Telecon, August 3, 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: 03-Aug-2011 12:00 AM Initiated by FDA? Yes
Telephone Number: -----(b)(4)-----
Communication Categorie(s):
1. Advice

Author: RAMANI SISTA
Telecon Summary:
The Sponsor requested clarification for some of the requests made in the 74 day letter.
FDA PARTICIPANTS:
Ramani Sista
Yong Fan
Mohammad Heidaran

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, the Sponsor requested clarification for some of the requested information included in the 74 day letter of July 3, 2011. These are:

Regarding Integrity testing, the Sponsor stated they use ----------(b)(4)---------- to test bag integrity and requested clarification as to FDA requirements. FDA stated as an end

user the Sponsor is not required to perform integrity tests provided that the containers are FDA cleared and/or approved. If you decide to perform a test to demonstrate the container's integrity, you are expected to use a more sensitive method, for example using staining method, involving filling the bag with colored liquid, and testing for leakage.

The Sponsor stated that they were confused with the request for information in the 74 day letter of July 14, 2011 regarding request for validation information for older units. FDA stated that this request was just a confirmation of the Sponsor's understanding on units they planned to license. FDA reiterated that the best approach is to request licensure for recent units and after inspection and approval of their BLA; they could submit a supplement with request for licensure for older units. If the sponsor's intention is to license the prospective inventory only then they do not need to submit information of the older unit.
FDA provided detailed explanations to the Sponsor regarding validation, retrospective validation, and Master Batch records.