Filing Meeting Minutes, June 21, 2011 - HPC Cord Blood

Filing Meeting Minutes

Applicant: **ClinImmune**
BLA #: **BLA 125391**
Product: **Hematopoietic stem/progenitor cells, cord (HPC-C)**

Review Team:

Discipline	Name	Phone
Product Reviewer/Chair	Yong Fan-manufacture and process validations	301 827 6038
	Lilia Bi-Testing and validations	301 827 4016
	Safa Karandish-DE	301 827 2477
	Fatima Abbasi-Flow	
	Joydeep Ghosh-Sterility validation	
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 and Sean Belouin	301 827 7186
BIMO Reviewer	Dennis Cato	301 827 2588
Statistics Reviewer	Chunrong Cheng	301 827 6053

Filing Letter Action/Comments: COB, Friday, June 24, 2011
60 day: July 3, 2011 (7/1because 7/3 is Sunday)
74 day/Filing Letter: Friday, July 15, 2011
Mid-cycle Review Meeting: September 30, 2011-Draft review ready
Team Meetings: August 10 and November 16, 2011
Wrap up Meeting: January 5, 2012

Product Filling Issues:

DE (Safa)-Donor ID testing validation data was not provided

Manufacture (Yong)-No filling issues

Testing (Lilia)-Viability, HLA, ABO/Rh and (b)(4) validation data were not provided

(b)(4) (Fatima)-CD34 validation data was not provided

Sterility (Joy)-Validation submitted but deficient, not a filling issue

GMP/Facility (Mo and Marion)-No filling issues

Pre-clinical (Shamsul)-No filling issues

Clinical (Rachel)-Safety data was not submitted

Labeling (Loan)-No filling issues

Discussion of filling issues:
Two t-cons with ClinImmune were held to request the missing elements. ClinImmune agreed to submit everything except donor ID testing validation data because the contract lab is not fully cooperating with this effort.

OCTGT management indicated that we need to prepare for RTF if we don't receive the requested validation data.

Discussion of other issues:

1. The NAT testing wasn't required until August 2007, therefore OCTGT management indicated that the units were not tested using NAT are not licensable. This is not a public knowledge yet. Further discussion is required.

2. ClinImmune intends to license the units that have been manufactured from July 2005 onward, however, most of the validations were not completed until 2010 and some of them are retrospective validations. The review team needs to decide what can be licensed based on the validations and GMP compliance.

3. There are some GMP issues which may be filling issues if we consider licensing the units before 2009/2010. We need to discuss this with ClinImmune and agree on what can be licensed.

Action Items:

1. Ramani will prepare both filling and RTF letters for the time being.
2. Reviewers need to send concurred RTF comments to Ramani by Friday, 6/24/11.
3. Ramani will schedule a t-con with ClinImmune on Monday to discuss filling issues.
4. Stephanie will discuss with legal regarding the Nat testing issue.

Participants:

Boguang Zhen
Changting Haudenschild
Kimberly Benton
Keith Wonnacott
Donna Przepiorka
Ellen
Mercedes Serabian
Atm S. Hoque
Stephanie Simek
Wilson Bryan
Lori Tull
Yong Fan
Lilia Bi
Safa Karandish
Fatima Abbasi
Joydeep Ghosh
Rachel Witten
Loan Nguyen
Mohammad Heidaran
Marion Michaelis
Dennis Cato
Chunrong Cheng