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March 19, 1998

Docket Management Branch (HFA-305)  
US Food and Drug Administration  
12420 Parklawn Drive Room 1-23  
Rockville, Maryland 20857

Re: Industry Comments - Docket No. 97N-0477

Dear Sir/Madam:

In response to a public request for comment published in the Federal Register of 12/23/97, Allegiance Healthcare Corporation (Allegiance) welcomes the opportunity to provide the following information. This correspondence supplements information previously provided to Mr. Casper E. Uldriks, FDA, by Allegiance on 10/3/97.

One of the strategic business units of Allegiance is directly involved with the manufacture of Custom Kits. This manufacture involves the arranging of various components, some of which are finished medical devices, into a convenience package configuration. These convenience kits often contain numerous components sometimes numbering in the hundreds. The final kit configuration is terminally sterilized rendering the product a medical device subject to relevant regulations identified in the Code of Federal Regulations. Included in the obligations with which a kit manufacturer must comply are, for example, registration, listing, complaint investigation, MDR reporting, all GMP or Quality System obligations and until 5/20/97, premarket notification.

Given this description of the kit manufacturing business and various "reprocessing" scenarios currently taking place in the industry, Allegiance believes that the current definitions of refurbisher, "as is" remarketer and servicer are in need of expansion. It appears to be becoming common practice in the health care industry for the end user to send unused components to an outside, contracted, third party who repackages unused components supplied by the end user and subjects these repackaged components to yet another sterilization. The reprocessed kit is usually then returned to the supplier of the unused components.

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Under current regulations and guidelines such a scenario of events would obviate the need for the reprocessor to comply with many of the obligations we feel are essential to maintaining the public safety. We ask the Agency to amend existent definitions and regulations thereby requiring the reprocessors to comply with the same requirements as the original kit manufacturer. Whether the third party “acquires ownership” of the unused components or not, there still remains the concern as well as the obligation, to ensure that the reesterilized product still performs as it was originally designed.

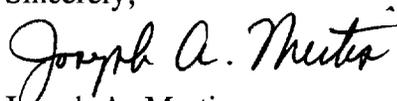
Since Allegiance is actively engaged in kit manufacture we intimately understand the complications involved in providing a safe and efficacious product to the end user. To assure the public safety reprocessors of kits must be obligated to comply with the Quality System regulation and more specifically Design Control. Essential tenets such as component qualification are equally, if not more, important in reprocessing operations to assure that the physical effects of reesterilization processes do not effect the safety, effectiveness or intended use of the component. Manufacturers devote countless resources to component qualifications. Lot traceability is another basic obligation that should be complied with by reprocessors. In the unfortunate event of a component recall the ability to know in which kits it was placed is essential. Complaint investigation and MDR reporting are also valuable tools necessary to protect the public safety.

Finally, the question of whether or not the reprocessed kit constitutes a “new” product must be considered. We feel that such a reprocessed kit is truly a new entity in and of itself. This opinion is based on the premises that the kit’s components were reconfigured by the reprocessor and more importantly by the fact that the reprocessor reesterilizes the completed kit. The sterilization of those unused components represents the “further processing” attribute which categorizes a kit manufacture as a medical device manufacturer. With this said Allegiance feels that kit reprocessors should be obligated to register their establishments as actual manufacturing sites and to list their products as medical devices. Through compliance to the registration and listing obligations the Agency would be better able to control remanufactured kits, thus ensuring the safety and effectiveness of the product.

Allegiance truly appreciates the opportunity to comment on the expansion of the current Compliance Policy Guides and Regulations. If you would like expansion of any aspect expressed in this document please do not hesitate to contact me.

I can be reached at 847-785-3310.

Sincerely,



Joseph A. Mertis  
Director, Regulatory Affairs

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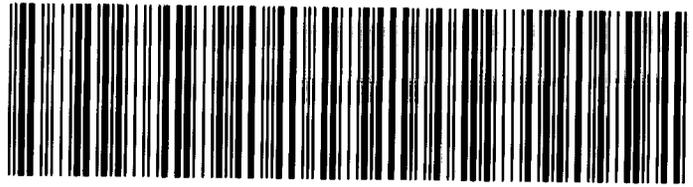
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