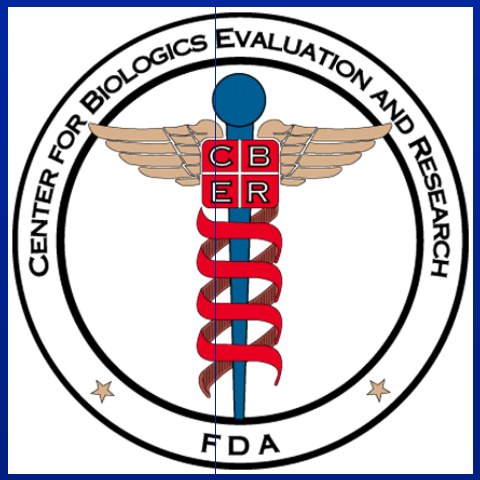

FDA Bar Code Requirements for Drugs

ICCBBA-GS1

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E R

Before the Bar Code Rule

No reference to bar codes in the 200s

Blood container labels cited the following 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 ensure that the right drug would be given to right patient, at the right time, by the right route of administration, and in the right dose.

Why Require Bar Codes?

- Reduce number of medicine and transfusion errors (502,000 in 20 years)
- Save healthcare costs ($93 billion in 20 years)

Bar Code Label Rule

- Final Rule – February 26, 2004
- Effective date – April 26, 2004
- Now mandates that bar codes appear on certain human drugs and biological products

Bar Code Label Rule

- Dates for compliance:
  - Products approved after effective date – within 60 days of approval
  - Products approved before effective date – within 2 years of effective date.

Applicable Regulations for Most Biologics

- 21 CFR 201.25 - Bar code label requirements
  - Applies to most prescription drugs and certain OTC drugs regulated under FD&C and PHS Acts.
  - Linear bar code –
    - NDC number
    - Must meet European Article Number/ Uniform Code Council (EAN/UCC) or Health Industry Business Communications Council (HIBCC) standards.

Applicable Regulations for Most Biologics

- 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)

Applicable Regulations for Most Biologics

- Who is subject to the rule?
  - Manufacturers, repackers, relabelers, private label distributors of both prescription and OTC products unless they are exempt from registration and listing
- What drugs are included:
  - Prescription drugs sold to to or used by hospitals
  - Does not apply to prescription drugs sold directly to patients

Applicable Regulations for Most Biologics

- What drugs are not included:
  - Drug samples, allergenic extracts, IUDs, Medical gases, Radiopharmaceuticals, and Low-density polyethylene containers with no overwrap
- Does not apply to hospitals, clinics or public health agencies

Exemptions Requests

- **Requesting an exemption from 21 CFR 201.25?**
  - **Manufacturers may submit a written request for an exemption.**
  - **The request must document why:**
    - **Compliance with the rule would adversely affect the safety, effectiveness, purity, or potency of the product, or**
    - **Why it is not technologically feasible, and**
    - **Why package redesign or overwraps could not address the issue,**
    - **What alternative methods are in place render bar codes unnecessary.**

Bar Code Regulation for Transfusible Products

- 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

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

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

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

  Email - matt@cber.fda.gov