

# Telecon, May 10, 2012 - HPC Cord Blood

## RECORD OF TELEPHONE CONVERSATION

Submission Type: BLA Submission ID: 125391/6 Office: OCTGT

Product:

HPC (Hematopoietic Progenitor Cells), Cord Blood

Applicant:

Clinimmune Labs, University of Colorado Cord Blood Bank

Telecon Date/Time: 10-May-2012 1:00 PM Initiated by FDA? Yes

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

Communication Category(ies):

Product

Author: Yong Fan

Telecon Summary:

Product – Stability Testing Protocol

### **FDA PARTICIPANTS:**

Ramani Sista

Yong Fan

### **NON-FDA PARTICIPANTS:**

Sharon Miller

Brian freed

Michael Aubrey

Linda Tapia

Sabine Stockinger

Trans-BLA Group: No

Related STNs: None

Related PMCs: None

Background: ClinImmune submitted stability study protocol to support the shelf- life of the product -----(b)(4)----- . The following acceptance criteria are not acceptable:

*(b)(4) of the products achieve at least (b)(4) post thaw by ----(b)(4)----*

*(b)(4) of the products achieve at least (b)(4) TNC recovery*

Telecon Body: FDA stated that the above acceptance criteria are not acceptable because when a acceptance criteria is established for a stability study, 100 % of the products should be included. FDA further stated that although the acceptance criteria are not acceptable, the data generated for the stability study does support the 5 years shelf life. Therefore, the acceptance criteria have to be amended and submitted to FDA as supplement after the BLA is approved. The future stability study can not be initiated until FDA reviews and approves the amended protocol. The applicant agreed.