

Telecon, May 7, 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: 07-May-2012 12:00 PM Initiated by FDA? Yes

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

Communication Category(ies): Carton and Container Labeling

Author: RAMANI SISTA

Telecon Summary:

Labeling

FDA PARTICIPANTS:

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NON-FDA PARTICIPANTS:

Brian Freed

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Trans-BLA Group: No

Related STNs: None

Related PMCs: None

Telecon Body

Following introductions the sponsor was referred to the label inserted on the cartridge/canister. APLB asked if some of the information on the label such as the cryopreservation date was necessary since FDA did not require it. The sponsor stated that including cryopreservation information was a requirement by AABB organization. FDA asked if there was any requirement of placement of information on the label, to which the sponsor stated there was not. APLB stated that they would like to rearrange the information on the label for clarity and to reduce medication errors. The sponsor stated that while they cannot delete information, it is acceptable to move it around for clarity. The sponsor was advised on the information that needed rearranging on the label. The sponsor agreed to make the changes and submit to the file.

The sponsor requested some clarifications regarding the package insert which were answered by APLB.