

Northern Illinois Blood Bank  
A Non-Profit Organization



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July 26, 1999

Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Rm. 1061  
Rockville, MD 20852

**RE: Docket No. 99D-1878, CBER9914**

Ladies and Gentlemen:

These comments are concerning sections 1A, 2A and 3A, whereby the statement is made that, "The record search should extend back indefinitely to the extent that electronic or other readily retrievable records exist." We consider this requirement to be a significant hardship to our transfusion services and to our own organization. We began the HCV Look-back process in June 1998 and it is virtually complete. It is our experience that 98% of the recipients identified thus far, dating back to 1988, are deceased. With this information, what purpose would it serve to continue the look-back beyond 1988? Why is it being changed one and one-half years into the process?

Please consider these comments and reconsider this requirement as you prepare the final guidance document.

Sincerely,

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Executive Director

99D-1878

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