

Telecon, December 6, 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: 06-December-2011 4:00 PM

Initiated by FDA? Yes

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

Communication Category(ies):

Sterility Issues

Author: RAMANI SISTA

Telecon Summary:

Sterility Issues – Data Table by Dr. Ghosh

FDA PARTICIPANTS:

Ramani Sista

Yong Fan

Joydeep Ghosh

Kim Benton

NON-FDA PARTICIPANTS:

Brian Freed

Sabine Stockinger

Linda Tapia

Michael Aubrey

Sharon Miller

Deborah Havens (Supervisor, Microbiology Lab)

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

Trans-BLA Group: No

Related STNs: None

Related PMCs: None

Telecon Body:

FDA asked the Sponsor to outline their current procedure for sterility testing and validation. The Sponsor stated that for their post processing procedure, they use -----

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

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

----- . The bottles are incubated for (b)(4) in a (b)(4) machine.

FDA stated that the Sponsor should also add their data to the attached table (Appendix 1), sent via email earlier in the day (12/06/2011) for the respective organisms and send the data to the BLA file. FDA also stated that the organisms should be calculated in numbers and not as cfu/ml. When adding the -----(b)(4)-----, FDA advised the Sponsor to measure the exact amount being added. The Sponsor asked if they could substitute any of the micro-organisms outline in the list send by FDA? FDA stated that substitution can be made only if the Sponsor can show that the organism is a strict aerobe. FDA asked the Sponsor regarding the growth of mold – -----(b)(4)-----. The Sponsor stated that temperature is an issue to promote growth of ----(b)(4)---, FDA asked the Sponsor to provide all information regarding the Sponsor's current procedure to test mold growth.