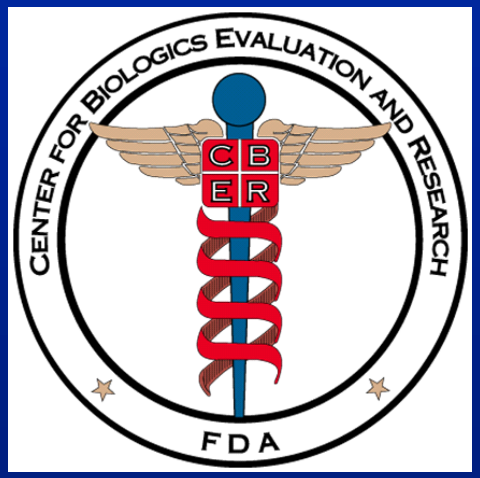

Bar Code Label Requirements for Blood and Blood Components

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ACBSA, May 9-10, 2006

C B
E R

Before the Bar Code Rule

Old regulation (21 CFR 606.121(c)(13)):

Container label may bear encoded information in the form of machine readable symbols approved for use the Director, CBER

Why Require Bar Codes?

- DHHS Secretary Thompson set up a Patient Safety Task Force in 2001
- Bar codes allow healthcare professionals to use scanning equipment to verify right drug (blood component) is given to right patient
- Reduce number of medicine and transfusion errors (502,000 in 20 years)
- Save healthcare costs ($93 billion in 20 years)

Bar Code Label Rule

- Now mandates machine readable information on label
- Final Rule – February 26, 2004 (69 FR 9120)
- Effective date – April 26, 2004
- Dates for compliance:
  - Products approved after effective date – within 60 days of approval
  - Products approved before effective date – within 2 years of effective date (April 26, 2006), includes blood components

Applicable Regulations

- **21 CFR 201.25 - Bar code label requirements**
  - **Applies to most prescription drugs and certain OTC drugs regulated under FD&C and PHS Acts**
  - **Minimum information in linear bar code – NDC number**
  - **Does not apply to hospitals, clinics or public health agencies**
- **21 CFR 610.17 – Bar code label requirements**
  - **Biological products must comply with 201.25**
  - **Does not apply to devices**
  - **Does not apply to blood and blood components for transfusion; these must comply with 606.121(c)(13)**

CBER

Applicable Regulations

- **21 CFR 606.121(c)(13) – Container label**
  - Container label must bear encoded information in format that is machine readable and approved by Director, CBER
  - Applies to blood and blood components intended for transfusion regulated under FD&C and PHS Acts
  - Applies to all blood establishments that manufacture, process, repack or relabel blood and blood components, including hospital transfusion services that pool or aliquot blood components
  - Does not apply to Source Plasma

Which Products Must Comply?

- **Any blood component that can be transfused to a patient and blood components used to make the final transfusible blood component. Also includes:**
  - **Aliquots**
  - **Split or divided units**
  - **Syringes**
  - **Pooled units**
- **Intraoperatively collected autologous blood that is stored in and dispensed from the blood bank**
- **Fibrin/platelet sealant manufactured for allogeneic use**

Which Products are Exempt?

- Products for further manufacturing use – recovered plasma, Source Plasma, Source Leukocytes
- Devices – e.g., filters, apheresis instruments, blood collection sets
- Intraoperative autologous blood collected and transfused in OR or RR; includes salvaged autologous blood that stays with patient
- Autologous fibrin/platelet sealant manufactured and used intra-operatively
- Drainage collected in OR or ER as part of trauma care

Machine Readable Information

- Unique facility identifier (e.g., FDA registration number)
- Lot number (unit or bleed number) relating the unit to the donor
- Product code
- ABO and Rh of the donor

Bar Code Information Requirements

- Must be on container label
- Must be unique to the blood component
- Must be surrounded by sufficient blank space so information can be scanned correctly
- Must remain intact under normal conditions of use

Symbology

- Machine readable vs. Bar code
- Did not specify a particular machine readable symbology to accommodate for new bar codes and changes in technology
- FDA recognized Codabar in 1985
- FDA approved ISBT 128 (v.1.2.0) in 2000
  - Some issues not consistent with regulations, requires variance submission

Bar Code Rule for Tissues

- Applies to human cells, tissues and cellular/tissue-based products subject to pre-market approval under Sec. 351 of PHS Act
- Does not apply to hematopoietic stem/progenitgor cells from peripheral or cord blood only regulated under Sec. 361 of the PHS Act
  - Autologous
  - First and second degree blood relatives

Are Exceptions Allowed?

- **Not consider requests based on:**
  - **Financial reason**
  - **Claim that there is a low rate of error associated with product**
- **We will review requests if complying with rule:**
  - **Affects safety, purity, potency and effectiveness of product**
  - **Not technically feasible**

Information and Guidance

- **Final Rule: Bar Code Label Requirements for Human Drug Products and Biological Products (2/26/04)**

  http://www.fda.gov/cber/rules/barcodelabel.htm
- **Frequently Asked Questions: Bar Code Label Requirements for Blood and Blood Components (4/7/06)**

  http://www.fda.gov/cber/faq/barcodefaq.htm
- **Guidance for Industry: Bar Code Label Requirements: Questions and Answers (4/06)**

  http://www.fda.gov/cber/gdlns/barcode.htm

Information and Guidance

- **Guideline for the Uniform Labeling of Blood and Blood Components (8/85)**

  http://www.fda.gov/cber/guidelines.htm#95
- **Guidance for Industry: Recognition and Use of a Standard for the Uniform Labeling of Blood and Blood Components (6/6/00)**

  http://www.fda.gov/cber/gdlns/unilabbld.htm
- **Manufacturers Assistance and Technical Training Branch of Office of Communication, Training and Manufacturers Assistance, CBER**

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