

Telecon, January 20, 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: 20-January-2012 1:00 PM Initiated by FDA? Yes

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

Communication Category(ies):

Barcode exemption

Author: RAMANI SISTA

Telecon Summary:

Barcode Exemption

FDA PARTICIPANTS:

Ramani Sista

Stephanie Simek

Kimberly Benton

NON-FDA PARTICIPANTS:

Sharon Miller

Trans-BLA Group: No

Related STNs: None

Related PMCs: None

Telecon Body

Following introductions, FDA stated that cord blood banks can request exemption from bar code for their BLA applications. ClinImmune can use their ISBT-128 code as their barcode. The Sponsor will have to formally request this exemption. FDA has prepared a template for the exemption request which will be emailed to the Sponsor after the call. The Sponsor will have to add their information and formally submit to the application. The Sponsor agreed to include the exemption in their amendment 4, scheduled to be sent shortly.