Cord Blood Guidance Update

ACBSCT Meeting
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Draft Guidance revises 2009 cord blood IND and BLA guidance

- **Investigational New Drug Applications for Minimally Manipulated, Unrelated Allogeneic Placental/Umbilical Cord Blood Intended for Hematopoietic and Immunologic Reconstitution in Patients with Disorders Affecting the Hematopoietic System**

- **Biologics License Applications for Minimally Manipulated, Unrelated Allogeneic Placental/Umbilical Cord Blood Intended for Hematopoietic and Immunologic Reconstitution in Patients with Disorders Affecting the Hematopoietic System**

http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/CellularandGeneTherapy/default.htm

Published June 2013 – comment period ends September 16, 2013

Submit electronic comments to http://www.regulations.gov

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Why update?

- Since 2009, CBER has gained experience through pre-IND and pre-BLA meetings and ongoing review of biologics license applications; 5 BLAs approved to date
- Scientific knowledge on cord blood banking and clinical use has advanced
- Revisions intended to maintain consistency with current FDA policy and current practice in the field of cord banking, and improve usability of the guidance

Limited changes to IND guidance

- Updates terminology (HPC, Cord Blood)
- Expands clinical indication based on review of docket data and considerations of the September 2011 meeting of the Cellular, Tissue, and Gene Therapy Advisory Committee
- Clarifies table of contents requirement

Changes to BLA guidance

- Updates terminology and clinical indication (same as IND guidance)
- Clarifies the types of clinical information that should be submitted for review, and adds reference to other relevant guidance documents