Telecon, September 21, 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: 21-September-2011 1:15 PM Initiated by FDA? Yes
Telephone Number: ------(b)(4)-----
Communication Categorie(s):
1. Advice

Author: RAMANI SISTA
Telecon Summary:
Clarification: Clinical Outcome data and Product Sterility.
FDA PARTICIPANTS:
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Trans-BLA Group: No
Related STNs: None
Related PMCs: None

Telecon Body:
Clinical Discussion

FDA stated that the dates provided to FDA as infused dates were same as shipped dates; FDA asked if this information was correct. The Sponsor stated that they could not confirm that the product was\ was not infused on the same day it was shipped, this was true for double unit shipments too, where one may have been infused, but there was no information on the second bag. FDA asked the Sponsor to clarify how they tracked their second unit bags if the first was used. The Sponsor stated that each bag consisted of a product I.D. on the first page, indicating that it belonged to a specific cord blood unit.

FDA stated that in the dataset sent by the Sponsor earlier, there were 130 records with infusion and shipment dates being reported as the same day. FDA also stated that of the 130 subjects, about 100 did not have the Posta(?) bag information. The Sponsor replied that lack of Posta bag information did not indicate that the product was infused. FDA asked the sponsor to verify all the shipping and infusion information for the 130 data points with same date and resubmit all the data in one flat file.

Regarding the consent forms, FDA asked the Sponsor to correct the day to 7 days from 30 days in their consent form for C21006.6, page 2 of 7. The Sponsor stated this was a typo and they would make the correction. The Sponsor stated that they have several different versions based on the sites; FDA cautioned that the language should be consistent for each ICF. FDA stated that if a protocol accompanied the consent at each center, the sponsor has to submit the protocol and ICF for each center to FDA for review as part of their BLA application. The Sponsor agreed to submit all the protocols.

Product Discussion

Dr. Ghosh, Sterility Product Reviewer, FDA, requested several clarifications from Sponsor regarding their sterility assay and validation protocol. The Sponsor agreed to send all the discussed information in amendment 3 for the BLA application.