FDA Update on Cord Blood Banking Regulations

Ellen Lazarus, M.D.
Division of Human Tissues
Office of Cellular, Tissue, and Gene Therapies

Cord blood for family-related use

- Regulated solely under set of HCT/P final rules with associated (draft) guidance, *unless more than minimally manipulated or for non-homologous use or combined with another article (with some exceptions)*
- Registration and listing
- Compliance with cGTPs, including donor eligibility regulations, assessed at inspection
- “Cross-over” (cord blood for family-related use converted to unrelated donor inventory) – no mechanism at this time

Cord blood from unrelated donors

- Regulated as HCT/P under 21 CFR Part 1271 Subparts A-D
- Also regulated as biological drug under the FD&C Act and section 351 of the PHS Act
- Other regulations that apply
  - Labeling and advertising (21 CFR Part 201 and 202)
  - CGMPs (21 CFR Part 211)
  - IND regulations (21 CFR Part 312)
  - Licensing and general biological products standards (21 CFR Parts 600, 601, 610)

HCT/P Regulations

- General provisions, definitions (21 CFR 1271 Subpart A)
- Establishment registration (21 CFR 1271 Subpart B) – not required if only manufacturing products under IND
- Donor eligibility rule (21 CFR Subpart C) – final guidance pending
- Current Good Tissue Practice (21 CFR Subpart D) – draft guidance under development
- Reporting – HCT/P deviation and adverse reaction reporting for “361” products only
- Imported products – field mechanism for expedited entry

Current Good Manufacturing Practice (CGMP)

- 21 CFR Parts 210 and 211
- Draft Guidance: INDs — Approaches to Complying with CGMP During Phase 1 (January 2006)
  - Under revision based on comment to the draft rule

When is an IND needed?

- Minimally manipulated unrelated allogeneic cord blood for homologous use
  - IND moratorium ongoing
- Cord blood for non-homologous use
- Cord blood that is more than minimally manipulated
  - Ex vivo expansion

Licensure

- Draft guidance for minimally manipulated unrelated allogeneic cord blood for homologous use under development
  - Recommendations for applying for a license
- Requirements to be phased in – announcement will be published in Federal Register
- Deviation and adverse event reporting under 21 CFR 600.14 and 600.80 for licensed biologic

Regulation of devices for cord blood processing

- Manufacturers may submit request for device classification - FD&C Act Section 513(g)
- Examples
  - Automated “closed system” processing devices
  - Final product containers