

Telecon, January 27, 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: 27-January-2012 4:00 PM Initiated by FDA? Yes

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

Communication Category(ies):

Product

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Telecon Summary:

Product – TNC Validation

FDA PARTICIPANTS:

Ramani Sista

Yong Fan

NON-FDA PARTICIPANTS:

Sharon Miller

Brian freed

Michael Aubrey

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Sabine Stockinger

Trans-BLA Group: No

Related STNs: None

Related PMCs: None

Background: ClinImmune submitted stability data with a -----(b)(4)----- processing method validation. All the units used for this validation were manufactured in 2005, therefore, the study is a retrospective data analysis, not a prospective validation.

FDA initiated a telecon to request a prospective --- (b)(4) --- processing validation.

Telecon Body: FDA stated that all processing procedures include the -(b)(4)- processing, should be validated prospectively. ClinImmune confirmed that they did perform a prospective validation of the -(b)(4)- processing with RBC depletion efficiency, TNC recovery, --- (b)(4) --- viability, sterility, and (b)(4) data. FDA asked ClinImmune to submit the validation data for review and ClinImmune agreed.