Summary of Industry's Concerns to Draft Guidance on *Minimally Manipulated, Unrelated, Allogeneic Placental/Umbilical Cord Blood Intended for Hematopoietic Reconstitution in Patients with Hematological Malignancies*

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Key Concerns

- How to demonstrate comparability.
- Continued use of Imported products.
- Requirement for NDC number on label.
- Broaden indications for use.

Demonstrating Comparability

- Previously manufactured cord blood units need to be available.
- Clarification of demonstrating comparability in guidance.

Use of Imported Products

- Importation of cord blood units is essential to meet our needs
- Approximately 20% of cord blood units transplanted in the US are imported.
- The availability of these cord blood products is especially important for racial and ethnic minorities.

Requirement for NDC Number

- NDC number is **not** a good fit for these products.
- ISBT 128 is a voluntary standard that has been accepted internationally.
  - Ensures traceability and trackability of imported/exported products.
  - Fosters global harmonization
- Redundant identification system
  - **No** increase to patient safety – no value added.

Broaden Indications for Use

- Indications for cord blood transplantation should be broadened to include non-malignant conditions.
  - Non-malignant disorders represented 27% of total transplants - Feb 2000 to Dec 2005
  - NMDP data suggests similar outcomes (engraftment and survival) for malignant and non-malignant hematologic disorders

Summary

- Overall, the draft guidance provides needed structure.
  - Excellent job of outlining what required and recommended tests should be performed for the licensed products.
  - Allows flexibility in areas that permit flexibility.
- Addressing the four key concerns would enhance the industry's ability to implement the FDA's recommendations.