

Telecon, February 2, 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: 02-February-2012 3:00 PM Initiated by FDA? Yes

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

Communication Category(ies):

Major amendment

Author: RAMANI SISTA

Telecon Summary:

Major amendment

FDA PARTICIPANTS:

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NON-FDA PARTICIPANTS:

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Trans-BLA Group: No

Related STNs: None

Related PMCs: None

Telecon Body

Following introductions, FDA stated that they had received amendment 4 from ClinImmune. Since this amendment was received within the last few weeks of the goal date and the volume of information was substantial, the division would consider this to be a major amendment, which will extend the clock by three months. This is a one time extension, with the new goal date being June 2, 2012. The Sponsor was also informed that they will receive a letter acknowledging the major amendment shortly.

FDA sterility team asked the Sponsor if any new sterility information was included in the amendment. The Sponsor stated that their sterility studies were ongoing and they have not submitted the information yet.