

Wrap up Meeting

Sponsor: ClinImmune
BLA #: BLA 124391
Product: HPC, Cord Blood

1. Review Team

Discipline	Name	Phone
Product Reviewer/Chair	Yong Fan	301 827 6038
	Lilia Bi	301 827 4016
	Safa Karandish	301 827 2477
Pharm/Tox Reviewer	Atm S. Hoque	301 827 9071
Clinical Reviewer	Rachel Witten	301 827 9134
RPM	Ramani Sista	301 827 5152
Labeling Reviewer	Loan Nguyen/Lisa Stockbridge	301 827 6333
DMPQ Reviewer	Mohammad Heidaran/Marion Michaelis	301 827 7186
BIMO Reviewer	Dennis Cato	301 827 2588
Statistics Reviewer	Chunrong Cheng	301 827 6053

Meeting attendees: Haudenschild, Changting; Wonnacott, Keith; Simek, Stephanie; Benton, Kimberly; Riggins, Patrick; Fan, Yong; Cheng, Chunrong; Heidaran, Mohammad; Michaelis, Marion; Witten, Celia (CBER); Karandish, Safa; Ghosh, Joydeep; Witten, Rachel; Bi, Lilia Lei; Nguyen, Loan; Abbasi, Fatima; Lee, Shiojjen; Sista, Ramani; Hoque, Atm;

2. Official Milestones and Monthly Goals

The current due date is **March 2, 2012**. **June 1, 2012 (10 month clock)**

~~Filing Meeting: June 21, 2011~~

~~Filing Letter Action/Comments: COB, Friday, June 24, 2011~~

~~60 day: July 3, 2011~~

~~74 day/Filing Letter: Friday, July 15, 2011~~

~~Mid-cycle Review Meeting: October 6, 2011~~ – **DRAFT Reviews Due to Celia**

~~Team Meetings: August 10 and November 16, 2011~~

~~Wrap up Meeting: January 5, 2012~~ Moved to April 26 due to Major amendment

3. Action items

All required information and data has been submitted by sponsor and reviewed.

The team proposed to take a early action and work towards completing reviews and other aspects to meet the early deadline. The proposed date is May 24, 2012.

The PDUFA date is June 1, 2012. Concurred reviews will be due by May 9, 2012.

The first draft of the Package Insert (PI) will be sent on May 2, 2012, and informed at the same time that no PMRs\PMCs are required.

Clinical and Product team will work on the package insert. Since this is a class label, it will be similar to the other labels approved for cord blood applications.

Loan Nguyen from APLB and Yong Fan, Kim Benton, OCTGT, will speak with Clinimmune and explain changes to the carton and container labeling.