

Telecon, March 1, 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: 1-March-2012 2:00 PM Initiated by FDA? Yes

Telephone Number: 303-724-1307

Communication Category(ies):

Product

Author: YONG FAN

Telecon Summary:

Product – Thaw instruction

FDA PARTICIPANTS:

Yong Fan

NON-FDA PARTICIPANTS:

Linda Tapia

Sharon Miller

Trans-BLA Group: No

Related STNs: None

Related PMCs: None

Telecon Body: FDA pointed out that the thawing instructions are not clear and difficult to follow. The applicant needs to revise the procedure and provide clear step by step instructions for cord blood units thaw, reconstitute and wash. ClinImmune agreed.