W1234 96 123456 44 S

8400

Accurate Blood Center
Anywhere, Worldwide
FDA Registration Number _____
US License Number _____

Properly Identify Intended Recipient
See Circular of Information for indications, contraindications, cautions and methods of infusion. This product may transmit infectious agents.

L only

VOLUNTEER DONOR

AB

Rh POSITIVE

9972322359

9972322359

Expiration Date

20 AUG 1997

RED BLOOD CELLS
ADENINE-SALINE (AS-1) ADDED

From 450 mL CPD Whole Blood
Store at 1 to 6 C

US License Number _____

Special Testing label goes here

Collected and Processed by and/or Further Processing by label can be placed here—may be followed by US License Number

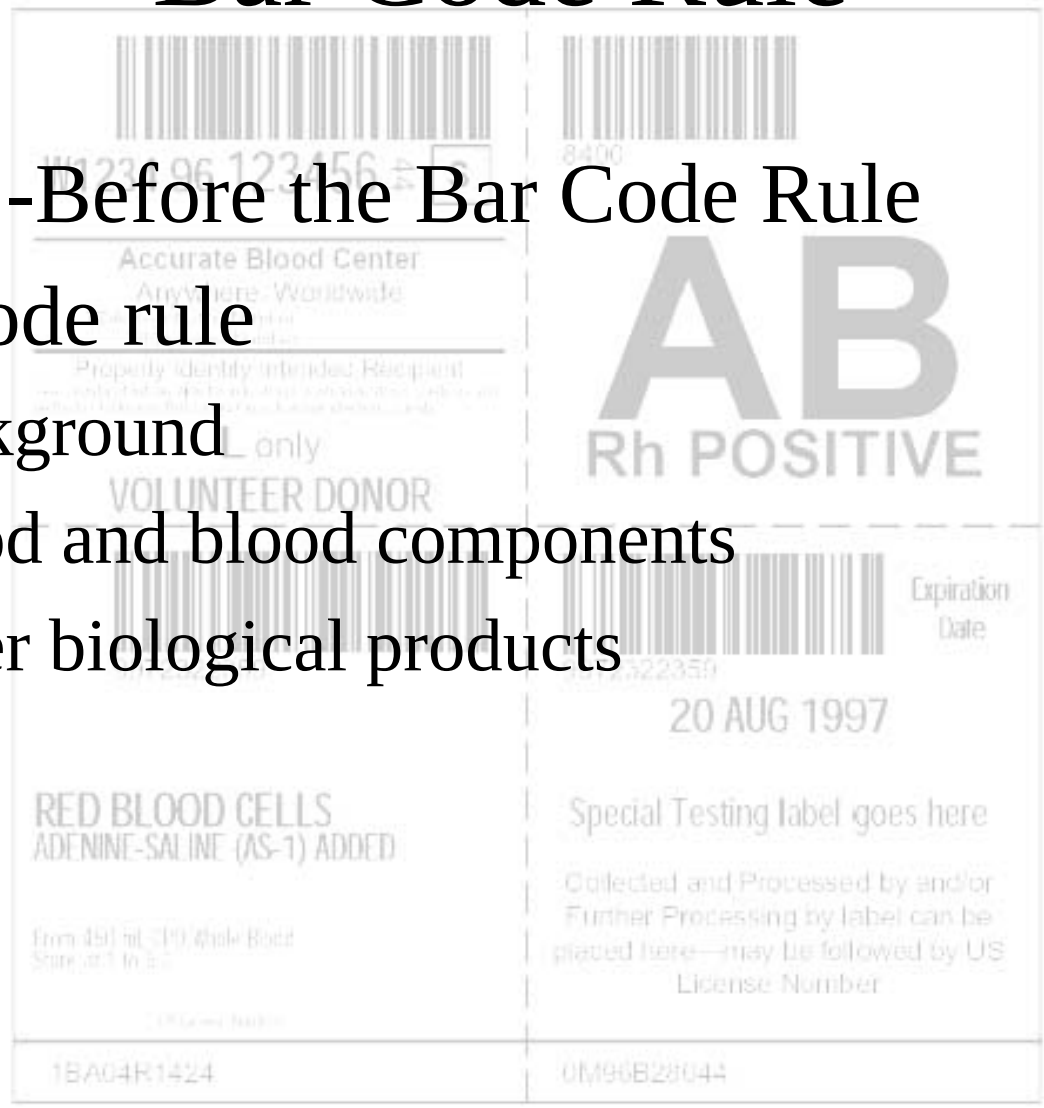
1BA04R1424

0M96B28044

Bar Code Requirements

Diane Maloney
Associate Director for Policy
CBER
January 20, 2006

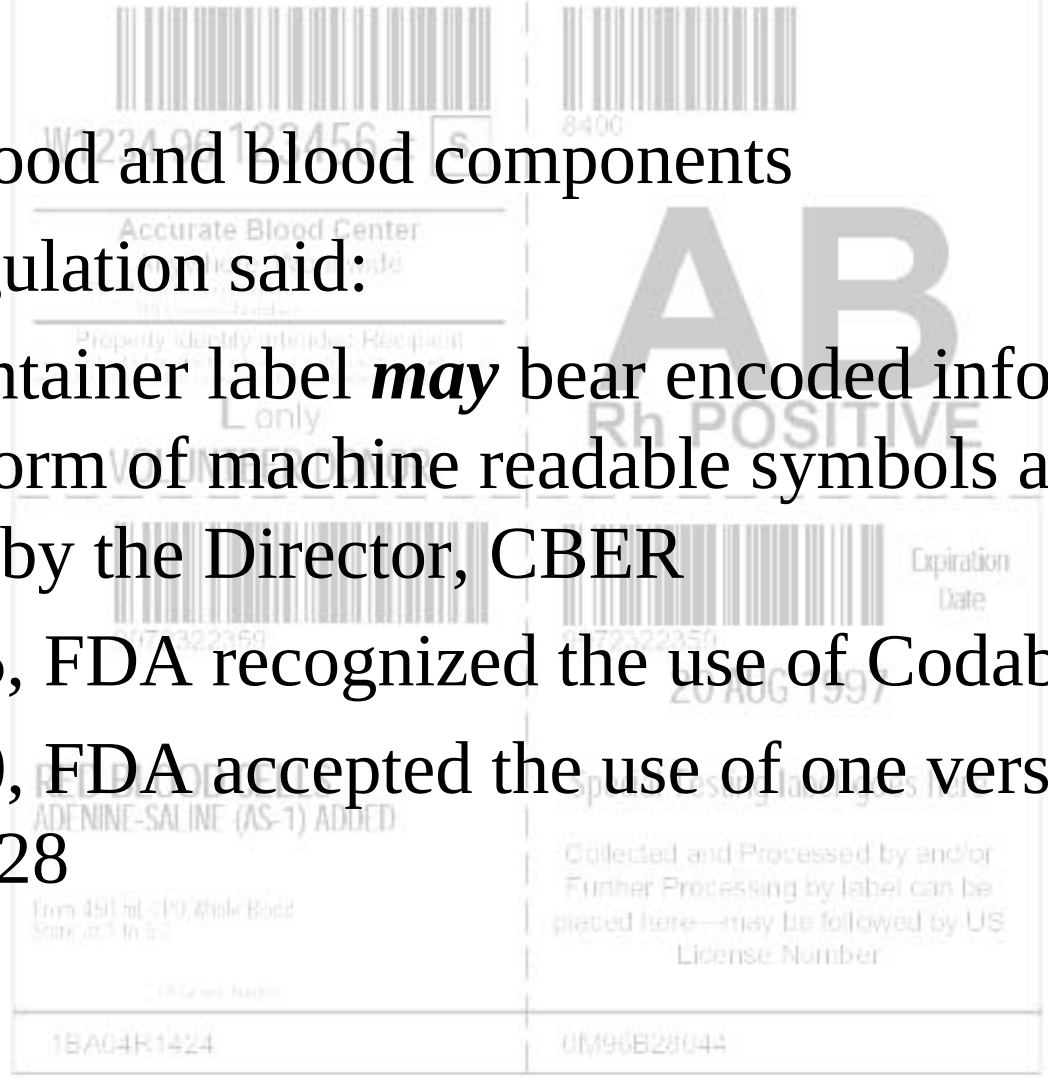
Bar Code Rule



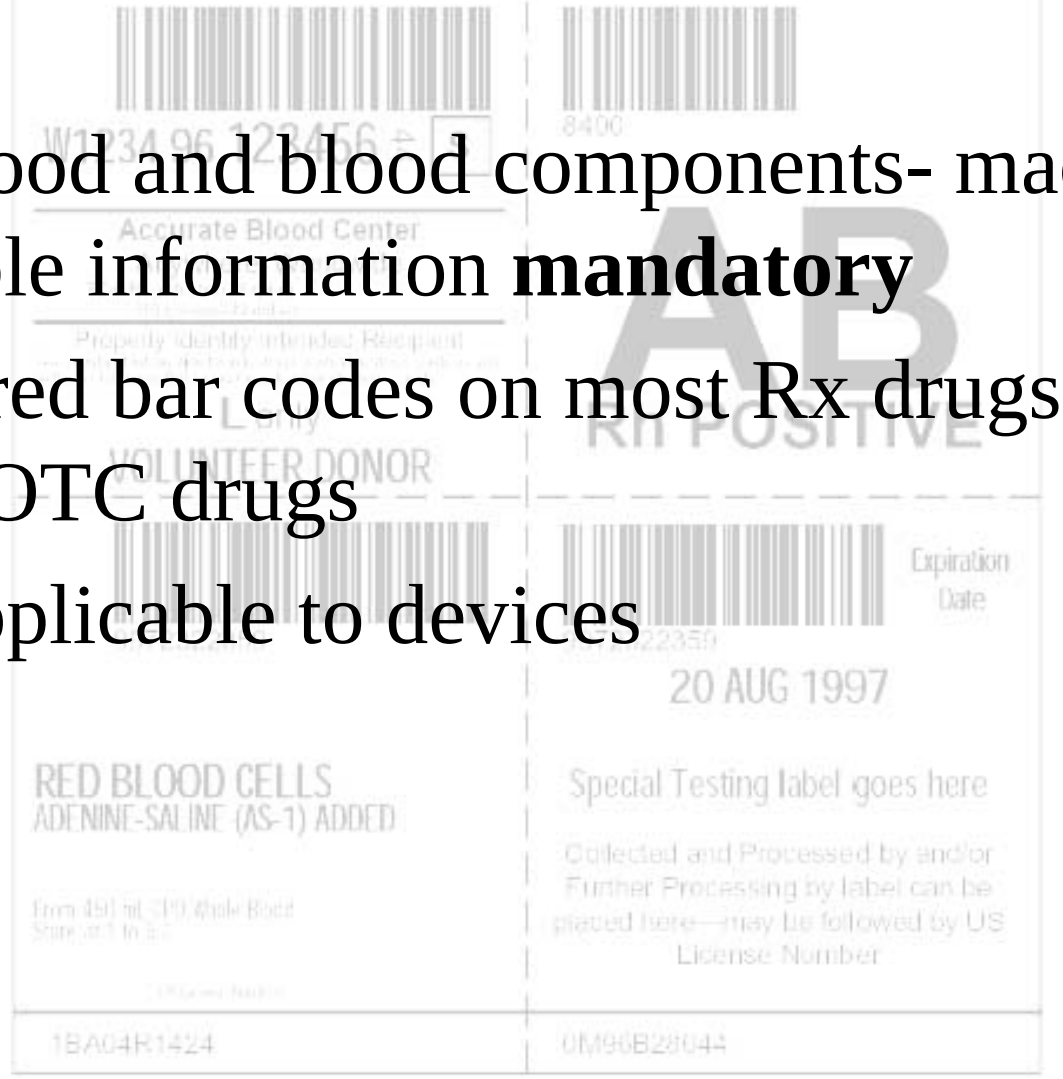
- Blood -Before the Bar Code Rule
- Bar Code rule
  - Background
  - Blood and blood components
  - Other biological products

Before the Bar Code Rule

- Re: Blood and blood components
- Old regulation said:
- The container label ***may*** bear encoded information in the form of machine readable symbols approved for use by the Director, CBER
- In 1985, FDA recognized the use of Codabar
- In 2000, FDA accepted the use of one version of ISBT 128



Bar Code Rule



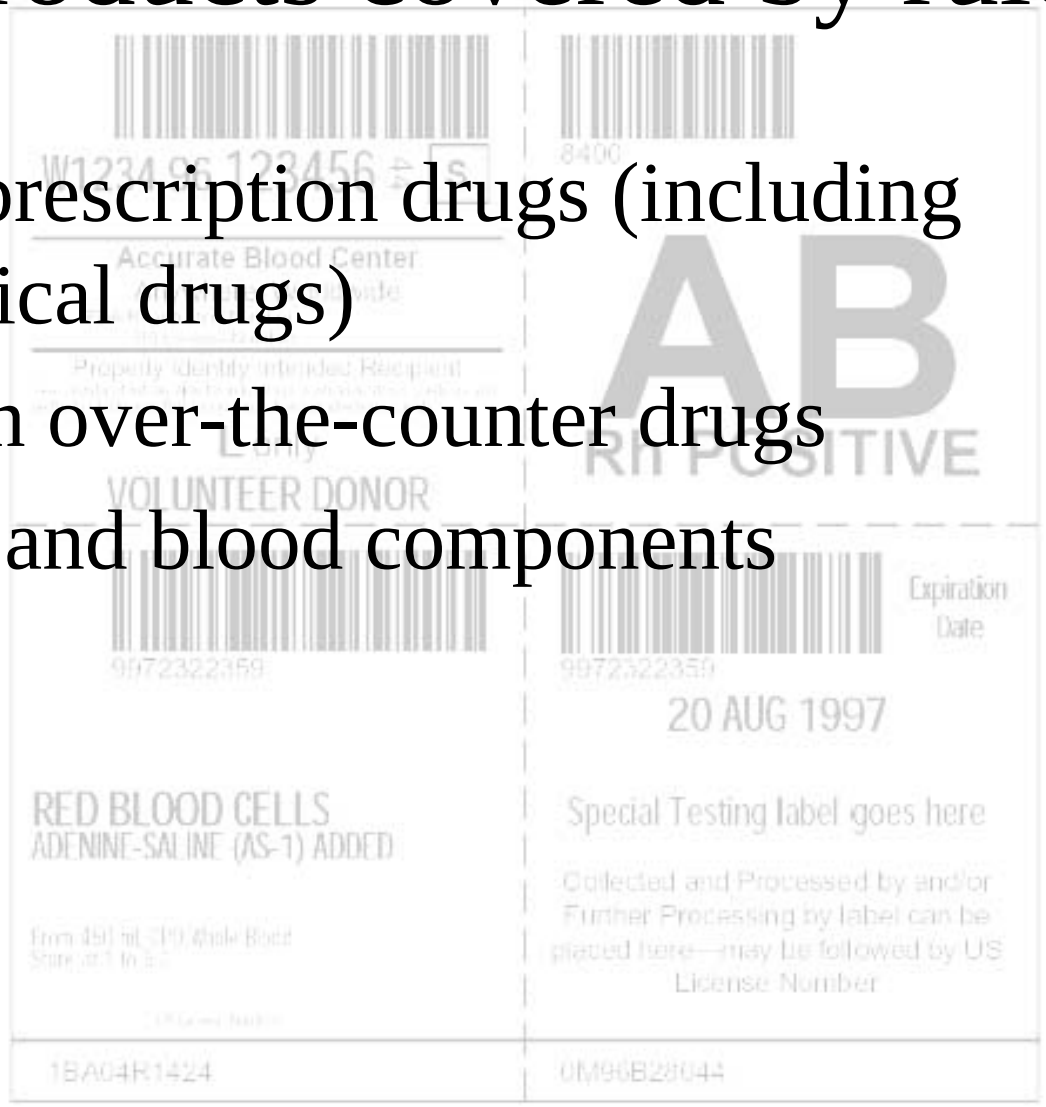
- For blood and blood components- machine readable information **mandatory**
- Required bar codes on most Rx drugs and some OTC drugs
- Not applicable to devices

Bar Code Rule

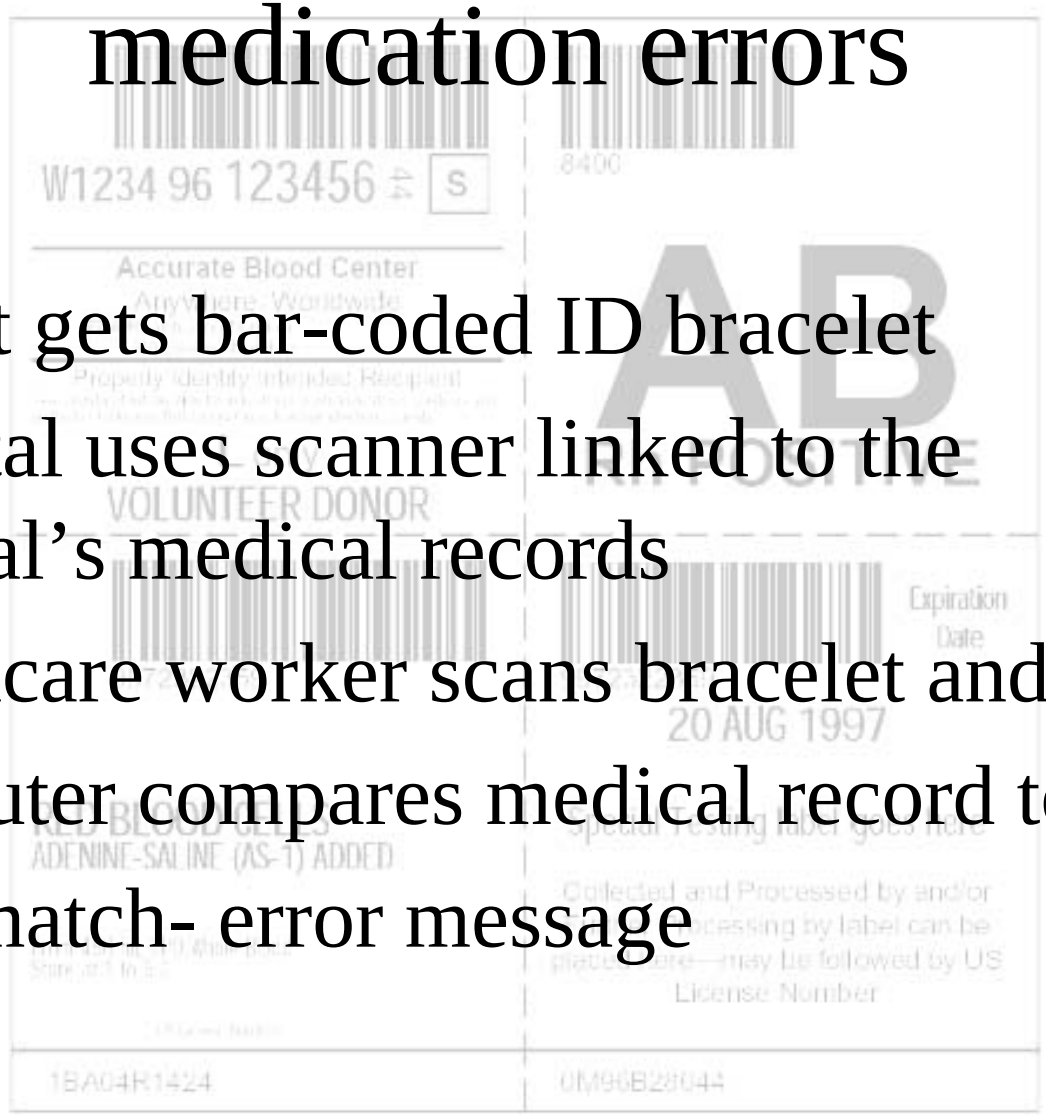
- Finalized: February 26, 2004
- Effective Date: April 26, 2004
- Products approved after effective date must comply within 60 days of approval
- Products approved before the effective date must comply within 2 years of effective date

Products covered by rule

- Most prescription drugs (including biological drugs)
- Certain over-the-counter drugs
- Blood and blood components



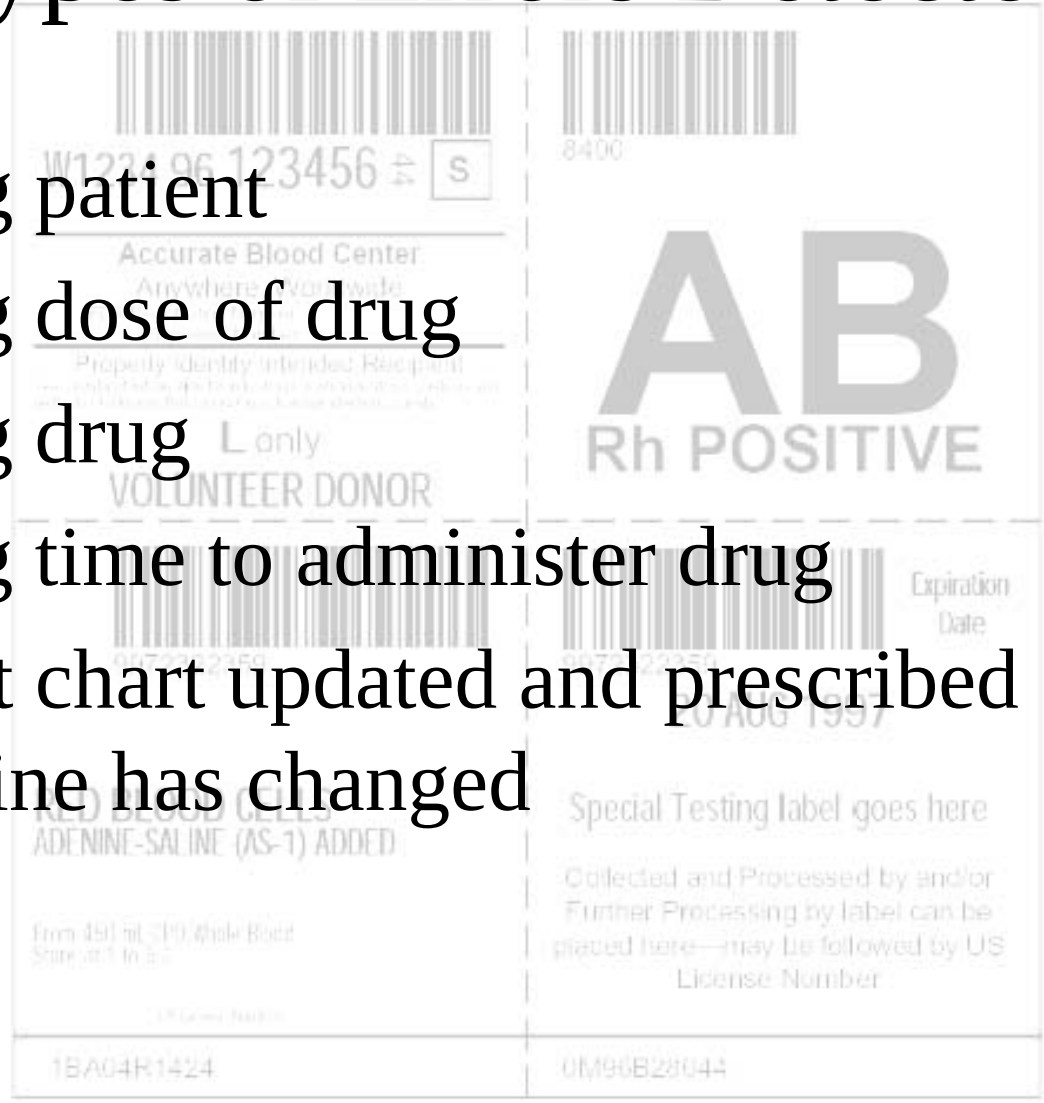
How bar coding can prevent medication errors



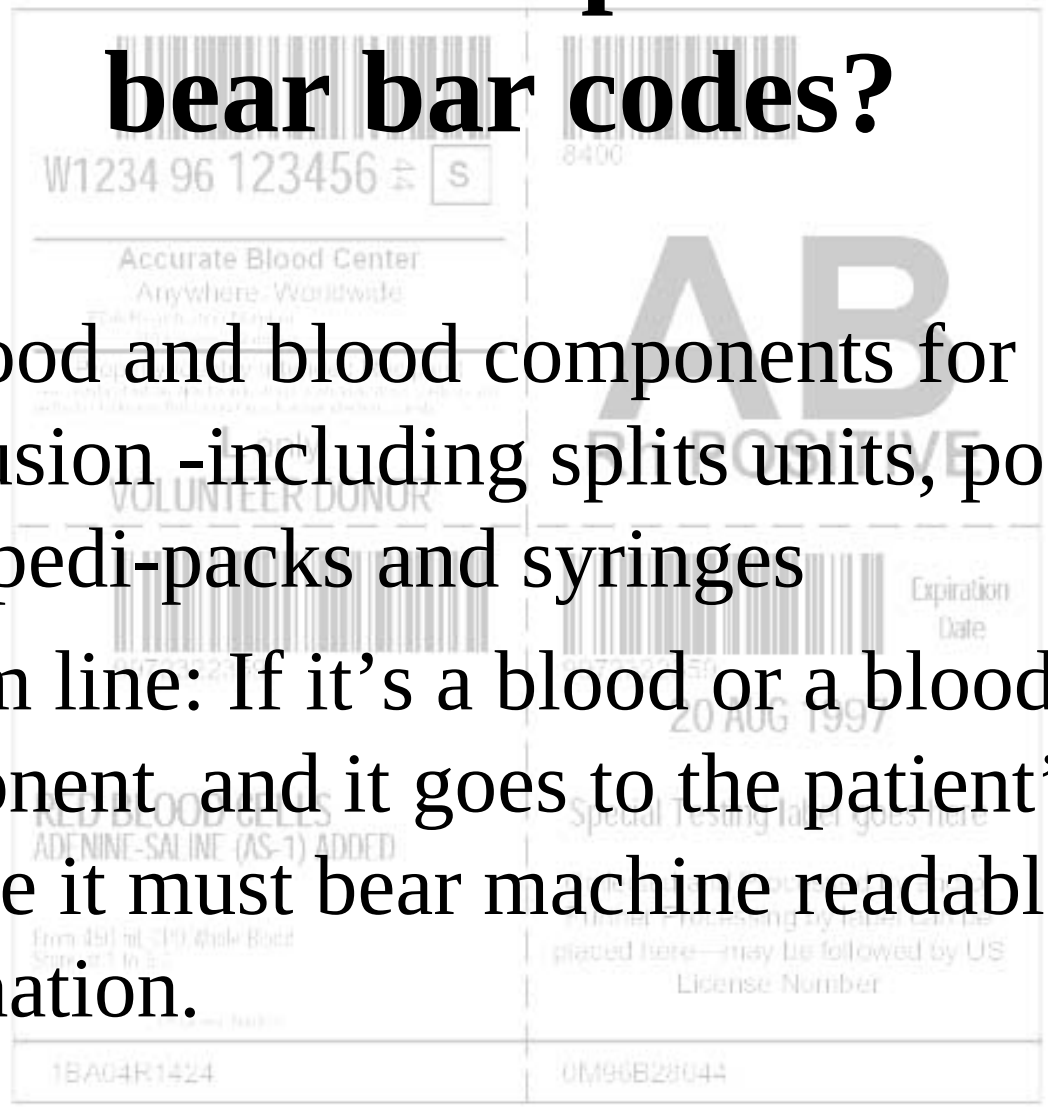
- Patient gets bar-coded ID bracelet
- Hospital uses scanner linked to the hospital's medical records
- Healthcare worker scans bracelet and drug
- Computer compares medical record to drug
- If no match- error message

Types of Errors Detected

- Wrong patient
- Wrong dose of drug
- Wrong drug
- Wrong time to administer drug
- Patient chart updated and prescribed medicine has changed



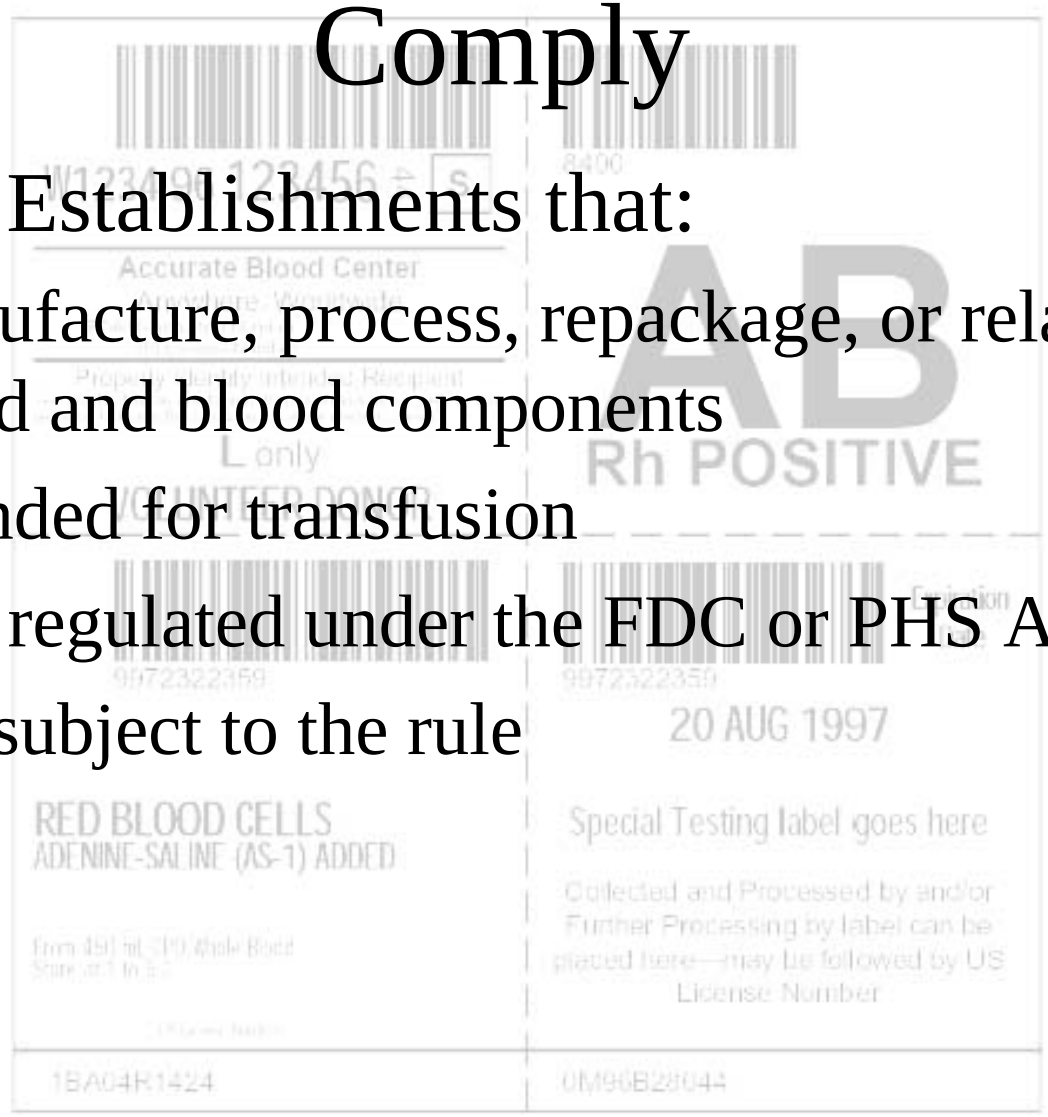
What blood components must bear bar codes?



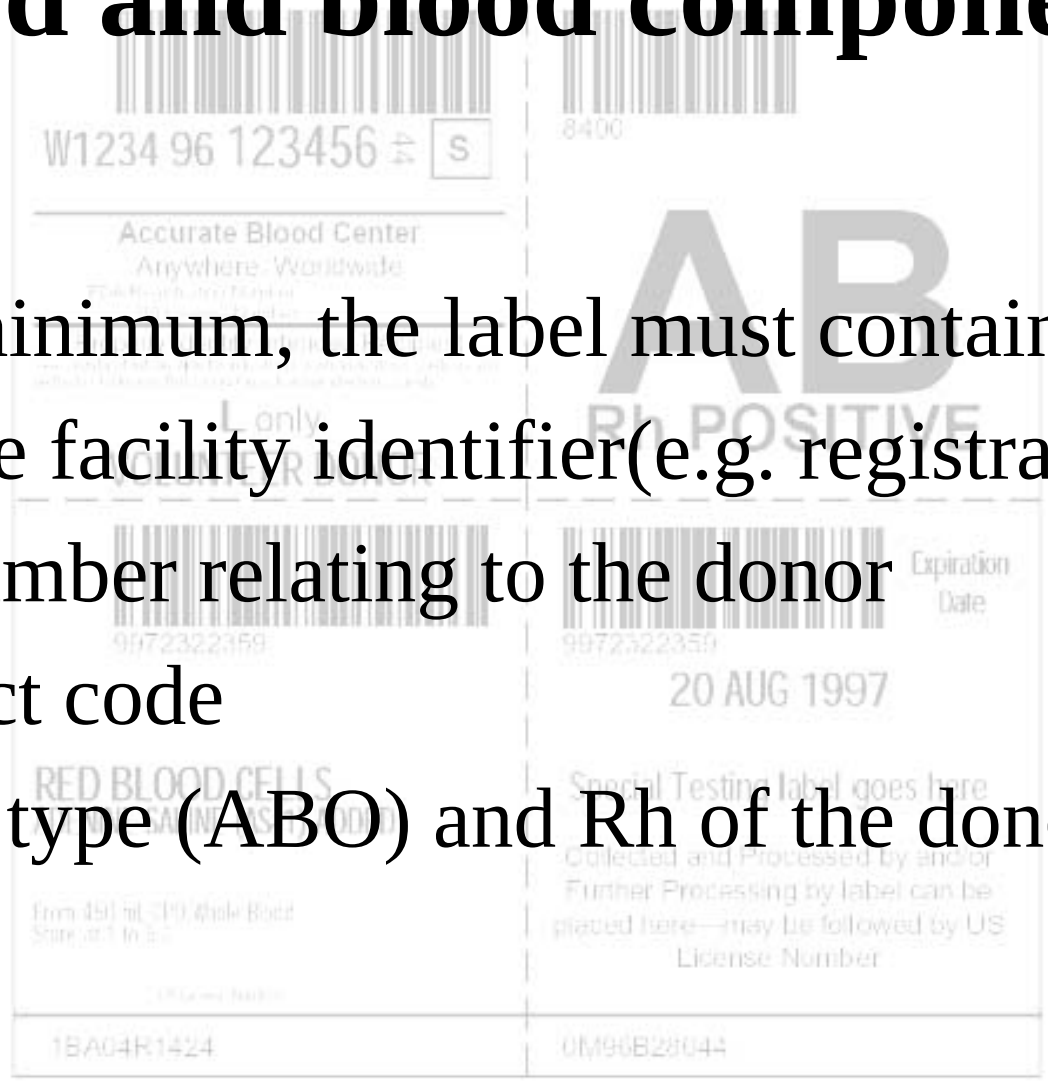
- All blood and blood components for transfusion -including splits units, pooled units, pedi-packs and syringes
- Bottom line: If it's a blood or a blood component and it goes to the patient's bedside it must bear machine readable information.

Blood Establishments Must Comply

- Blood Establishments that:
  - Manufacture, process, repackage, or relabel blood and blood components
  - Intended for transfusion
  - And regulated under the FDC or PHS Act
  - Are subject to the rule



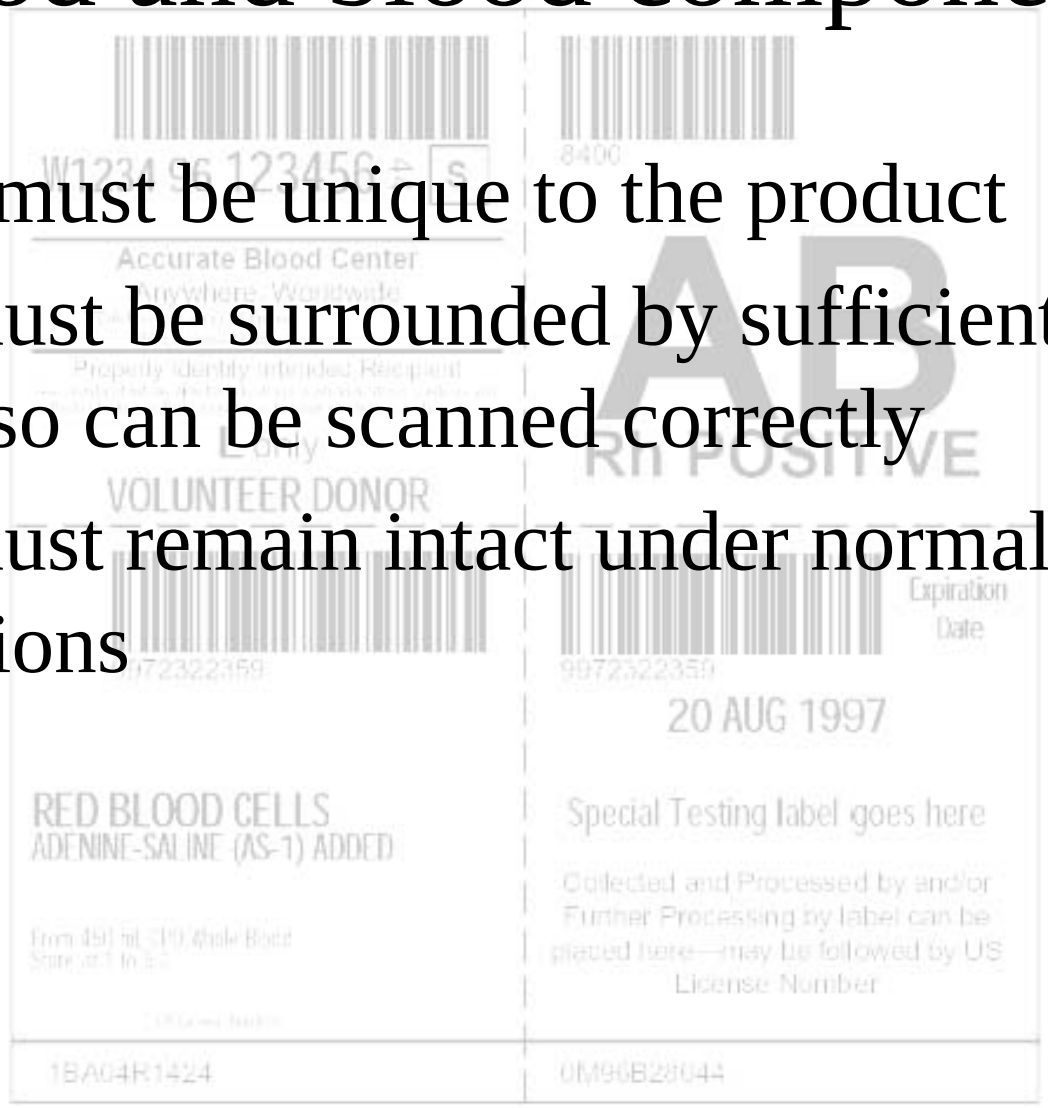
Blood and blood components



- At a minimum, the label must contain:
- Unique facility identifier(e.g. registration #)
- Lot number relating to the donor
- Product code
- Blood type (ABO) and Rh of the donor

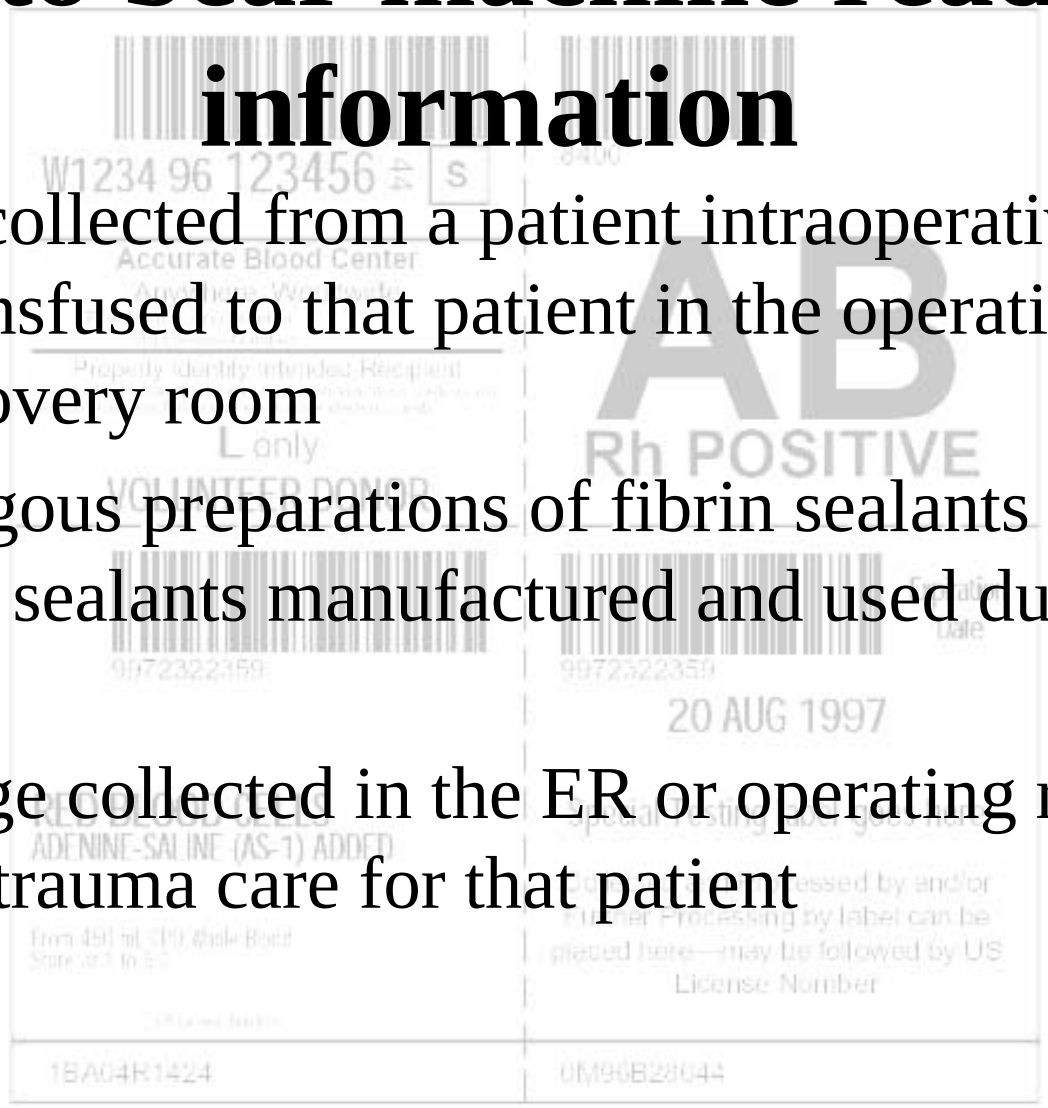
Blood and blood components

- Label must be unique to the product
- Info must be surrounded by sufficient blank space so can be scanned correctly
- Info must remain intact under normal conditions



What blood components do not have to bear machine readable information

- Blood collected from a patient intraoperatively and transfused to that patient in the operating or the recovery room
- Autologous preparations of fibrin sealants or platelet sealants manufactured and used during surgery
- Drainage collected in the ER or operating room as part of trauma care for that patient

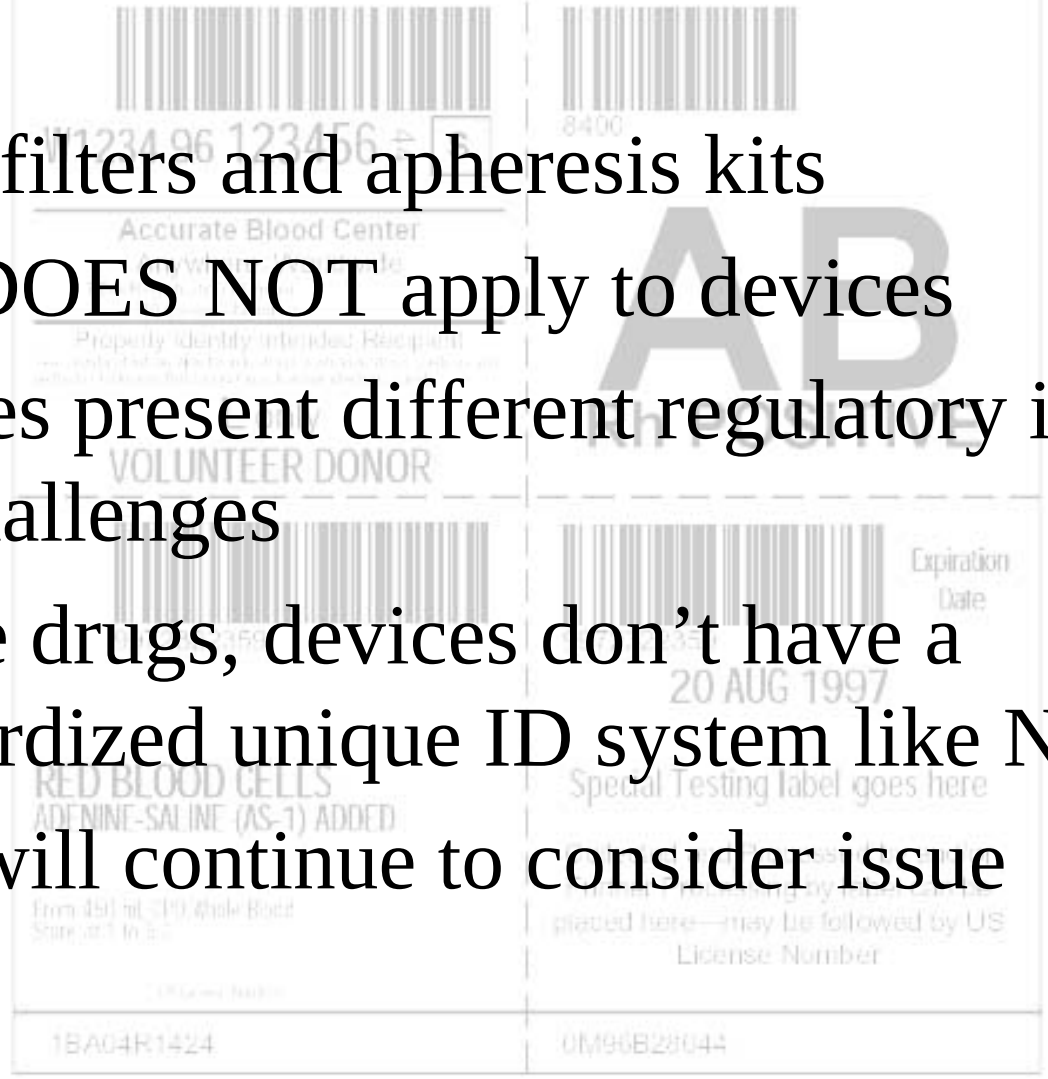


Requirements for other blood products

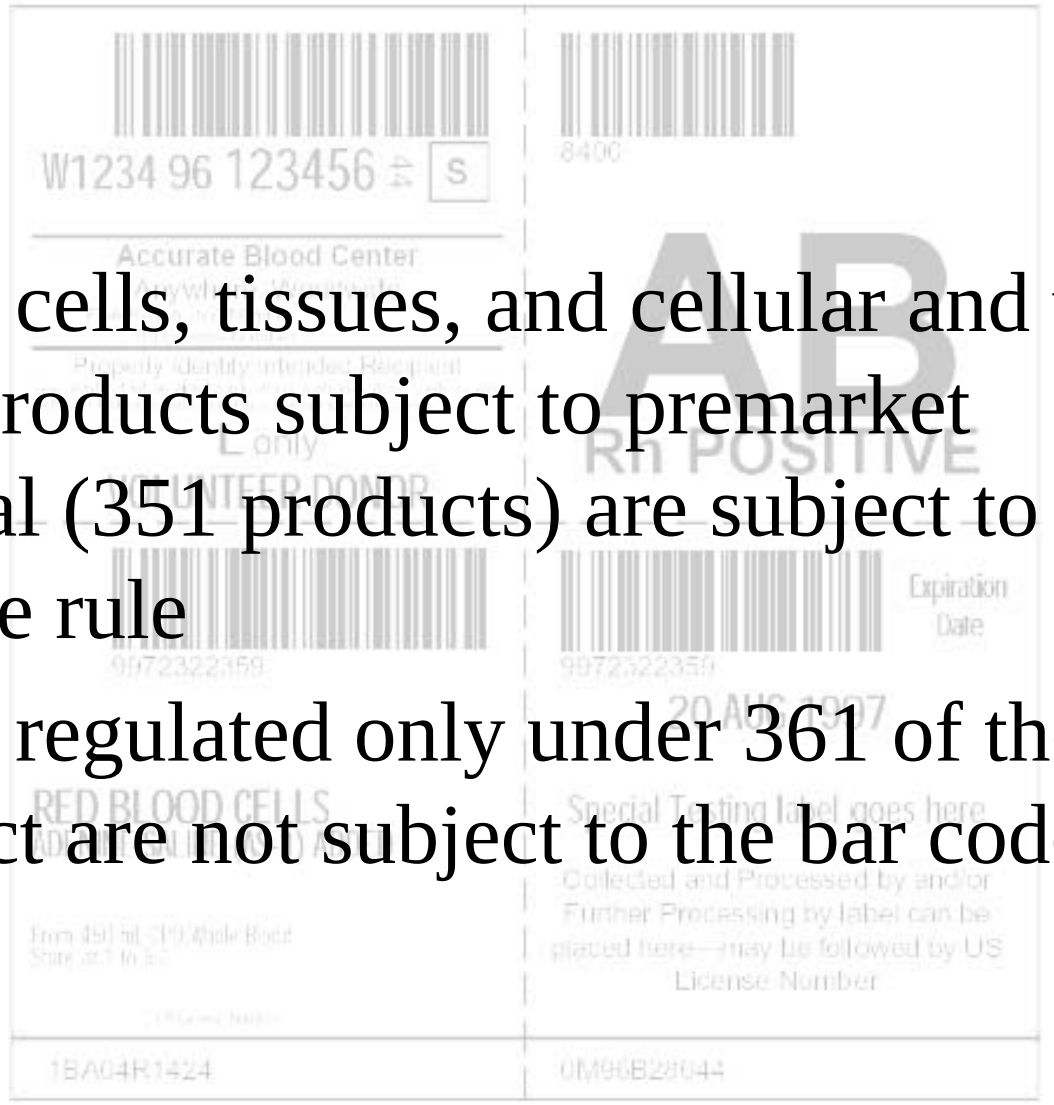
- Source Plasma used to manufacture plasma-derived therapies –SP not intended for transfusion – so does not need to bear machine readable information. However, the resulting products would be subject to the bar code rule
- Plasma derivatives (e.g. IGIV) are subject to the bar code requirements for drug products (see 21 CFR 610.67 and 201.25)

What about devices?

- E.g. – filters and apheresis kits
- Rule DOES NOT apply to devices
- Devices present different regulatory issues and challenges
- Unlike drugs, devices don't have a standardized unique ID system like NDC
- FDA will continue to consider issue



What about "Tissues?"



- Human cells, tissues, and cellular and tissue based products subject to premarket approval (351 products) are subject to the bar code rule
- HCTPs regulated only under 361 of the PHS Act are not subject to the bar code rule

Exemptions from the bar code requirement

- FDA may exempt a product from the bar code requirements
- Factors:
  - Compliance would adversely affect safety, effectiveness, purity or potency or not technologically feasible
  - Alternative regulatory program renders bar code unnecessary for patient safety

Thank You.