Telecon, January 19, 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: 19-January-2012 4:30 PM Initiated by FDA? Yes
Telephone Number: ----(b)(4)----
Communication Categorie(s):
Donor Eligibility

Author: RAMANI SISTA
Telecon Summary:
Donor Eligibility
FDA PARTICIPANTS:
Yong Fan
Safa Karandish

NON-FDA PARTICIPANTS:
Sharon Miller

Trans-BLA Group: No
Related STNs: None
Related PMCs: None

Telecon Body:
The following issues were discussed with the sponsor:

1. Sponsor clarified that testing on CB units was discontinued on 1/1/2007 (SOP C1.110.6).
2. Sponsor was informed that the “Unit Release Report” for licensed products was acceptable (E5.103.14). The “Unit Release Report” for IND products (E5.103.13) includes a statement regarding the use of FDA approved test kits for infectious disease testing. However, this statement would not be applicable to all units in the existing inventory (e.g. unapproved test kits used in the past, test kits used for testing of cord blood sample were not approved, cleared or licensed by FDA). Reviewer recommended revision of this report but this report does not affect the licensed products.
3. Sponsor explained that for samples with initial reactive syphilis results, the contract testing laboratory performs -(b)(4)- tests per manufacturer’s

instructions and reports the results of the (b)(4) test -----(b)(4)------. (refer to Jan 20th email from the testing lab).

4. Sponsor was informed that the described process for assessing the birth mothers for possibility of plasma dilution prior to the collection of infectious disease test samples was still not adequate (SOPs C3.110.7, C1.110.6, B9.320). Reviewer discussed options for revising the applicable SOPs and offered to review the draft SOPs. Sponsor agreed to work on the SOP revisions.