First Meeting Minutes, September 28, 2011 - Ducord

Sponsor: Duke University School of Medicine
BLA #: BLA 125407
Product: Hematopoietic stem/progenitor cells, cord (HPC-C)
Submission Received: September 9, 2011
Date: September 28, 2011
Objective: Meeting centered on monthly milestones and goals for the review of BLA STN 125407.
1. Review team introduced (see attendees): Denise and Mark made commitment to make sure each reviewer has necessary materials to complete reviews in timely manner.
2. Official Milestones were discussed:

> The current due date is July 9, 2012. (10 month clock)
> Filing Meeting: October 14, 2011
> Reviewer update if necessary: October 21, 2011 (filing issues)
> Filing Letter Action/Comments: COB, Wednesday, November 2, 2011
> Filing Letter: No later than 60 days from submission (by November 8, 2011)
> Mid-cycle Review Meeting: February 16, 2011

Please make sure outlook calendar is accessible to Mark and/or up to date.

ACTION ITEMS:

- Filing meeting for BLA #125407: October 14, 2011:
  o Each Reviewer will briefly (<5 min) discuss relevant section(s), please ensure the following are addressed:
  - o Summary of the application/section
  - o Any major issues (RTF or non RTF comments)
  - o A description of any material needed for the review not included in the application to be requested from the Sponsor.
  - o Deficiencies to be included in the 74 day letter (in addition to those in 60 day letter)
  - o Mid-Cycle deliverables
  - o Labeling proposals
- **Reviewers should finalize filing comments by October 21, 2011**. Mark has scheduled a meeting on Oct 21, 2011 from 1-2 if needed, to discuss outstanding filing issues.

- All reviewers must have **supervisor concurred** filing review/comments to Mark by **November 2, 2011 COB.**

3. **Prior history with Sponsor:** 9-17-10 preBLA meeting minutes in BLA **Vol 1, 1.6.3**.
4. **Review Team expectations:**

A. **Sponsor communications:**

- Reviewers were asked to funnel communication and info requests through Mark Davidson and cc Chair (Denise).
- Reviewers should inform Mark/Denise and review team prior to direct communications with Sponsor in case other reviewers have issues.
- Mark should participate in all communications with sponsor (by cc email or on t-con). This will help ensure that issues can be organized and compiled before discussing with sponsor; and to ensure that the necessary review team members are in attendance.
- All communications with sponsor should be documented in EDR (possible exception may be case of brief communication asking to set up future t-con, etc).
- When communicating with sponsor and asking for review documentation, please give the sponsor a distinct deadline to submit information to ensure timely review (i.e. for filing OTRR gave <10 day time limit).
- If Sponsor submits any information to reviewers electronically, Sponsor must follow up with official documentation as an amendment to the BLA STN.

B. **Regarding BIMO and DMPQ inspections:**

a. DMPQ said that they will plan to go on an inspection around the Mid-Cycle review period

b. Dennis Cato, said BIMO inspection would be just before Mid Cycle, if necessary. He said that BIMO may only play a limited role because the product is a HPC-C and these have not required BIMO inspection in the past.

C. **Team meetings:**

a. At least one review update meeting will be scheduled monthly and 2 meetings after the mid cycle meeting in February 2012.

b. Also, Sponsor teleconference meetings will be put on the calendar monthly in case there are issues that require reviewer clarification.

D. **Documentation/Records:**

a. Keep excellent records.

b. Lori Tull asked Mark Davidson to inform reviewers that **MS Word documents should be attached to all PDF documents before document certification.**

i. This is done in Adobe by clicking on Document icon, then clicking on attach file, next select the MS Word document used as template source for pdf.
ii. Make sure correct version is attached.
iii. Make sure your version of Adobe can do this
iv. Other questions check with Mark or Denise.

c. All emails related to file should be saved for future records. Do not communicate other information on BLA email chain…it will be in record and is FIOA-able.

5. **Review updates** will be scheduled as needed.

6. **Regarding scheduling AC meetings**: it was noted that because this particular product HPC-C is no longer considered first in class that it would be unlikely that an Advisory Committee Meeting would be scheduled.
7. **Next Steps:** see action items above.
General discussions:

- Denise asked that all appropriate **filing check lists** be sent to her and Mark Davidson. She had product check list but wanted to know if everyone else had any check list for their particular discipline. Lori Tull said that she had an example of a standard check list from OTRR and she could forward to Mark. Yao-Yao Zhu will send her clinical filing check list and clinical review outline generated by Donna.
- Denise asked if there was a particular filing letter format for HPC-C products since HPC-C's do not fall under PDUFMA. Currently, there were two different formats that the chair will review- regular/standard BLA and a new HPC-C format.
- Stephanie Simek noted that these types of products will not require NDC number or inspection related SPL requirements-She said that she would give more detail regarding this topic later.
- Review team will review the HPC-C submission for a proprietary name. So far a formal request for review by APLB has not been established.

Attendees

Mark Davidson, RPM
Denise Gavin, Chair Product Reviewer
Yao-Yao Zhu
Shamus Atm Hogue
Joydeep Gosh
Cheng-Hong Wei
Safa Karandish
Nancy Waites

Lisa Stockbridge
Renee Rees
Dennis Cato
Celia Witten
Wilson Bryan
Stephanie Simek
Keith Wonnacott
Kimberly Benton
Ellen Lazrus
Mercedes Serabian
Lori Tull
Patrick Riggins

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