

Filing Meeting

Sponsor: Cleveland Cord Blood Center
BLA #: BLA 125594
Product: Hematopoietic Progenitor Cells, Cord (HPC-C)
Date: July 24, 2015

Meeting Attendees:

Chad Burger, Atm Hoque, Stan Lin, Loan Nguyen, Steve Winitsky, Jean Gildner, Celia Witten, Stephanie Simek, Raj Puri, Kimberly Benton, Eric Dollins, Carolyn Yong, Steven Oh, Ilan Irony, Changting Haudenschild, Boguang Zhen, Mercedes Serabian, Becky Robinson, Alex Bailey, Shiojwen Lee, Patrick Riggins, John Eltermann, Laurie Norwood, Lisa Stockbridge, Yong Fan Fatima Abbasi, Joydeep Ghosh, Safa Karandish, Qiao Bobo, Lori Tull

1. Important dates:

- **Filing Letter Comments Due: July 30, 2015**
- **Filing Letter Due Date: August 7, 2015**
- **Day 74 Letter Comments Due: August 17, 2015**
- **Day 74 Letter Due: August 21, 2015**

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

CMC- Collection and DE information needed:

- Donor questionnaires (medical and family history)
- Collection staff training SOPs

Other information not provided:

- Barcode rule exemption (using ISBT 128)
- Complete batch records

- *DMPQ* – no RTF issues
- *Pharm/tox* – no RTF issues
- *Clinical* – no RTF issues
- *Stats* - no RTF issues
- *Labeling* - no RTF issues

3. Reach agreement on filing decision

Submission is acceptable for filing

4. **Next Steps**

Monthly Team Meetings to be scheduled.

The **Mid cycle Review Meeting** will be scheduled for December, please ensure you provide the following information in your presentation.

- Status of your review and discussion of findings is so far regarding approvability of application
- Any pertinent issues requiring input from other disciplines or requiring information\clarification from the Sponsor.
- Decisions regarding lot release requirements, such as submitting samples and test protocols.
- Discuss lot release testing plan.
- Labeling proposals.
- Determine if PMRs\PMCs required
- Wrap up deliverables.