ICCBBA, Inc
Incorporated in 1995 in the Commonwealth of Virginia as a not-for-profit organization

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

Re: Docket Number 02N-0204

To the Commissioner:

We are responding to a request for comment regarding the recently published proposed rule for bar coded labels that included the requirement that labels for blood components carry a machine-readable symbol. As the organization dedicated to the maintenance and extension of the *ISBT 128* standard, we may be perceived to have a vested interest, but we are also in a position to provide unique perspective on behalf of the entire transfusion medicine community.

We would like to address several issues in Section H of the proposed rule:

Although, as the FDA suggests, broad flexibility in selecting current and future symbology might be obtained by specifying only machine readable information be present without requiring a specific symbology, this approach contradicts what is stressed by the FDA throughout the document: it is the need for a standard that is more important than the symbol itself. Furthermore, as the document also makes clear, there should be only a single standard: it is cost-effective and most likely to achieve the major purpose of the proposal, the elimination of errors and improvement of safety.

Section H enumerates the advantages of *ISBT 128* except what we consider to be the two most important features: first, it is technology-independent. *ISBT 128* data structures are designed to be used with any modern machine-readable technology (that excludes CODABAR, but includes two-dimensional symbologies and newer technologies such as RFID) and also any electronic data information exchange technology such as HL7. Furthermore, application software developed to support *ISBT 128* using linear bar codes would require little modification should a different technology for data capture become prevalent. More importantly, less time would be spent on validation, one of the more expensive procedures involved in changing any aspect of information technology.

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Second, *ISBT 128*, once implemented, will play a major role in process control, enhancing the ability to track and trace blood components and hematopoietic progenitor cells, thereby enhancing the safety of the manufacturing and transfusing processes. [A similar statement can be made with respect to stored tissues].

Finally, we would like to address what seems to a concern to CBER: that end-users pay to use *ISBT 128*. Incurred costs and reimbursement for these costs exist for other standards. For example UPC and HL7 require an extensive support system because they are constantly evolving. As with *ISBT 128*, costs for maintaining these standards are supported by manufacturers, passed on to end-users and ultimately the consumer. As a point of clarification hospitals that do not manufacture or remanufacture blood products are not required to pay registration and /or license fees. Furthermore, as the FDA so eloquently argues in the proposal, competing standards actually increase costs and standardization produces an offsetting cost saving, yet another reason to require a standard for labeling blood components.

With regard to labeling blood components, FDA should mandate a standard. We believe that standard should be *ISBT 128*. Those who receive blood components are entitled to the same considerations expressed by FDA in the sections of this proposal dealing with drug labeling. Designed as an international standard, *ISBT 128* has been successfully implemented throughout Europe and the Middle East as well as in other countries in other parts of the world. It is supported by the major blood collecting and professional organizations in the US. Implementation is beginning in the US and Canada. The FDA proposal could delay implementation in these countries to the detriment of patient care and safety.

Sincerely yours,

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