DIGI-TRAX
CORPORATION

June 22, 2002

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

RE: Docket No. 02N-0204

Digi-Trax Corporation has been actively involved during the 12 years development and implementation of the ISBT 128 bar code labeling initiative for blood and blood products. We have also been a consulting member to the ISBT Working Party on Automation and Data Processing that produced the Standard.

Digi-Trax has also been a member of the North American Technical Group (NTAG) that produced the United States Industry Consensus Standard for the Uniform Labeling of Blood and Blood Components using ISBT 128. We are writing in support of the Secretary's initiative to reduce medical errors and the proposal from HHS-FDA to mandate the use of bar codes on human drug products and biological products.

Of particular interest is question #1 related to Drugs and Biologics. "Should blood products and vaccines carry a bar code?" Our response is yes. Under the current FDA Guidelines for the Uniform Labeling of Blood and Blood Products (1985-89) the Blood Industry has been using ABC CODABAR. This technology dates back to the early 70's.

It has been universally accepted that CODABAR has deficiencies in light of today's needs and doesn't provide adequate information. With the support of AABB, the American Red Cross, the ISBT, the Armed Services Blood Program Office (ASBPO), American Blood Centers (ABC) and others: the ISBT 128 standard was established by the blood banking industry and managed by the ICCBBA, but not aggressively implemented.

Historically Blood and Blood Products have been treated by the FDA (cber) in a similar fashion to drugs. In the FDA proposal published December 3, 2001, the FDA recognizes that "a voluntary bar coding program would be akin to a no action alternative". This has certainly been the well documented case with ISBT 128. The benefits to the industry and the public of a change from CODABAR to ISBT 128 have been clearly established.

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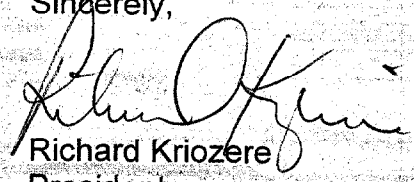
It is our hope that as part of the current HHS-FDA initiative that the existing ISBT 128 standard can be incorporated into any FDA rule or mandate. Adopted almost three years ago, this existing Industry Standard should clearly be included in any FDA mandate.

If drugs have rationale to be bar coded then blood certainly ought to be included. The public today can reliably use bar coding to check out groceries or find a Federal Express or UPS package. Why shouldn't it be assured that they are receiving the proper drug, biological or blood product?

The FDA should be applauded for this effort and should act now where a clear well defined industry standard exists.

Sincerely,



Richard Kriozere
President

RK/ka

cc: John Roberts

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