Telecon, January 17, 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: 17-January-2012 12:00 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. For collections performed under the State-wide Program, the instructions provided to the birth mother does not specify how the collection kit should be stored. Sponsor explained that the instructions are given to the mother verbally. Sponsor was informed that the written instructions should specify the appropriate storage condition of the collection kit. Sponsor will submit revised documents.

2. For collections performed under the State-wide Program, the data logger provided in the collection kit is not activated until after the collection is completed. Sponsor was asked to explain how they could determine whether or not the collection kit was stored properly especially since the kit includes

the cord blood collection bag containing anticoagulant. Sponsor explained that they have had internal discussions about this but decided not to activate the data logger when the collection kit is shipped to the birth mother because of the cost. Since the data loggers are battery operated, running them for >30 days would deplete the battery life and therefore requiring a new logger for each shipment. Data loggers can not be re-used. Sponsor will re-evaluate the available options and get back to the reviewers.

3. Sponsor was informed that the most recent (b)(4) validation would have been acceptable if there wasn't such a high positive sterility rate -(b)(4)-. The reviewer is not able to determine whether or not the --(b)(4)-- processing contributed the positive sterility results. Sponsor was asked for a validation study that includes processing of at least 3 consecutive units.