

Telecon, January 13, 2012 - 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: 13-January-2012 1:00 PM Initiated by FDA? Yes

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

Communication Category(ies):

CMC - Sterility Issues

Author: RAMANI SISTA

Telecon Summary:

Sterility Issues

FDA PARTICIPANTS:

Ramani Sista

Joydeep Ghosh

NON-FDA PARTICIPANTS:

Brian Freed

Sabine Stockinger

Linda Tapia

Michael Aubrey

Deborah Havens (Supervisor, Microbiology Lab)

Trans-BLA Group: No

Related STNs: None

Related PMCs: None

Telecon Body:

Following introductions, Dr. Ghosh stated that this telecon was to further discuss the sterility validation issues, outlined in previous calls.

Regarding validation for robustness, FDA stated that since using a (b)(4) temperature may increase the minimum time of detection, the Sponsor may provide the following information in writing in lieu of conducting the test at -(b)(4)-. FDA asked the Sponsor to provide the following:

- Plan of action in the event of machine failure
- Temperature failure

FDA recommended the Sponsor to summarize their procedures in detail at -(b)(4)- and submit to application.

Regarding ruggedness, FDA recommended the Sponsor to use (b)(4) lots of media at (b)(4) in triplicate for the (b)(4) microorganisms listed in the table of the word document provided to the Sponsor earlier.