



August 2, 2002

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Documents Management Branch (HFA-305)  
Food & Drug Administration  
5630 Fisher Lane, Room 1061  
Rockville, MD 20852

RE: Docket No. 02N-0204

After attending the public meeting of July 26<sup>th</sup> at NIH Digi-Trax Corp., a stakeholder specifically focused on the issues related to blood banking and ISBT128, would like to add the following comments to our submission of July 22<sup>nd</sup>, 2002.

It is clear from the joint statement made on behalf of AABB, ABC and ARC by Kay Gregory, AABB's director of regulatory affairs, that the FDA has their full support for the subject proposal. Since blood banking has used bar coding, Codabar under the 1985-89 FDA Guideline, all that is now needed is an immediate rule mandating the use of ISBT128.

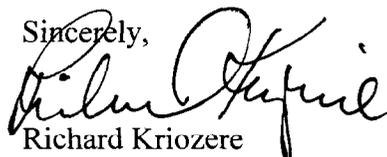
Many pressing issues face the blood banking industry today and there are always reasons to continue to delay ISBT128 implementation. There will be as yet unseen issues to face. But, further delay is unwarranted and unconscionable at this point after over 10 years of development, repeated voluntary target dates and publishing of US Standards in June 2000. The FDA should act now especially where an agreed upon industry currently exists.

Digi-Trax is a commercial enterprise providing an on-demand labeling solution for printing all ISBT128 required labels. In this position we have been in contact with every blood bank software provider for both donation centers and transfusion services. Some already support on-demand ISBT128 label printing and almost all have modified their software to receive ISBT128 data. This makes us believe that an FDA rule to require ISBT128 within 1-2 years is reasonable.

Digi-Trax has been a supplier of on-demand Codabar ABO printers to the ARC and we have developed both a conversion strategy for their current printer hardware to ISBT128 and we have successfully integrated our TCP/IP server into several major blood bank software systems, leading us to believe that we can do the same for any system. We do not know the status of the ARC computer system, but feel that we could integrate our TCP/IP product give the opportunity and we do have our stand-alone PC print systems in operation. Again, a 1-2 year window would seem appropriate.

We look forward to decisive action by the FDA on ISBT128.

Sincerely,

  
Richard Kriozere

02N-0204

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