Telecon, August 10, 2011 - 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: 10-Aug-2011 11:30 AM Initiated by FDA? Yes
Telephone Number: ------(b)(4)------
Communication Categorie(s):
1. Advice

Author: RAMANI SISTA
Telecon Summary:
FDA determined that Sponsor needed guidance on Aseptic Processing Validation.
FDA PARTICIPANTS:
Ramani Sista
Yong Fan
Mohammad Heidaran
Marion Michaelis

NON-FDA PARTICIPANTS:
Sharon Miller
----(b)(4)----
Brian Freed
Michael Aubrey
-----(b)(4)-----
-----(b)(4)-----
Sabine Stockinger
Linda Tapia
Stephanie Warnell
----(b)(4)----

Trans-BLA Group: No

Related STNs: None
Related PMCs: None
Telecon Body:
Following introductions, FDA stated that the Sponsor will have to run a media fill process through their -(b)(4)-- system. The Sponsor stated that they cannot guarantee the running of -(b)(4)- system and pump the media to the collection bag. Since the running of -(b)(4)- system is based on the -------(b)(4)------- of the blood product, it may

shut down if media is used. The Sponsor said they could try to simulate the time and purge the media in to the bag. FDA advised the Sponsor to simulate based on time and running conditions.
FDA stated that the Sponsor needs to verify the ability of media to support growth promotion, either using positive or negative controls. FDA explained that the Sponsor should test the ability of the media used for media fill studies to support growth of representative microorganisms found the facility. The Sponsor asked if they could send it to a testing lab outside. FDA stated that the Sponsor has to ensure that the media goes though the same processes as it normally would if it was being used and then the Sponsor could send it out to a contracting lab.