

# Mid-Cycle Review Meeting Minutes, June 10, 2011 - Hemacord

## Mid-Cycle Review Meeting Minutes

**Sponsor:** New York Blood Center  
**BLA #:** BLA 125397  
**Product:** Hematopoietic stem/progenitor cells, cord (HPC-C)  
**Date:** June 10, 2011  
**Time:** 2:30PM -4:00PM

**Meeting Attendees:** Thomas, Terrolyn; Witten, Celia; Bryan, Wilson; Przepiorka, Donna;; Nguyen, Loan; Stockbridge, Lisa L; Heidaran, Mohammad; Wang, Gang; Serabian, Mercedes; Hoque, Atm S.; Wonnacott, Keith; Quagraine, Mercy; Karandish, Safa; Wise, Robert; Riggins, Patrick; Puri, Raj K. Benton, Kimberly; Bross, Peter; Joshi, Bharat; Rees, Renee; Hyde, John E; Bauer, Steven; McCright, Brenton; Norwood, Laurie; Ghosh, Joydeep; Lazarus, Ellen;; Stevens, Ted; Bi, Lilia Lei; Witten, Rachel; Dapolito, Gail; Fan, Yong

### 1. Introductions

### 2. Important dates

Draft FDA Briefing Document  
Due to Supervisors:

COB, July 8, 2011

Primary Reviews Due:  
PDUFA GOAL Date:

COB, August 18, 2011  
November 10, 2011

### 3. Discipline Specific Reviews of Application (handouts provided)

- **CMC - M. Quagraine; B. McCright; B. Joshi; S. Bauer; J. Ghosh; S. Karandish**  
*Requested teleconference with sponsor to discuss outstanding issues.*
- **DMPQ – M. Heidaran & G. Wang**  
*Requested teleconference with sponsor to discuss outstanding issues (483 citation update ; quality and batch record verification by August 1,2011).*
- **Clinical – D. Przepiorka & J. Hyde**  
*Team will move forward with PeRc waiver. OCTGT Director, Dr Witten stated that OBE needs to review the data; OBE reviewer should be invited back to review team.*
- **Labeling – L. Stockbridge & L. Nguyen**  
*Noted that mock package insert was sent to sponsor.*

### 4. Issues Requiring Resolution

- It was indicated that additional Malignancy and Metabolic Hematology Disease Specialist should be added to Advisory Committee panel.
- DMPQ will review the DCGT recommendation on NYBC's sample retention management for adequacy and update management

## **5. Scheduled Meetings**

- Advisory Committee Meeting: September 22, 2011
- Wrap-UP Meeting: October 6, 2011
- Labeling Meeting: TBD
- Team Meeting: June 21, 2011
- Sponsor Meeting to Discuss Outstanding Issues: June 20, 2011

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