
Bar Code Label Requirements for Blood and Blood Components

Frequently Asked Questions (FAQs)

Is it true that we must label blood and blood components with specific machine-readable bar code information by April 26th, 2006?

- Yes, under the bar code label requirements final rule of Feb 26, 2004, products subject to the rule, including blood and blood components intended for transfusion, must be in compliance by April 26, 2006. The regulation for blood and blood components is located at 21 CFR 606.121(c)(13). The final rule is entitled: Bar Code Label Requirement for Human Drug Products and Biological Products (69 Federal Register 9120, February 26, 2004).

What machine-readable information is required for blood and blood components?

- 21 CFR 606.121(c)(13)(ii-iii) states the container label must bear encoded information in a format that is machine-readable and approved for use by the Director, Center for Biologics Evaluation and Research.
- Currently, two types of machine-readable label types are recognized by FDA: FDA recognized the use of Codabar (a specific bar code symbology) in 1985; and FDA accepted the use of ISBT 128, version 1.2.0, in 2000. CBER has recognized the second version (2.0.0.) effective September 22, 2006. Please see our latest Guidance on this: <http://www.fda.gov/cber/gdlns/unilabld.htm> as well as the new ISBT 128 Uniform Labeling document: <http://www.fda.gov/cber/gdlns/ISBT128.pdf>.
- Each label must have at a minimum: (A) A unique facility identifier; (B) Lot number relating to the donor; (C) Product code; and, (D) ABO and Rh of the donor.

We are a transfusion service and very infrequently prepare split units, pediatric units, and pooled cryoprecipitate units; do we need machine-readable labels for these units?

- Yes, This situation was described in the preamble to the proposed rule (68 Federal Register 12500 at 12513):

"The unit of blood or blood component label would contain the machine-readable information if the blood or blood component has any possibility of being transfused to a patient, whether or not the unit is actually transfused. Additionally, the phrase, "from which the blood or blood component can be taken and transfused to a patient" would include the circumstance where blood or a blood component is extracted or aspirated with a syringe from the container of blood or blood component in order to transfuse to a patient. This technique might be used when transfusing neonates or under other medically necessitated circumstances. In this case, the blood or blood component from which the aspirate is taken must have affixed to it a label containing the required machine-readable information. This would be consistent with the pre-existing requirement at § 606.121(c)(8)(iii) that requires specific statements if a product is intended for transfusion."

I have questions about how to encode facility identifiers and product codes for pooled and aliquoted units for Codabar or ISBT 128? Where do I get information about these issues?

- Please contact CBER's Manufacturers Assistance and Technical Training Branch (MATTB) at matt@cber.fda.gov for additional information. The regulation requires a unique facility identifier.

How will FDA evaluate compliance with the rule?

- Our investigators will evaluate compliance with these regulations during routine inspections of blood establishments.

May I request an exception or alternative under 21 CFR 640.120 for this requirement of the blood and blood component container label regulations?

- The purpose of the bar coding rule is to reduce transfusion errors and increase patient safety. CBER will carefully review any request for exception or alternative. The bar code regulation for drug products recognizes that exemptions may be warranted when compliance would adversely affect the drug's safety, effectiveness, purity or potency or not be technologically feasible. In the preamble to the rule discussing exemptions for drug products, FDA noted that almost all drug products are capable of bearing a bar code. FDA noted that we would not consider written requests based on reasons such as financial reasons, a claimed low rate of medication errors, or a claim that the product is unique such that medication errors do not occur or rarely occur. In assessing requests for exemptions for blood and blood components, FDA would follow the same approach as that described in the drug regulations (21 CFR 201.25(d)).

Guidance & Rules

- [Bar Code Label Requirement for Human Drug Products and Biological Products; Final rule](#)
 - [Bar Code Label Requirement for Human Drug Products and Biological Products; Final rule; Correction](#)
- [Guidance for Industry: Bar Code Label Requirements - Questions and Answers](#)
- [Guideline for the Uniform Labeling of Blood and Blood Components \(PDF\)](#)

Presentations

- [Bar Code Requirements for Blood Banks](#)
- [Bar Code Label Requirements for Blood and Blood Components](#)

[ISBT Label Checklist for Licensed Establishments](#)

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