidance documents for third-party reprocessing of disposable medical devices. A hard copy of this document will also be sent, postmarked April 11, 2000. This document is in Microsoft Word format, and if you cannot access it, please contact me at 202-887-4105.

Theodore M. Sullivan
Akin, Gump, Strauss, Hauer, & Feld

<<Comments to OEM Guidance.DOC>>

00D - 0053

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Docket Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm.10-61
Rockville, MD 20852

RE: Comments on Guidance Documents "Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals" and "Reprocessing and Reuse of Single-Use Devices: Review Prioritization Scheme" (**Docket Number 00D-0053**)

Dear Sir or Madam:

Tri-State Hospital Supply Corporation submits the following comments on FDA's proposed strategy for regulating reprocessing of disposable medical devices, as embodied in two draft guidance documents released for comment on February 8, 2000: "Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals" (hereinafter referred to as the "Enforcement Guidance") and "Reprocessing and Reuse of Single-Use Devices: Review Prioritization Scheme" (hereinafter referred to as the "Prioritization Guidance").

Tri-State is a registered medical device manufacturer and provider of contract services to the medical manufacturing industry. We have been active in this industry for 36 years and operate three manufacturing facilities with sales in all 50 states. A significant proportion of our volume is directly related to products consisting of or containing manual surgical instruments.

Tri-State supports the requirements that hospitals and third party reproducers of disposable medical devices be held to the same standards as original equipment manufacturers ("OEM"). However, Tri-State believes that the guidance needs to be more explicitly clear as to whom it applies, and disagrees with the risk characterization of all disposable devices not currently on the "list" provided in Appendix 2 of the Prioritization Guidance, and Appendix B of the Enforcement Guidance (hereinafter referred to as "the list") as "high risk." In particular, Tri-State disagrees that manual surgical instruments, most of which are not included in the current list, should be classified as "high risk" by default. We believe that manual surgical instruments are more appropriately classified as "low risk unless application of the flow charts to the specific instrument demonstrates a higher level of risk", and request that FDA include these devices (along with this, or similar, classification language) in the list as devices that are low risk for reprocessing.

Additionally, Tri-State is concerned that the Guidance may be applied in some fashion to OEMs, and therefore requests that FDA clarify that this Guidance is not intended to apply, directly or indirectly, to OEMs.

A. Risk Category Classification

The Prioritization Guidance provides two flowcharts that together are used to determine the “risk category” for reprocessed single use medical devices. The decision making process represented in the flowcharts presents a reasonable approach to determining level of risk for these devices. Based upon application of the flowcharts, FDA has placed a number of frequently reprocessed devices onto the list. Unfortunately, the list, as it is currently constituted, is markedly deficient in coverage. Notably absent are most manual surgical instruments (considered class I medical devices under 21 C.F.R. § 878.4800). When the decision making process of the flowcharts is applied to manual surgical instruments, most of these devices fall into the “low risk” category. This should be reflected in the list.

Tri-State is concerned that absent a specific categorization, manual surgical instruments will by default be considered “high risk” for reprocessing. According to both Guidance Documents, “FDA will consider any SUD not on the current list or subsequently revised lists to be one that poses a high risk if it is reprocessed.” This is not an appropriate classification for devices that are subject to recognized performance standards, and present few difficulties in sterilization. Categorization as high risk incorrectly implies that manual surgical instruments present significant reprocessing issues such that they may not be safe or effective after reprocessing.

In the event that FDA decides to continue to classify all devices not on the list as high risk for reprocessing, Tri-State suggests that the Agency develop a specific procedure through which interested parties can propose devices to be added to the list.

Tri-State is also concerned that the guidance documents may suggest that the Class I status of manual surgical instruments will be reevaluated. The Enforcement Guidance states that “[i]f any device designated by the companion Risk Scheme guidance as moderate or high risk is currently exempt from premarket requirements, FDA will propose to amend its classification regulations for those devices to require premarket submissions.” This statement suggests, but does not make clear that FDA’s proposed reclassification of moderate and high risk devices applies only to devices that have been categorized per the flow charts. An explicit statement should be added that this proposed reclassification does not apply to devices that are high risk on the basis of not having been evaluated for reprocessing risk, and therefore, not on the list.

B. Applicability to OEMs

We are concerned that the documents are not explicit enough as to their scope, particularly since they are being distributed directly to hospital users who may not be familiar with the interpretation and implementation of FDA guidance documents. We believe that an explicit statement should be included in the introduction, stating that the guidance does not apply to OEM's because they are already subject to specific device requirements such as registration, listing, surveillance, and quality system requirements. The guidance documents state that their scope is applicable to hospitals and third party reprocessors, but its application could indirectly be significantly broader. For example, as discussed above, the risk categorization for a device could ultimately result in the reclassification of medical devices, requiring OEMs to submit to premarket clearance or notification for previously exempt devices. This would present a significant and unjustified burden to OEMs. Additionally, FDA should explicitly provide that these guidances would not subject OEMs to any additional requirements for single use devices, such as labeling the device with reprocessing instructions or risk category. Any burden for compliance with reprocessing rules should fall upon parties that desire to use the devices outside the scope of their labeling and intended use.

* * *

Based on the forgoing, Tri-State requests that FDA change its draft guidances to add manual surgical instruments to the list of devices categorized for reprocessing risk as low risk devices, and to clarify that these documents are not intended to apply, directly or indirectly, to OEMs.

Sincerely,

George Pluta
Tri-State Hospital Supply Corp.



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Sincerely,



George Pluta

Tri-State Hospital Supply Corp.

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