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March 20, 1998

Dockets Administration Branch (HFA-305)
Food and Drug Administration
12420 Parklawn Drive Rm. 1-23
Rockville, MD 20850

Reference Docket No. 97N-0477

Dear Sir:

Our company manufactures medical devices and is presently considering sales of remanufactured clinical chemistry analyzers. Because we may soon become a seller of remanufactured devices, we submit the following comments on the proposed rule referenced above.

First of all, we believe the agency has properly defined the term "refurbisher" as including "remarketers" and "servicers". However, before proceeding from these definitions the agency should separate and distinguish among the various regulated devices. This is necessary because the general category of devices proposed by the rule is very broad. It contains everything from clinical chemistry analyzers up to and including critical *in vivo* medical devices such as endoscopes. The current rule does not allow for differences, which are directly proportional to the potentially serious public health risks associated with different types of devices.

By including all of the thousands of devices capable of being "serviced," "remanufactured," "refurbished" or sold "as is" the proposed rule is unwieldy and cannot succeed in meeting its stated objectives. Attempting to codify and regulate an overly broad range of devices using the proposed definitions and regulations will not serve the public interest. This becomes clearer when we compare specific devices covered by the proposed rule. For example, refurbishers using other than OEM reagents for analyzer validation studies present health risks that are significantly different from those associated with endoscopes coming apart while in use.

It is our opinion that FDA has made it clear that it intends for "refurbished", etc., medical devices to be covered by the QSR and underlying cGMP regulations.

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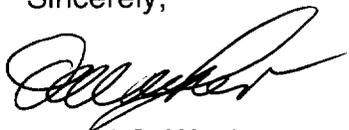
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Since this is the case, a better way to further regulate these diversified elements of the medical device industry would be the issuance of individual guidance documents aimed directly at "refurbished" devices that present real public health problems.

Obviously, any such individual guidance documents should be circulated for comments by the companies they potentially impact.

Sincerely,

A handwritten signature in black ink, appearing to read "D. Weyker", written in a cursive style.

Daniel C. Weyker
VP Ops and RA



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