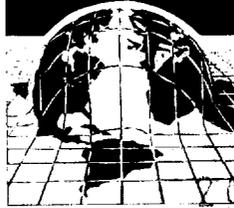


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EQUIPMENT

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March 12, 1998

Dockets Management Branch (HFA-305)
Food and Drug Administration
12420 Parklawn Dr.
rm. 1-23
Rockville, MD 20857

Docket No. 97N-0477

Dear FDA:

I am writing in response the FDA's Advance notice of proposed rulemaking Federal Register Vol. 62, No. 246 12/23/97 Docket No. 97N-0477 pages 67011-67013.

Currently the FDA has a compliance policy guide (CPG 7133.20) which covers companies such as mine which refurbish medical equipment. At this point it is strictly a guide and, as I understand it, the FDA is proposing to drop the guide and make refurbishers follow some of the same regulations which apply to manufacturers. This would create an unnecessary burden on companies such as mine due to the fact that there have been no documented problems ever reported to the FDA that have been caused by the refurbishment of medical equipment.

The only problem refurbishing companies such as mine create is in the pocketbooks of larger medical equipment companies we compete with. They would like to see us regulated out of business.

You state in your Reasons for Review that you feel that "persons who perform such functions (servicers and refurbishers) meet the definition of manufacturer". Nothing could be further from the truth. When I refurbish an operating room table I do no more than return it to its original condition. I had no say, however, in its design or the choice of which materials were originally used. I didn't decide whether it had certain safety features or whether it had three feet or four. I simply refurbished it to function as the original manufacturer designed it, complete with all of its original good and bad features.

97N-0477

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"Buyers and Sellers of Quality Refurbished Medical Equipment"

Refurbishers do not make products. We do not convert raw materials into finished goods. Refurbishers simply restore equipment to its original specifications.

Here is my brief response to the comments requested on page 67013 of the proposed rule:

- 1) I feel that the FDA's proposed definitions of "refurbisher", "as is remarketers", and "servicers" are appropriate.
- 2) There is no evidence that I am aware, of any safety issues with regard to the performance of medical equipment which are the result of refurbishing. If there is not a documented safety issue, then I feel that creating new regulations is overstepping the FDA's mandate to protect the public's health since there is no documented health risk.
- 3) I feel that the appropriate level of regulatory control would be for the FDA to keep it at the level of the compliance policy guide and allow the industry to police itself through the International Association of Medical Equipment Remarketers (IAMER).
- 4) Refurbishers, "as is" remarketers and servicers should be subject to the same regulatory requirements. The difference between refurbishers and "as-is" remarketers is the level of service and the only difference between refurbishers and servicers is who actually owns the equipment. Whether you own the equipment or not should not be the defining factor as to whether or not you are going to be regulated.

Thank you for your reading my response and I would more than willing to answer any questions you may have for me.

Sincerely,



Bob Mighell



516-237

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