

Telecon, June 27 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: 27-Jun-2011 02:00 PM Initiated by FDA? Yes

Telephone Number: ----(b)(4)----, Participant PIN is: ---(b)(4)---

Communication Category(ies):

1. Information Request

Author: RAMANI SISTA

Telecon Summary:

Product clarification of earlier IR

FDA Participants:

Yong Fan

Rachel Witten

Lilia Bi

Kimberly Benton

Mohammad Heideran

Donna Przepiorka

Non-FDA Participants:

Sharron Miller

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Brian Freed

Michael Aubrey

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Trans-BLA Group: No

Related STNs: None

Related PMCs: None

Telecon Body:

Following introductions, the product team stated that this call was primarily to follow up on the status of product and clinical requests made in the teleconferences dated May 31 and June 14. The Sponsor responded that they were planning to submit the requested information as amendment 1 to the BLA on June 28. The Sponsor also stated that the contract lab information requested by the product reviewer was not available since the

lab refused to provide it. The requested information is very large in volume and the contract lab is not willing to share it with the Sponsor. The FDA reiterated that their request is reasonable and the team is looking for a summary of the data, not the entire data. The FDA also informed the Sponsor that they will need to review and inspect the contract lab information as an essential part of their BLA application.

Regarding Licensure inventory, the FDA stated that at this point, it would be easier to look at all the information the Sponsor provided in their application and license units produced recently. The FDA team will be inspecting the facility as per requirement for licensure, at that point they can also look at all the available information for older units and based on their findings, the Sponsor may be able to request licensure for older units in subsequent supplements to BLA.