

National Drug Codes for HCT/Ps

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Can a drug be exempted from the bar code requirement?

21 CFR Part 201, Subpart A, Section 201.25

- (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

- Ø HPCs/TCs not a fit for NDC System
- Ø Benefits of ISBT 128 Standard
- Ø Negative Impact of Implementing NDCs



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NDC System is not a good fit for HPCs and TCs

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



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Benefits of ISBT 128 Standard

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



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Negative Impact of Implementing NDCs on HPCs and TCs

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



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Summary

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



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