Filing Meeting Minutes, October 14, 2011 - Ducord

Sponsor: **Duke University School of Medicine**
BLA #: **STN 125407**
Product: **Hematopoietic stem/progenitor cells, cord (HPC-C)**
Filling Meeting Date: **October 14, 2011 2:00pm**

Meeting Attendees:

Denise Gavin, Chair
Nancy Waites
Nicole Trudel
Lisa Stockbridge
Renee Rees
Dennis Cato
Keith Wonnacott
Kimberly Benton
Patrick Riggins
ATM Shamus Hogue
Safa Karandish
Celia Witten
Wilson Bryan
Mark Davidson, RPM
Yao-Yao Zhu
Changting Haudenchild
Donna Przepiorka
Joydeep Ghosh
Cheng-Hong Wei

1. Introductions:
Attendees
2. Important dates:

- **Filing Letter Comments Due**: COB, November 2, 2011
- **Filing Letter Finalized:** November 8, 2012
- **Day 74 Letter Comments Due:** COB, November 18, 2012
- **Day 74 Letter Due:** COB, November 22, 2011

3. Overview of Application by Discipline:

- *CMC* - Denise Gavin, Safa Karandish
  a. Denise stated that sufficient CMC information was submitted for filing the BLA, and specifications and viability seems to be in range.
  b. Deficiencies in stability and process/methods validation protocols will be assessed as part of the review process.
  - The main issue being that retrospective data analyses were performed and different assay methods were used to evaluate pre/post thaw critical product quality attributes, including TNCC, CD34+, and viability.
  - Additional information will be necessary to complete review.
  - There was also a discussion of past and present compliance with cGMPs and how compliance will affect which units are licensed, and thus, relevance of above issues. Production capacity was also discussed as a possible review issue.

- Safa Karandish stated that additional information may be needed regarding donor eligibility screening and review of maternal medical records in particular.

- *DMPQ* – Nicole Trudel, Nancy Waites / 5 minutes

  a. Nancy Waites stated that DMPQ reviewers had just received most of the file and thus, did not have adequate time to review prior to meeting. They stated that they will get their findings (e.g., comparability information, production capacity of the two different processes) to Mark/Denise prior to Nov 2.

  b. Sponsor's desire to license both the ---(b)(4)--- and ---(b)(4)--- manufacturing processes was discussed. It was concluded that this is a review issue, and will require validation of both processes, and past and present compliance with CGMPs.

  c. Both reviewers indicated that material is most likely sufficient to file the BLA.

- *Pharm/tox* – Shamsul Hoque/5 minutes

  Shamsul stated that no RTF issues were found, and that collection, processing and storage containers and materials were all FDA cleared or approved.

- *Clinical* – Yao-Yao Zhu /5 minutes

  Additional information was requested and received from the sponsor regarding missing data from CBU dataset. Screening Test Kits have been used that still need to be reviewed. No RTF issues found.

- *Stats–Renee Rees/5 minutes*

  Reviewer did not have CD of missing data from CBU dataset, but will review data in EDR by Nov 2 filing date.

- *Labeling* – Lisa Stockbridge & Loan Nguyen / 5 minutes

  No RTF issues. May request word version of package insert at later date.

- Epidemiology – No representative at meeting, discussion of having ----(b)(6)---- as a consultant/review for this class of products.

- *BIMO* - Dennis Cato / 5 minutes

  BIMO indicated they will have a limited role with these files but wanted, if needed, to stay as a consultant in case a BIMO issue rises. Mark will continue to send any meeting updates and materials in order for BIMO to stay in the review loop.

4. Reach agreement on filing decision:

Denise Gavin stated that no committee member had RTF issues therefore, the BLA would be accepted for filing

5. Updates:

- Any Facility Inspection Updates:

  Nancy Waites suggested that the facility inspection would be scheduled for sometime around the mid-cycle meeting: in Jan, Feb or March of 2012, to give the sponsor time to respond to any possible 483 citations.

- Consult - Any consult for computer system validation.
  There was a discussion of how computer system validation will be reviewed. DMPQ will review facility related computer systems, and DCGT will review process and analytical assay computer systems. It was determined that a consultant may be required for this review.

6. Next Steps:

Monthly Team Meetings: 11/22; 12/20; 1/17/12, 3/20/12 *Time*: 1-2PM
Call in: call-in number ----------(b)(4)----------

The **Mid cycle Review Meeting** is scheduled for **February 16, 2012,** please ensure you provide the following information in your presentation by **COB, February 9, 2012:**

Celia Witten requested that instead of overhead presentations please send reviews to review team and senior staff prior to mid-cycle. Please include the following information in your review:

- 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.

Please keep presentations to no more than **5-7 minutes, or let me know if additional time is required.**