

# Meeting Minutes, February 24, 2011 - Hemacord

**Sponsor:** New York Blood Center  
**BLA #:** BLA 125397  
**Product:** Hematopoietic stem/progenitor cells, cord (HPC-C)  
**Date:** February 24, 2011  
**Time:** 3:30 -4:30PM

**Meeting Attendees:** Thomas, Terrollyn; Witten, Celia; Simek, Stephanie; Bryan, Wilson; Sista, Ramani; Przepiorka, Donna; Nguyen, Loan; Stockbridge, Lisa; Heidaran, Mohammad; Wang, Gang; Hoque, Atm S.; Wonnacott, Keith; Quagraine, Mercy; Jordan, Carla; Cato, Dennis; Karandish, Safa; Riggins, Patrick; Benton, Kimberly; Bross, Peter; Hyde, John E; Fan, Yong; Ou, Alan C.; Rees, Renee; Irons, Bennett; McCright, Brenton; Anatol, Rachael;

## 1. Important dates:

- **Filing Letter Comments Due:** COB, February 28, 2011 (*The team agreed to include filing comments in the Day 60 filing letter*)
- **Filing Letter Finalized:** March 11, 2011

## 2. Overview of Application by Discipline: Studies/info submitted; identification of Info Requests; Day 74 letter items

*The review team reached an agreement to file the BLA and stated whether or not they had letter comments for the Day 60 filing letter.*

- CMC - M. Quagraine; S. Karandish / *no filing issues and letter comments*
- DMPQ – M. Heidaran & G. Wang/ *no filing issues and letter comments*
- Pharm/tox – A. Hoque/*no filing issues and no letter comments*
- Clinical – D. Przepiorka & J. Hyde /*no filing issues and letter comments*
- Stats – Rees, Renee /*no filing issues and letter comments*
- Labeling – L. Stockbridge & L. Nguyen / *no filing issues and letter comments*
- Epidemiology – A. Ou/ *no filing issues and letter comments*
- BIMO - C. Jordan & D. Cato / *The clinical reviewer stated that since there is no clinical trial; there is nothing for BIMO to inspect.*

## 3. Identification of RTF Issues by Discipline

*No RTF issues were identified.*

## 4. Action Items

- *Request CDER consult for clinical team*
- *Rachel Antol agreed to put BLA on SWAG calendar*
- *Possible telecon with sponsor to discuss Donor Eligibility*
- *Patrick Riggins will send email address for E-room.*
- *Fix roadmap links in EDR*
- *AC Meeting – Stephanie Simek is waiting for feedback.*

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