Bar Code Label Requirements For Human Drug Products and Biological Products

April 7, 2004

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Bar Code Label Requirements For Human Drug Products and Biological Products

- Proposed Regulation published - 3/14/03
- Final rule published - 2/26/04
- Effective date – 4/26/04

Purpose of the Rule

- Help reduce medication errors in hospitals and other health care settings
- Medication Error: any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the healthcare professional, patient, or consumer.

How will the purpose be Accomplished?

- Require drugs to contain barcodes allowing health care professional to use scanning equipment to verify:
  - Right drug
  - Right dose
  - Right route of administration
  - Right patient
  - Right time

Scope of the Regulation?

- Require certain human drugs/biologics to have bar codes
  - Linear Bar Codes
    - UCC or HIBCC standards
  - National Drug Code (NDC)
    - Lot number & expiration date voluntary

Scope of the Regulation?

- Blood and Blood Components
  - NDC #s not applicable to blood and blood components
  - Require machine readable information on container labels of transfusible products
  - Approved by the Director, CBER
  - specific pertinent information

How does this Rule effect blood and blood components?

- 606.121(c)(13) read:

  "The container label **may** bear encoded information in the form of machine readable symbols approved for use by the Director, Center for Biologics Evaluation and Research."

How does this Rule effect blood and blood components?

- Final rule 606.121(c)(13) reads:

  "The container label **must** bear encoded information that is machine readable and approved for use by the Director, Center for Biologics Evaluation and Research."

How does this Rule effect blood and blood components?

(i) Who is subject to this machine readable requirement?

- All blood establishments that manufacture, process, repack, or relabel blood or blood components intended for transfusion and are regulated under the FD&C Act or the PHS Act.

How does this Rule effect blood and blood components?

(ii) What blood products are subject to this machine readable requirement?

- All blood and blood components intended for transfusion are subject to the machine readable information labeling requirements in this section.

How does this Rule effect blood and blood components?

(iii) What information must be machine readable?

- Each label must have machine readable information that contains, at a minimum:
  - A unique facility identifier
  - Lot number relating to the donor
  - Product code, and
  - ABO and Rh of the donor

How does this Rule effect blood and blood components?

(iv) How must the machine readable information appear?

- The machine readable information must:

  (A) Be unique to the blood or blood component

  (B) Be surrounded by sufficient blank space so that the machine readable information can be scanned correctly; and

  (C) Remain intact under normal conditions of use.

How does this Rule effect blood and blood components?

(v) Where does the machine readable information go?

- The machine readable information must appear on the label of any blood or blood component which is or can be transfused to a patient or from which the blood or blood component can be taken and transfused to a patient.

How does this Rule effect blood and blood components?

- This requirement to have machine readable information also includes:
- aliquots,
- divided units,
- washed cells,
- syringes,
- pooled components,
- etc.