Blood Product Labeling

The labeling process for blood and blood components is strictly controlled and includes a final review of records, manufacturing, testing and quality control results. In accordance with the Food and Drug Administration (FDA) “Guideline for the Uniform Labeling of Blood and Blood Components” and Code of Federal Regulations (CFR), the container label of products intended for transfusion include the:

- Proper name of the component and any modifiers as appropriate;

- Name, address, registration and/or license number of each manufacturer;

- Donation number relating the unit to the donor;

- Expiration date including the day, month and year (and hour of expiration for products with a dating period of 72 hours or less);

- Donor classification statement, e.g., “volunteer donor”, “autologous donor” or “paid donor”;

- Volume of the product, accurate to within +/- 10 percent, for Whole Blood, Plasma, Platelets and partial units of Red Blood Cells;

- Volume and type of anticoagulant from which the product was prepared;

- Name and volume of source material, where applicable;

- Recommended storage temperature (in degrees Celsius);

- Statements

- “Rx only”

- “See circular of information for indications, contraindications, cautions, and methods of infusion”

- “Properly identify intended recipient” and

- “This product may transmit infectious agents”

- ABO and Rh groups of the donor.

Additional information specific to autologous and directed donations may also be present on the label or attached to the unit by the use of a tie-tag.

The labels also contain in a format approved for use by the Director, Center for Biologics Evaluation and Research (CBER) the four (4) items required to be machine-readable and are:

- Unique facility identifier (the FDA registration number);

- Lot number relating to the donor (the donation number);

- Product code; and

- ABO and Rh of the donor.

A list of the product descriptions and associated Codabar Product Label Codes is available.

The American Red Cross (ARC) is currently planning for the implementation of a new industry standard for labeling blood and blood products known as ISBT128. Click here for an example of the new label. ISBT128 is not in the public domain and there are registration and licensing requirements for the end-user of the ISBT128 codes. In preparation for this transition, the ARC has developed a “Product Code Translation Table” which provides examples of some of the ISBT128 product codes assigned for some of the products routinely collected or manufactured by the ARC. This is only a partial list and a complete list and additional information concerning the application and use of ISBT128 can be obtained from ICCBBA, Inc. at www.iccbba.org.