

Planning Meeting Minutes, May 24, 2011 - HPC Cord Blood

21 Day Planning Meeting Minutes

DATE: May 24, 2011
Time: 12 -1 PM EST
Sponsor: ClinImmune
BLA #: BLA 125391
Product: Hematopoietic stem/progenitor cells, cord (HPC-C)

Attendees: Simek, Stephanie; Ramani V; Przepiorka, Donna; Witten, Rachel, Fan, Yong; Nguyen, Loan; Heidaran, Mohammad; Hoque, Atm S.; Wonnacott, Keith; Cato, Dennis; Karandish, Safa; Bi, Lilia; Riggins, Patrick; Benton, Kimberly; Cheng, Chunrong; Waites, Nancy;

1. Introduction of Review Team

- Product Team stated that each member will review a particular area of the CMC section.
 - Yong Fan -Manufacture
 - Lilia Bi-Assays and validations (except Sterility and Flow)
 - Safa Karandish-Donor eligibility(DE) and labeling relevant to DE
 - Steve Bauer-Flow cytometry (CD34 enumeration and validation)
 - Joydeep Ghosh Sterility tests and validation

2. Official Milestones and Monthly Goals

A draft timeline was agreed upon. Please see Appendix 1 (Page 3)

All reviewers will check for filing issues using the BLA filing check list. The filling issues will be discussed at the filing meeting.

Reviewers should also identify major deficiencies and missing information.

All communications with the sponsor will be initiated through and documented by Ramani.

Reviewers should bring major issues to the review committee and management for potential AC meeting items.

3. Action Items

The following action items were identified:

Task	Responsible Party	Due Date
Coordinate Facility Inspection dates to include 2 OCTGT participants.	Mohammad Heidaran Yong Fan and Lilia Bi	Soon
Contact Sponsor regarding data listings and data dictionary	Rachel Witten\Donna P. Chunrong Cheng Ramani Sista	Before filing
Send E-Room link to team	Ramani Sista	ASAP
Schedule a post inspection meeting	Ramani Sista	When Inspections scheduled
Post marketing registry – Speak with Rachel Anatol	Rachel Witten	Soon
Add filing checklists to eroom	Ramani Sista	ASAP
Prepare presentations for Filing Meeting	Review Team	6/21/11
Draft Reviews to Celia by Midcycle	Review Team	10/06/2011

4. Next Steps

- Filing Decision Meeting scheduled for 6/21/2011

Appendix 1. GRMP timeline for BLA 125391

Timeline	Activity	Comments/Meeting Dates
Day 0	Application Receipt	May 04, 2011
Days 0 – 14	Assign RPM	
	Begin Regulatory Filing Review (RPM)	
By Day 14 05/18/2011	Acknowledge application receipt in writing	
	Assign Review Team- Team Leaders	Product Chair &: Yong Fan Reviewers: Lilia Bi Safa Karandish MO: Rachel Witten P/T: Shamsul Hoque Facilities: Mo H. & Marion M. Stats: Chunrong Cheng BiMO: Dennis Cato

Timeline	Activity	Comments/Meeting Dates
		APLB: Loan Nguyen PM: Ramani Sista
	Schedule Filing Meeting (RPM)	
Days 0 – 45(30)*	21 Day Meeting Request Consults , schedule PeRC	05/24/2011
21 Day Meeting	Identify Inspection Actions (DMPQ\BiMO)	
	Designate Priority or Standard Review Status	
	Identify Signatory Authority	
	Determine if PeRC Meeting necessary	
	Proprietary Name	
By Day 45 (30)* June 18, 2011	Hold Filing/Planning Meeting	June 21, 2011
	Conduct Filing Review- decide if AC necessary	
By Day 60 July 3, 2011	Inform Applicant of a Priority Designation in Writing	60 day letter out on or before 1, 2011
	Communicate Filing Determination to Applicant, if RTF	
By Day 74 July 17, 2011	Communicate Filing Review Issues to Applicant	Letter out on or before July
	Convey Potential RTF Issues to Applicant	
	Team Meeting	August 10, 2011
By End of Month 5(3)* October 4, 2011	Mid-Cycle Meeting	October 6 , 2011
	Update on reviews, consults, and inspections, Notify SWG if PMRs Notify OCC if REMS PeRC forms and scheduling	
	Define need for additional interaction with applicant related to labeling, risk management, PMCs	
	Draft reviews to Celia	Due 10/06/2011
	Revise review plan, if needed <i>ie, internal consults</i>	
	Team Meeting	November 16, 2011
By End of Month 8(5)* January 4, 2012	Completed Review DUE DATES	Signed off reviews in EDR\RM BLA January 4, 2012
	Wrap-Up Meeting	January 5, 2012

Timeline	Activity	Comments/Meeting Dates
	Integrate outcomes of reviews, consults, inspection reports, and AC input	
6 (4-6)* weeks before action	Labeling Meetings	
	5-6 weeks before action fax proposed labeling	
	Compile Action Package Draft action letter	
4 weeks before Approval action	Lot release clearance Submit final Product Testing Plan to Office Director for signoff	February 3, 2012
4 (3-4)* weeks before action	Circulate and Review Action Package and Letter	February 3, 2012
Begin 3 weeks before Division sign-off	Finalized Action Package to Office Director	February 10, 2012
3(2-3)*weeks before action	Labeling telecom/discussion with applicant, Negotiation of PMC, Risk Mgmt	February 10, 2012
By PDUFA Goal Date	Action	March 2, 2012