

Telecon, December 22, 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: 22-December-2011 1:00 PM Initiated by FDA? Yes

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

Communication Category(ies):

Outstanding information\BLA timeline

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Telecon Summary:

Outstanding information\BLA timeline

FDA PARTICIPANTS:

Ramani Sista

Stephanie Simek

NON-FDA PARTICIPANTS:

Sharon Miller

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Trans-BLA Group: No

Related STNs: None

Related PMCs: None

Telecon Body

FDA stated that after an internal meeting, several disciplines indicated that there are outstanding issues requiring information from the Sponsor to complete their reviews. Since the PDUFA goal date for this application is March 2, the team should have completed their reviews by now. FDA briefly explained the BLA timeline and review process to the Sponsor and indicated that the team could not wait till the end of the cycle to complete their reviews and make a recommendation. There were in built processes that required reviews to be completed several weeks ahead of the goal

date. Unfortunately, in this case the team was still waiting for data. Despite repeated requests, the Sponsor has failed to submit or submitted information in power point slides which is unacceptable. FDA strongly recommended the Sponsor submit all the outstanding information as soon as possible. The Sponsor agreed to work with FDA team to submit information in a timely manner.