

NYBC-BLA: Kick Off Meeting Minutes

DATE: January 28, 2011
Time: 3:30 -4:30 PM EST
Sponsor: New York Blood Center
BLA #: BLA 125397
Product: Hematopoietic stem/progenitor cells, cord (HPC-C)

Attendees: Witten, Celia; Simek, Stephanie; Bryan, Wilson; Sista, Ramani V; Przepiorka, Donna; Schneider, Bruce; Nguyen, Loan; Stockbridge, Lisa L; Heidaran, Mohammad; Wang, Gang; Hoque, Atm S.; Wonnacott, Keith; Quagraine, Mercy; Holobaugh, Patricia; Karandish, Safa; Wise, Robert; Riggins, Patrick; Martin, David; Benton, Kimberly; Bross, Peter; Hyde, John E; McCright, Brenton; Joshi, Bharat; Bauer, Steven; Ghosh, Joydeep; Fan, Yong; Waites, Nancy; Ou, Alan C.; Rees, Renee; Jarvis, Candace

1. Introduction of Review Team

Product Team stated that each member will review a particular area of the CMC section. The reviews will be done in modular form so there is consistency on all CB BLA review.

2. Official Milestones and Monthly Goals

The milestones and monthly goals will be updated prior to the next meeting.

DRAFT TIMELINE: See Appendix I (pg 3)

3. Action Items

The following action items were identified:

Task	Responsible Party	Due Date
Joydeep Ghosh is having trouble accessing roadmap links. He requested a meeting with sponsor to obtain additional information.	Joydeep Ghosh Terrolyn Thomas	Email sent to sponsor to request information.
DMPQ cannot find FEI #	# found on pg 1/4 on form 356h-Establishment Information	Done
Environnemental Assessment exclusion request- DMPQ cannot find	Document found in CMC section	Done
Consult for Software System- all equipments using this interface -AXP, ---(b)(4)---, Flow (Consults from OBRR	Gang Wang Terrolyn Thomas	
Coordinate Facility Inspection dates to include 2 OCTGT participants.	Gang Wang Mercy Quagraine	

Applications/forms for credentials for facility inspection to product personnel	Gang Wang	Done
Obtain WORD version of labeling document	Terrolyn Thomas Lisa Stockbridge	
PNR request- Hemacord- reviewed within 90 days	Terrolyn Thomas	
Create E-Room for BLA	Terrolyn Thomas	Done
Forward Filing Checklist to reviewers	Terrolyn Thomas	Done
Contact appropriate person (Gail Dapolito and Dr. Midthun) regarding AC meeting. Mngt will check on legality of not holding one since product is first in class (two ACs held already on product)	Stephanie Simek Celia Witten	

4. Next Steps

- Invite Rachel Antol and Ricky Wilson to next meeting to discuss post marketing
- Filing Decision Meeting

APPENDIX I: DRAFT TIMELINE for BLA 125397

Timeline	Activity	Comments
February 24, 2011	Filing Meeting	Please be prepared to discuss filing review and make filing recommendations.
COB, February 28, 2011	Filing Letter Comments Due	Please forward comments to Terrolyn Thomas.
March 2, 2011	Circulate Draft Filing Letter	
COB, March 8, 2011	FINAL Draft Comments Due For Filing Letter	
(Day 60) Friday, March 11, 2011	Filing Letter Due	
COB, March 16, 2011	Filing Review Issue Letter Comments Due (if any)	Please forward comments to Terrolyn Thomas.
March 18, 2011	Circulate Draft Letter	
COB, March 22, 2011	FINAL Draft Comments Due for Filing Review Issues Letter	
(Day 74) March 25, 2011	Filing Review Issues Letter Due	
COB June, 2, 2011	Mid-cycle Reviews Due	Please forward reviews to Terrolyn Thomas.
June 10, 2011	Mid-cycle Review Meeting	
COB, August 19, 2011	Primary Reviews Due Labeling Draft Due	Please forward reviews to Terrolyn Thomas.
1 st week of September (8/29-9/2)	AC Meeting (tentative)	
September 9, 2011	Wrap UP Meeting	
	Send Labeling information to sponsor (1 week response)	
COB, September 15, 2011	Secondary Reviews Due	Please forward reviews to Terrolyn Thomas.
	Lebeling Discussion w/Sponsor	
	Compliance Check Request	
	Negotiate Postmarking Commitments & Risk Management Program (if any	
COB, September 22, 2011	Contents for Action Package Due	Please forward reviews to Terrolyn Thomas.
September 26, 2011	Circulate Action Package to Division Directors for Review	
COB, October 7, 2011	Action Package Feedback Due	Please forward comments to Terrolyn Thomas.
COB, October 17, 2011	Submit Final Action Package to Celia	
November 10, 2011	PDUFA GOAL Date	