



An XR Imaging Network Company

"We care about your image"

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March 6, 1998

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Dockets Management Branch
HFA-305
FDA
12420 Parklawn Drive, Room 1-23
Rockville, MD 20857

Dear Director:

In response to the FDA request for comments on whether GMP's should be required for refurbishers, we feel that this expense should not be added to the market.

Refurbishers are already controlled by both the FDA and local state agencies, and further control is not necessary. Most serious refurbishers are moving in the direction of ISO 9000 certification or equivalent to remain competitive in the market place. Furthermore, the increased federal staff and costs associated, are not in the best interest of the taxpayer or the FDA

All players in the medical imaging market are doing their best to keep costs in control. GMP's will not make an appreciable change in an already controlled segment of the market.

Thank you for requesting opinions.

Sincerely,

Richard F. Ernst
President, XRI
An XR Imaging Network Company

RFE/lm

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