

# **National Drug Codes for HCT/Ps**

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- AABB



- America's Blood Centers



- American Red Cross



- American Society for Blood and Marrow Transplantation



- Foundation for the Accreditation of Cellular Therapy



- ICCBBA



- International Society for Cellular Therapy



- National Marrow Donor Program



## Hematopoietic Progenitor Cells

HPC, APHERESIS

HPC, CORD BLOOD

HPC, WHOLE BLOOD

## Therapeutic Cells

TC, APHERESIS

TC, WHOLE BLOOD

TC, CORD BLOOD

TC-T CELLS

TC- CTL

TC- T REG CELLS

TC- DC

TC- NK CELLS

TC- TUMOR DERIVED

TC- MSC

TC-APC

# 21 CFR Part 201, Subpart A, Section 201.25

- (d) *Can a drug be exempted from the bar code requirement?*
- (1) On our own initiative, or in response to a written request from a manufacturer, repacker, relabeler or private label distributor, we may exempt a drug product from the bar code label requirements set forth in this section. The exemption request must document why:
- i. ....; or
  - ii. an alternative regulatory program or method of product use renders the bar code unnecessary for patient safety.

# Bar Code Rule and Hematopoietic Progenitor Cells / Therapeutic Cells

- NDC - Square Peg for a Round Hole
- ISBT 128 Standard
- Negative Impact of Implementing NDCs

# Square Peg for a Round Hole

- Biological nature of HPCs and TCs
- Variable contents of HPCs and TCs
- HPCs and TCs are not mass-produced
- HPCs and TCs do not fit the NDC system
- Overly burdensome with no increase to patient safety
- NDC number is not a useful reference in any federally maintained database - products are infused / transplanted by the time the NDC number is available.

# ISBT 128 Standard

- Greater benefits and increase to patient safety than an NDC
- Globally unique product identifier
- Cellular Therapy Coding and Labeling Advisory Group - AABB, ASBMT, EBMT, FACT, ICCBBA, ISBT/SITS, ISCT, ISCT Europe, JACIE, NMDP and WMDA
- Industry familiarity with ISBT 128
- Excellent traceability and trackability of products
- Contains more information than the NDC code

# Negative Impact of Implementing NDCs on HPCs and TCs

- Current information systems cannot accommodate the NDC system
- Small package size of some products will not accommodate the NDC label
- Loss of standardization
- Multiple products and attributes of cellular products are not easily managed
- Overly burdensome and duplicative with no increase to patient safety
- Loss of confidentiality

- NDC - no increase in patient safety.
- Implementing NDC will interfere with progress on ISBT 128
- Tracking using two different labeling systems will
  - Have a negative impact on patient safety
  - Introduce opportunities for error
- NDC will not replace the need to use ISBT 128