Telecon, June 14, 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: 14-Jun-2011 02:00 PM Initiated by FDA? Yes
Telephone Number: -----(b)(4)-----, PIN: ---(b)(4)---

Communication Categorie(s):
1. Information Request

Author: RAMANI SISTA
Telecon Summary:
Product information request and Sponsor requested clarification earlier Clincial IR
FDA Participants:
Yong Fan
Rachel Witten
Chunrong Chen
Mohammad Heideran
Donna Przepiorka

Non-FDA Participants:
Sharron Miller
Brian Freed

Trans-BLA Group: No

Related STNs: None
Related PMCs: None
Telecon Body:
Following introductions, the product team stated that there were deficiencies in the submission from CMC perspective and would like the Sponsors to provide the information before the filing date which is July 1, 2011.
The Sponsor referred to raw clinical data requested in the previous tcon on May 31, with the clinical team and stated that according to the guidance and pre BLA meeting, they need not submit any data. The clinical reviewer pointed out that according to the guidance data is not required for CMC section of the application and to prove efficacy, but was necessary to prove safety of the product. This point was reiterated in the pre BLA meeting in July 2010, and is captured in the meeting minutes. FDA also stated they need the raw data to verify the tables and figures in Section 5.4 of their submission.

The Sponsor stated that they plan to delete confidential information such as recipient names from the spreadsheet before they submit to their file. FDA stated it was acceptable to delete patient names, but all of the other information in the dataset had to match exactly what was in their records.

The Product team requested the Sponsor to provide the following or if already submitted in the application, where in the submission they can find:

1. Assay validation. If the testing is done by a contract lab, then the validation for CLIA and other professional organization certifications will be acceptable. The Sponsor stated that the labs use FDA approved kits and actual validation was never asked for. FDA stated that validations for implementing new tests such as IQ\OQ\PQ that show the use can reliably performed the tests and generate the expected results are required not matter if approved kits were used or not.
2. Validity testing, ----------(b)(4)----------.
3. CD34+ ------(b)(4)------- testing
4. HLA typing
5. ABO, Rh typing
6. ----------(b)(4)----------.

FDA requested the Sponsor to submit all the requested information by 29th or 30th of June, 2011.

An additional request which was not a filing issue is for Lot release information, a section that clearly describes the list of tests, test methods, acceptance criteria for lot release.

The Sponsor requested for information regarding a contact to help them send their amendments. FDA agreed to provide the information via email.