

# Telecon, December 2, 2011 - HPC Cord Blood

## RECORD OF TELEPHONE CONVERSATION

Submission Type: BLA Submission ID: 125391/0 Office: OCTGT

Product:

Hematopoietic Progenitor Cells, Cord (HPC-C)

Applicant:

Clinimmune Labs

Telecon Date/Time: 02-December-2011 11:00 AM Initiated by FDA? Yes

Telephone Number: -----(b)(4)-----

Communication Category(ies):

1. Sterility

Author: RAMANI SISTA

Telecon Summary:

Sterility Discussion

### FDA PARTICIPANTS:

Ramani Sista

Yong Fan

Joydeep Ghosh

Kim Benton

### NON-FDA PARTICIPANTS:

Brian Freed

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----- (b)(4) -----

Trans-BLA Group: No

Related STNs: None

Related PMCs: None

Telecon Body:

Following introductions, FDA stated that they needed some clarifications regarding their processing:

1. FDA asked the Sponsor if plasma is added to the RBCs. The Sponsor stated that ----- (b)(4) ----- . FDA stated that they have to specify in the BLA application what surrogate they want to use – ----- (b)(4) ----- and validate accordingly.

2. FDA asked the Sponsor the centrifugation speed they use. The Sponsor stated that they use (b)(4) to precipitate the RBC fraction.

FDA stated that if they are planning to use the ---(b)(4)--- surrogate they don't need to demonstrate the effect of --(b)(4)-- and centrifugation on the distribution of microorganisms in the surrogate sample.

The Sponsor requested additional clarification regarding points 7, 8 and 9 related to sterility information, requested in the AI letter dated October 28, 2011. FDA provided adequate clarification.